Medtronic

Medtronic
950 F Street NW
Suite 500
Washington, DC 20004
www.medtronic.com
Tel: (202) 393-0444

January 26, 2016

The Honorable Orrin Hatch
Chairman, Senate Finance Committee
104 Hart Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member, Senate Finance Committee
221 Dirksen Senate Office Building
Washington, D.C. 20510

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 Chairman Hatch, Ranking Member Wyden, and Senators Isakson and Warner:

Medtronic supports the Senate Finance Committee's focus on improving care for Medicare patients with chronic conditions and we appreciate the opportunity to comment on the Bipartisan Chronic Care Working Group's Policy Options Document, issued on December 18, 2015. Your leadership in this critical area will help to produce better outcomes for patients with chronic disease and ensure efficiency in health care delivery, accelerating the shift toward value in the health care system. Developing and implementing policies designed to improve chronic disease management, streamline care coordination, improve quality, and reduce Medicare costs is a significant challenge. We look forward to working with the Committee as it moves forward with its efforts.

Medtronic supports the use of innovative care delivery models that improve disease management, streamline care coordination, and reduce costs while simultaneously promoting improvements in quality of patient care. Medtronic has broadly embraced the shift toward pay-for-value and has adopted a variety of new business models and approaches as the health system transitions toward rewarding both improvements in clinical outcomes and economic efficiencies. In this letter, we focus specifically on the working group's proposals to improve and expand the use of telehealth as a method to improve care for Medicare patients with chronic conditions. We also offer thoughts on improving chronic care for Medicare beneficiaries. We appreciate the Committee's consideration of these ideas and recommendations.

I. Expanding the Use of Telehealth

Many of the existing care management initiatives have focused on disease states and device therapies of interest to Medtronic and we have been actively engaged in the policy surrounding these reforms since their early development. Expanded use of telehealth in particular presents a pathway for improving beneficiary access to care while also reducing utilization and cost to the Medicare system. Medtronic is supportive of proposals to grow access to telehealth services for chronic care management, and we offer the following comments based on our early policy and business development experiences working on integration of telehealth into chronic care management services.

Improving Care Management Services for Individuals with Multiple Chronic Conditions and Encouraging Beneficiary Use of Chronic Care Management Services. Medtronic supports the committee's proposals recognizing the importance of chronic care management services (CCM). We believe CCM services have the potential to make a real impact on the management of chronic diseases. However, challenges with the current CCM code, including limitations on eligible beneficiaries, documentation requirements, and copay requirements, make it difficult to find opportunities to use the code. We encourage the committee to find ways to make the current code useful in addition to promoting use of the code by both providers and Medicare beneficiaries, instead of creating so many limitations that the services are rarely used.

Providing Accountable Care Organizations (ACOs) the Ability to Expand Use of Telehealth. Medtronic supports modifying the requirements for reimbursement for telehealth services provided by ACOs in the Medicare Shared Savings Program (MSSP). We encourage the committee to review current limitations on how telehealth is utilized and suggest the use of waivers to help eliminate restrictions. Medtronic commented on the Centers for Medicare and Medicaid Services (CMS) MSSP ACO proposed rule to encourage use of waivers to eliminate restrictions, and also recommended waiver use to this committee last summer. We continue to believe that including the flexibility to use waivers will encourage and promote adoption of telehealth services, in turn, improving care coordination for patients, benefitting both beneficiaries and providers.

Medicare coverage and payment for telehealth services is currently restricted to a limited number of originating sites and geographic locations. Additionally, telehealth services are not typically accounted for under the ACO's historically-based benchmark. The upfront investment and ongoing implementation costs of telehealth creates a disincentive to use these technologies at a time when cost pressures and restricted budgets limit the ability of ACOs to do so. Consequently, the current coverage and payment issues coupled with the benchmark issues make it difficult for ACOs to realize the full benefits of telehealth technologies for their patients. Medtronic again recommends the use of Medicare waiver authority to establish broader coverage and payment for telehealth and remote patient monitoring services.

Specifically, Medtronic recommends that CMS use each of the payment tracks of the MSSP program to assess: (1) coverage and payment for a more comprehensive set of technologies that today are understood to encompass telehealth technologies, and (2) coverage and payment for a broader range of services for conditions that are known to benefit from telehealth and remote monitoring connection with patients. The expansion of the waiver authority under MSSP provides CMS with the ability to assess, on a smaller scale, the specific services and circumstances under which telehealth and related services can be demonstrated to improve the quality and efficiency of care.

To limit new spending under the waiver, CMS could control the scope of the waiver by applying it only to telehealth services for a limited set of conditions. These conditions could encompass chronic conditions, such as diabetes, chronic obstructive pulmonary disease, and congestive heart failure, as well as more acute postoperative conditions including overall health, pain, fever, incision appearance, activity level, and any patient postoperative concerns. Limiting the scope of the waiver will allow CMS to test the effects of the use of telehealth services and remote patient monitoring in

these critical populations, while ensuring that the program is well-defined. Overall, the MSSP program provides a unique opportunity to assess expanded telehealth services and remote patient monitoring and their impact on population health across at least two different models of risk and CMS should move forward with waivers to cover these services.

Maintaining ACO Flexibility to Provide Supplemental Services. Medtronic supports clarifying that ACOs participating in the MSSP may furnish a remote patient monitoring service, payment of which is not made under fee-for-service Medicare. As the committee notes in the policy options document, such clarifications would allow ACOs the flexibility to spend their own resources on a broader range of services (including remote patient monitoring) and capabilities that better suit the beneficiaries they serve.

Expanding Use of Telehealth for Individuals with Stroke. Medtronic supports the committee's proposal to improve systems for stroke identification and diagnosis, and believes there are positive implications for identifying stroke patients. We also encourage the committee to consider proposals that improve stroke care overall. While the committee's proposal allows for increased use of telehealth, it is only one component of stroke care, and the entire continuum of stroke management should be addressed. For example, recent clinical studies and revisions to the American Heart Association/American Stroke Association (AHA/ASA) guidelines conclude that certain endovascular procedures (particularly mechanical thrombectomy involving stent retriever devices) have been demonstrated to provide clinical benefit in selected patients with acute ischemic stroke. The new AHA/ASA guidelines recommend that systems of care should be organized to facilitate the delivery of this care. We believe it would be appropriate for the Committee to consider options and approaches to improve systems of care for acute stroke and we would look forward to working further with you on this topic.

Expanding the Independence at Home Model of Care. Medtronic supports expansion of the current Independence at Home (IAH) demonstration. We believe inclusion and integration of telehealth services into this proposal would enhance the ability of physician and nurse practitioner-directed home-based primary care teams to provide items and services in a way that will further improve health outcomes for Medicare beneficiaries with multiple chronic conditions in addition to reducing expenditures.

Increasing Convenience for Medicare Advantage (MA) Enrollees through Telehealth. Medtronic supports allowing MA plans to include certain telehealth services in its annual bid amount, and continue to encourage the committee to find ways to allow broader adoption of telehealth and remote patient monitoring services to improve the health of chronically ill Medicare beneficiaries.

II. Improving Chronic Care for Medicare Beneficiaries

Expanding Access to Home Hemodialysis Therapy. Medtronic supports expansion of the qualified originating site definition to include free-standing renal dialysis facilities located in any geographic area and further recommends that the home also be considered an originating site for the purpose of completing the monthly clinical assessment for beneficiaries receiving dialysis treatment. CMS should continue to pursue efforts to improve access to dialysis in the home setting, particularly given the improved quality of life for patients receiving dialysis at home.

Providing MA Enrollees with Hospice Benefits. Medtronic supports requiring MA plans to offer the hospice benefit provided under traditional Medicare, so as to avoid any unnecessary disruptions in care or fragmented care delivery for MA enrollees electing to use hospice. Though MA enrollees have access to the hospice benefit, the process for accessing those benefits is not streamlined. Medtronic encourages CMS to implement efforts to decrease burden to access services on MA enrollees, particularly those enrollees making the difficult decision to enroll in hospice.

Adapting Benefits to Meet the Needs of Chronically Ill MA Enrollees. Medtronic supports giving MA plans the flexibility to establish a benefit structure that can be tailored to better serve enrollees with chronic conditions, including waivers to allow MA plans to provide supplemental benefits to those enrollees with chronic conditions and a reduction in cost sharing for particular items/services that treat the condition. Allowing MA plans this flexibility, while also requiring that enrollees with chronic conditions can never receive fewer benefits or have to pay higher cost-sharing than other enrollees as a result, will likely improve management of chronic diseases for the enrollees.

Developing Quality Measures for Chronic Conditions. Medicare should prioritize the development and implementation of appropriate quality measures – particularly those based on trueoutcomes. Quality monitoring is necessary to protect patients and access to appropriate care, especially in the context of bundled payments where providers are incentivized to lower spending on patient care. When designing a program to better tie payment to value and quality, it is imperative that Medicare be equipped to measure quality. To do this, CMS should look to organizations such as the International Consortium for Health Outcomes Measurement (ICHOM) which create standard sets of publicly available measures that are outcomes driven and truly evaluate quality of care.

When possible, the data collection of the outcome measures should be tied to existing registries to alleviate administrative burdens for health systems tasked with reporting clinical outcomes. Quality thresholds based on outcomes will ensure that providers examine and implement evidence-based care and utilize care pathways to better target clinicalinterventions.

Expanding Access to Prediabetes Education. Medicare should pursue every available option, including access to prediabetes education, to help beneficiaries avoid chronic conditions such as diabetes. Individuals who are at risk of developing diabetes may significantly benefit from lifestyle changes, either delaying progression to development of diabetes or avoiding the condition in its entirety. Either outcome would improve the health of Medicare beneficiaries as well as reduce Medicare spending.

In addition to educating beneficiaries on strategies to avoid diabetes, Medicare also needs to address gaps in care for beneficiaries with diabetes, particularly as patients move from private insurance to Medicare and lose access to innovative therapies evidenced to manage their disease. One particular example of such a disruption in care is continuous glucose monitoring technology (CGM). Although therapy innovation is moving forward at a rapid pace for those living with chronic conditions, including those with insulin-dependent diabetes, for some this access ends abruptly once beneficiaries become Medicare eligible. Terminating access to CGM technology puts seniors at undue risk and creates additional economic burdens for the health care system.

Diabetes therapies, including integrated insulin pump and continuous glucose monitoring (CGM) technologies, are progressing toward closed-loop "artificial pancreas" systems. These systems will enable people with insulin-dependent diabetes to automatically and better control their blood glucose levels. CGM is a key component to the artificial pancreas and has been on the market for nearly a decade. With these technology advancements, thankfully, most children with type 1 diabetes will be Medicare beneficiaries one day, something that could not have been said with such certainty even 20 years ago. According to CMS, however, CGM technology does not fit into a statutorily defined benefit category.

All leading diabetes professional societies recognize the clinical value and medical purpose of CGM and recommend it in their clinical guidelines, and 95 percent of private insurers cover CGM, including FEHBP. By detecting glucose every five minutes and providing trending and alerts to warn of dangerous high or low blood glucose levels, this technology can provide life-saving information before negative clinical events occur. Numerous studies, including an analysis by AHRQ, show CGMs improve glucose control and health outcomes. Since keeping blood glucose levels as close to normal can help prevent or delay diabetes complications, it is critical for patients to have access to the best tools to achieve their health goals.

CGM technology now allows for data to be delivered in real-time to smartphones and iPhones so beneficiaries and those that care for them can have immediate access to information wherever they are and be alerted to changes before they are dangerous. As a result, seniors can therefore live more independently at home and with caregivers having this access, potentially avoid unnecessary visits to the ER.

The "Medicare CGM Access Act of 2015" (S. 804) would provide Medicare coverage of CGM devices and allow patients to transition to Medicare and continue to use the lifesaving chronic care therapy they are used to using. We believe it would be highly useful and productive for the working group to explore ways to ensure that Medicare benefit, coverage, and reimbursement decisions keep pace with innovation and support the goals of chronic care.

Increasing Transparency at the CMMI. The models and initiatives created at the CMMI are promising for improving care coordination, quality, and reducing overall costs to the health care system. However, these initiatives alter the incentives for health care providers and change the way Medicare and Medicare Advantage plans pay for care; modifying incentives and reimbursement comes with significant risk and thus development of the initiatives should be transparent and include opportunities for review of proposals and solicitation of formal comment from a variety of stakeholders.

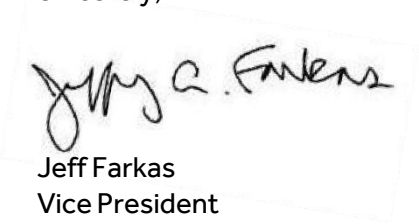
The CMMI has been granted authority under the Affordable Care Act that is unique in that it is not required to follow a formal rulemaking process; however, this has resulted in a less than transparent process which results in initiatives that stakeholders face challenges in adequately preparing for and engaging in the initiatives successfully and meaningfully. As Medicare seeks to move 50% of payments into Alternative Payment Models (APMs) by 2018, the CMMI's work in shaping future reimbursement will only increase in importance. The expectation is that many of the APMs, if not

the majority, will be developed and implemented by the CMMI; consequently there is a need for a more transparent process for model creation, refinement, and evaluation.

III. Conclusion

Medtronic appreciates the opportunity to provide ideas and recommendations to the Senate Finance Committee's chronic care working group. We look forward to continuing to collaborate with the Committee to accelerate patient access to life-saving therapies and promote the use of innovative technologies that bring value to the health care system. We appreciate your consideration and are happy to provide further information or assist with any additional questions. Please feel free to contact me at (202) 393-0444 or jeff.a.farkas@medtronic.com if you need further information.

Sincerely,



Jeff Farkas
Vice President
Health Policy, Reimbursement, and Health Economics