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Statement to The
U.S. House Energy and Commerce Committee, Subcommittee on Health
Hearing on "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare"

September 13, 2018

Thank you for the opportunity to provide Medtronic's views regarding barriers to value-based care in Medicare.

Today, health systems across the country, including Medicare, are driving greater accountability for improved outcomes and reduced costs through new healthcare payment and delivery approaches that pay for value instead of volume. Medtronic's mission similarly guides us to deliver technology innovations that enable providers to manage chronic disease and improve patient outcomes – alleviating pain, restoring health and extending life. We believe fundamentally in the importance of shifting to payment models that include shared alignment and accountability with our healthcare system partners for the patient outcomes achieved in the use of our services and technology.

To realize the promise of value-based healthcare, Medtronic has formed partnerships with healthcare stakeholders and developed comprehensive technology and service solutions to address inefficiencies in healthcare delivery and foster value creation. We have a deep understanding of how cutting-edge technology can drive better clinical outcomes. We also know from experience that many technologies will not realize their full potential if they are simply placed into the care setting in a vacuum without the proper support services and training to fully leverage their capabilities in the clinical environment.

Medtronic's partnerships with providers, payers and healthcare systems include services and solutions to assist in optimizing the care pathway, coordinating care along that pathway, tracking outcomes, and sharing accountability for the results. Our capabilities in behavioral economics, reimbursement policy, data analytics, and care coordination allow us to meaningfully contribute to the optimized use of our technology to enable less invasive procedures, faster recovery times, fewer complications, and reduced utilization of clinical resources.

Value-based arrangements provide for the sharing of direct accountability for healthcare costs and patient outcomes between two or more healthcare entities and include the following characteristics:

- Targeted and meaningful outcomes must be identified in advance, with relevant metrics approved by stakeholders;
- Relevant costs of care must be known and agreed upon by stakeholders; and
- Payment by and between stakeholders is based or contingent on meeting the clinically meaningful outcomes and economic value created by the products, services and/or solutions provided.

Medtronic has established a process when considering and developing potential value-based arrangements to ensure rigor and discipline around the targeted disease or condition, identification of the appropriate patient

cohort, establishment and tracking of meaningful clinical and economic outcomes, and creation of payment models. This process helps ensure that:

- Relevant clinical and economic outcomes are related to the underlying disease or condition;
- Patient cohorts can be well-defined so best practice care pathways may be developed to reduce costs and improve outcomes;
- Outcome measures are well-defined, meaningful to patients, achievable in a defined timeframe, and agreed upon by key stakeholders;
- Outcome measures can be accurately collected through claims data, existing registries, Electronic Health Records (EHR), or other low-cost mechanisms; and
- The offering delivers measurable value – improved outcomes to patients and other benefits to the healthcare system through lower cost of care and/or other efficiencies or shared accountability.

One example of a Medtronic value-based arrangement is the Medtronic TYRX™ Risk-Share Program. The TYRX™ Antibacterial Envelope is the first commercially available implantable medical device designed to stabilize Cardiac Implantable Electronic Devices (CIEDs) and may help reduce the risk of infection. It is essentially an absorbable antibacterial envelope in which the CIED is housed when implanted into a patient.

The TYRX™ Risk-Share Program was designed to address a clear healthcare problem. Today, infections occur in 1-4 percent of all CIED implants, costing an average of $46,000-$87,000 per patient. The mortality rate of such infections is significant – ~50 percent at three years. Clinical studies have demonstrated that TYRX™ may help reduce CIED infections by 70-100 percent.

Under the TYRX™ Risk-Share Program, Medtronic will provide a rebate to participating facilities if a CIED infection occurs when a TYRX™ Envelope is used. In other words, the program incorporates accountability, such that failure to meet its clinical objectives – avoidance of CIED infection – results in Medtronic sharing the risk associated with this clinical outcome.

A second example is an innovative value-based relationship between Medtronic and UnitedHealthcare focused on delivering patient-centered solutions that improve health outcomes while reducing healthcare costs related to diabetes treatment and management.

In 2016, UnitedHealthcare and Medtronic announced an expanded relationship that gave UnitedHealthcare members with diabetes access to advanced insulin pump technologies and comprehensive support services offered by Medtronic. The partnership includes a value-based component, tying a portion of our payment from UnitedHealthCare to improved patient HbA1C levels and total cost of care.

Medtronic and UnitedHealthcare recently announced first year results stemming from the agreement. An analysis of over 6,000 UnitedHealthcare members with diabetes on Medtronic MiniMed™ 630G and previous generation insulin pumps demonstrated 27 percent fewer preventable hospital admissions compared to plan participants who are on multiple daily injections of insulin.

While Medtronic and other medical technology companies have launched a number of value-based arrangements similar to those summarized above, the existing healthcare fraud and abuse laws generally limit our ability to more robustly share risk for achieving "value" in our offerings, i.e., the improvements in patient outcomes in relation to the cost, within Medicare.

The Anti-Kickback Statute, the physician self-referral law – known as the Stark Law – and related fraud and abuse regulations were designed for a fee-for-service healthcare system to target behaviors that inappropriately increased utilization and costs. Unfortunately, the narrow interpretation and historical application of these laws stand at odds with the goals and objectives of a value-based healthcare system and prohibit full implementation of value-based programs.

The outdated fraud and abuse regulatory landscape combined with the government's historical enforcement approach creates a chilling effect for new models and partnerships, encumbering our nation's progress to achieve value-based care. Simply put, participants who can bring new and innovative ideas and relationships to the healthcare delivery system are reluctant to take on the risk of violating these outdated laws.

Medtronic believes that maintaining but modernizing these laws is critical to advancing the promise of value-based healthcare. We applaud the recent Requests for Information issued by CMS and the HHS Office of the Inspector General on the Stark Law and Anti-Kickback Statute that recognize this challenge, as well.

Specifically, the Anti-Kickback Statute was intended to protect against fraud and abuse by limiting certain types of financial arrangements and related incentives among healthcare parties, keeping them financially separated. Yet, under value-based payment arrangements, the goals are the opposite; parties are encouraged to be financially aligned to create incentives to encourage better coordination of care and other behaviors that improve outcomes and efficiencies. However, the law's existing safe harbors have not kept pace with how healthcare is delivered today and provide very limited protections for innovative value-based arrangements.

Today, much of the legal analysis for value-based arrangements depends on a somewhat subjective facts and circumstances analysis as opposed to a more objective, predictable and consistent value-based safe harbor application. For example, current law presents a significant challenge to arrangements that bundle devices and services, such as post-surgery or post-discharge remote monitoring services, which can help prevent unnecessary and costly rehospitalizations, or help catch health issues before they become serious and costly.

The Anti-Kickback Statute has very narrow technical requirements that must be met for a proposed arrangement to fit squarely within the law's existing discount safe harbor. The provision of such typically non-reimbursable services alongside the sale of a reimbursable product in a risk-sharing arrangement raises complex questions under the discount safe harbor requirements for bundling products and/or services, which require that all the items in the bundle be reimbursed by the "same methodology."

There is no meaningful consensus among the health law bar as to what "same methodology" means, which stifles true development and implementation of value-based healthcare programs. Absent clear safe harbor protection, the analysis depends on a facts and circumstance review, which as noted above may be highly subjective and inconsistent and lead a manufacturer or other stakeholder to decide that the risk of criminal prosecution is not worth the effort to offer innovative value-based programs.

Additionally, the services could be reviewed under the Anti-Kickback Statute's services safe harbor which requires, among other things, that the services be priced and charged at "Fair Market Value." The challenge with this is that because the healthcare market is so new to these types of value-based services and products programs, it is hard to find comparable offerings to serve as benchmarks for pricing. The risk of the services being priced at an amount that is arguably not consistent with a Fair Market Value also causes many manufacturers and other stakeholders to avoid potential legal exposure and decline to innovate in this important area.

To address these and similar challenges slowing the shift to value-based healthcare, we urge Congress to support consideration of new Anti-Kickback Statute and Stark Law value-based arrangement exceptions and/or safe harbor protections that provide appropriate opportunities for collaborative arrangements between and among all healthcare stakeholders, including providers, payers, therapy manufacturers, healthcare services and solutions providers and others, while maintaining protections for patients and the healthcare system.

Related, fraud and abuse waivers granted by the Centers for Medicare and Medicaid Services (CMS) and the Health and Humans Services Office of the Inspector General (OIG) for federal value-based healthcare programs such as through the Center for Medicare and Medicaid Innovation (CMMI) have generally been limited to provider entities. This appears to envision a healthcare system that is absent of any meaningful participation by non-provider entities to the enablement of clinical services that can help drive improvements in outcomes and efficiencies in patient care.

This means that some entities, including medical technology companies like Medtronic, are not able to fully avail themselves of the same protections that are available to traditional healthcare providers. This perspective makes sense historically, in a fee-for-service only system; however, as the healthcare industry continues to evolve toward value-based care, we need to account for the various entities that must collaborate to coordinate patient care, including under CMMI and other federal value-based programs.

To address this challenge, we urge the Congress to work with CMS and the OIG to extend federal value-based healthcare program waivers to more comprehensively allow for non-provider, manufacturer participation and risk-sharing in CMMI pilots, Medicare Alternative Payment Models (APMs), such as the Bundled Payments for Care Improvement-Advanced (BPCI-Advanced) program, and other initiatives.

In the case of both new exceptions/safe harbors and waivers, the incorporation of the concepts of shared financial risk and accountability, such that failure to meet pre-defined and -determined clinical and/or economic outcomes and objectives would force parties to incur financial exposure for missing those goals, would serve as a critical disincentive for overutilization and protection of both patients and federal healthcare dollars.

We appreciate this opportunity to provide insight into the role of medical technology companies like Medtronic in the delivery of value-based healthcare. We hope it is helpful in illustrating the need for Congress to modernize both the Anti-Kickback Statute and Stark Law through enactment of new value-based arrangement safe harbors, and the extension of federal healthcare program fraud and abuse waivers, in order to advance the collaborations needed to achieve the ultimate goals of value-based healthcare – improved patient outcomes at lower cost.

Thank you, again, and we welcome the opportunity to continue to work with you on this important issue.