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The Honorable Orrin Hatch
Chairman, Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member, Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Johnny Isakson
131 Russell Senate Office Building
Washington, DC 20510

The Honorable Mark R. Warner
475 Russell Senate Office Building
Washington, DC 20510

Submitted electronically to chronic_care@finance.senate.gov

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

On behalf of Sanofi, I commend your leadership to address the needs of millions of Medicare beneficiaries with chronic health conditions through the formation of a bipartisan Finance Committee chronic care working group.

Sanofi is an integrated, global healthcare company focused on patients' needs and engaged in the research, development, manufacturing and marketing of an array of healthcare products. We have world-class therapies in several therapeutic areas, including: cardiovascular diseases, oncology, diabetes, central nervous system, vaccine-preventable diseases, and rare diseases. As a company, we are dedicated to keeping people healthy, and chronic disease management is of paramount importance to our work.

As you know, chronic diseases and conditions are the leading causes of death and disability in the United States and account for most health care costs. But perhaps most importantly, we have an opportunity to prevent chronic diseases before they start. Identifying and screening for chronic disease is essential to prevent rapid progression and the development of concomitant diseases. Ultimately, investing in prevention-oriented strategies and embedding prevention in the health care delivery system presents a way to simultaneously improve health outcomes and reduce health care costs.

We appreciate the opportunity to share our comments on chronic care reform with the Committee. We also support the comments from our trade associations, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO). Below are our comments on selected policy categories outlined by the Committee.

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Transformative policies that improve outcomes for patients living with chronic diseases either through modifications to the current Medicare Shared Savings ACO Program, piloted alternate payment models (APMs) currently underway at CMS, or by proposing new APM structures;

- The Committee should closely monitor the incentives and structure of alternative payment models (APMs) underway at CMS to ensure they encourage appropriate care for all beneficiaries. While APMs present an opportunity to improve outcomes for patients living with chronic diseases, they also present a risk of "cherry-picking" only the healthiest patients and skimping on care to those beneficiaries with more costly conditions. Incentives must be aligned so that all parties involved—health care professionals, plans, pharmaceutical manufacturers, and patients—have a vested interest in providing the necessary care to patients with chronic diseases. In particular, it's important that these models support patient access to new medicines and medical technologies by providers. We must embrace innovative therapies to better treat and manage chronic disease in the future.

- The concept of Value Based Insurance Design (V-BID) in Medicare Advantage deserves consideration; however protections are necessary before a demonstration could be extended to Part D drugs. The purpose of V-BID is to reduce barriers to high-value services and providers and to discourage utilization of low-value health services and providers.[1] For example, V-BID could reduce barriers to care by lowering copays for prescriptions or services to increase treatment adherence—in turn, lowering future spending by maintaining health and managing chronic conditions. Additionally, V-BID could minimize barriers to targeted preventative measures like vaccines and screenings which could help to prevent the occurrence of disease or identify it for earlier treatment.

  It will be important for any V-BID model to include clinical nuance, which is the recognition that treatments, services and providers have different clinical benefits depending on the patient, their prognosis, and who is delivering the care.[2] Incorporating clinical nuance into V-BID is essential because it aims to provide care to patients with the highest clinical benefit while maintaining the role of the provider in determining the best course of care for the patient.

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[1] The University of Michigan Center for Value-Based Insurance Design, *Implementing Value-Based Insurance Design in Medicare Advantage, June 2013*, available at http://vbidcenter.org/wp-content/uploads/2014/10/V-BID-Brief-Medicare-Advantage-June-2013.pdf.

[2] Patel, Kavita, Cliff, Elizabeth and Fendrick, A. Mark. Clinical Nuance: Benefit Design Meets Behavioral Economics. *Health Affairs Blog*, April 3, 2014, available at http://healthaffairs.org/blog/2014/04/03/clinical-nuance-benefit-design-meets-behavioral-economics/.

Before the concept of V-BID could be extended to Part D, parameters must be clearly established on the determination of "value" of any particular service and provider. The "value" of the service must be based on clinical evidence and determined at the plan level. Furthermore, it is crucial that V-BID models be evaluated in a robust and transparent process that does not negatively affect patient access to care. Additionally, any V-BID demonstration must not disrupt Part D's successful, competitive structure nor undermine important affordability protections in statute.

Reforms to Medicare's current fee-for-service program that incentivize providers to coordinate care for patients living with chronic conditions;

- Medicare must do more to adequately address problems around transitions of care. According to CMS, nearly one in five Medicare patients discharged from a hospital—approximately 2.6 million seniors—are readmitted within 30 days, costing over $26 billion every year.[3] Helping Medicare beneficiaries better navigate care transitions is a key component of reducing unnecessary hospital readmissions.

  The Affordable Care Act (ACA) created the Community-Based Care Transition Program (CCTP), which is providing funding to 72 community-based organizations that partner with hospitals to test different methods to improve patient health when they transition out of the hospital. The Patient-Centered Outcomes Research Institute (PCORI) is now funding research to compare different types of transitional care services to determine which are more effective in improving patient health and lowering costs. However, additional measures are necessary to ensure that Medicare beneficiaries who are at the highest risk for hospital readmission have access to evidence-based transitional care services based on the best practices in the field. Specifically, patients should have access to a comprehensive medications management plan, ensuring that the patient's care is coordinated among the multiple providers and facilities they encounter.

- Medicare should better facilitate the use of shared medical appointments/group medical visits for beneficiaries with chronic conditions. Shared medical appointments represent an innovative and interdisciplinary care model that allows multiple patients with similar conditions and care needs to have an extended appointment with their medical provider. For example, diabetes patients would meet with their physician and other members of a health care team including diabetes educators, dieticians, nurses and health educators, as well as with other patients that share the same disease diagnosis. This group interaction has been shown to facilitate education and counseling and improve disease management.

[3] Centers for Medicare and Medicaid Services, *Community-based Care Transitions Program*, available at http://innovation.cms.gov/initiatives/CCTP/.

The Greater Flint Health Coalition is a nonprofit health coalition in Michigan that pioneered an initiative in 2008 known as the Diabetes Group Visit Project. They found group visits improved care and outcomes, increased patient and physician satisfaction, engaged patients in the management of their diabetes, and improved physician productivity and practice efficiency.[4]

An increasing number of health care providers across the country are utilizing shared medical appointments for patients with chronic conditions. However, we understand that providers can face challenges when seeking reimbursement for shared medical appointments. According to the American Academy of Family Physicians (AAFP), Medicare has not published any official payment or coding rules for these group visits.[5] Providers must currently cobble together a series of codes reflective of the care team present at the appointment. Congress should examine the current coding and billing of shared medical appointments in Medicare and enact any necessary reforms to facilitate their use for beneficiaries with chronic conditions.

- The Committee should explore the out-of-pocket costs of chronic care on beneficiaries in fee-for-service (FFS) Medicare. While beneficiaries in Medicare Advantage plans are likely to have access to disease management programs and coordinated care, beneficiaries in FFS Medicare are less likely to receive these interventions and could face unexpected out-of-pocket costs that act as a barrier to care. For example, Medicare's new chronic care management (CCM) code that went into effect in January is subject to the Part B deductible and a 20 percent beneficiary coinsurance because it has not been assigned an "A" or "B" rating by the United States Preventive Services Task Force (USPSTF). Similarly, Part B coinsurance requirements are triggered when beneficiaries unexpectedly need to have a polyp or abnormal growth removed during a routine colonoscopy. This could cost a beneficiary more than $300 and becomes a financial disincentive to seeking preventive screenings that have been proven effective.[6]

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[4] The Greater Flint Health Coalition, *Diabetes Group Visits Brochure*, available at http://www.gfhc.org/Greater%20Flint%20Health%20Coalition/docs/PUBLICATIONS/GR-8D%20brochure.pdf.version.022311tc.pdf.

[5] American Academy of Family Physicians, *Coding for Group Visits*, available at http://www.aafp.org/practice-management/payment/coding/group-visits.html.

[6] American Cancer Society Cancer Action Network, *Removing Barriers to Colorectal Cancer Screening Act, H.R. 1220 and S. 624*, Available at http://www.acscan.org/content/wp-content/uploads/2015/04/Removing-Barriers-to-Colorectal-Cancer-Screening-Act.pdf.

The effective, use, coordination and cost of prescription drugs;

The Committee is well aware that strengthening medication adherence not only improves patient health, it also reduces health care costs. According to the Congressional Budget Office, a one percent increase in the number of prescriptions filled by Medicare beneficiaries would reduce spending on medical services by one-fifth of one percent.[7] This type of savings only occurs when patients take their medicines as prescribed. We believe that medication adherence could be improved through changes to the Part D Medication Therapy Management (MTM) Program and the use of medication synchronization for Medicare beneficiaries.

- The Committee should consider a number of changes to reach beneficiaries who would benefit from MTM. In particular, we encourage the Committee to make changes to the eligibility criteria, including:
    - lowering the targeting criteria to one or more chronic conditions if one of those conditions has shown to be adherence responsive, such as diabetes;
    - targeting MTM enrollment based on a beneficiaries recent medical history, such as a hospital discharge; and
    - focusing on beneficiaries with high total medical spend.

  When considering changes to MTM, it's also important to properly align incentives for stand-alone prescription drug plans (PDPs) in Medicare Part D. Part D plans do not offer medical benefits and thus cannot realize cost-savings due to increased medication adherence. To help address this issue, the Committee could clarify that all MTM activities are "quality improving" for the purposes of calculating the Medical Loss Ratio (MLR). Similarly, it's also important for PDPs to have timely access to Medicare Parts A and B data so they can identify beneficiaries who should be enrolled in the MTM program.

  One way that Sanofi is trying to help address adherence is through novel approaches to patient support. In addition to bringing innovative medicines to market, Sanofi is pairing them with wrap-around patient support services, like its COACH program, to engage patients in taking an active role in managing their diabetes. COACH is a comprehensive, tailored support program that proactively reaches out to patients to provide one-on-one education that helps them understand how to appropriately utilize their medication, set goals toward lifestyle changes, and develop sustained healthy routines.

[7] Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services*, November 2012, available at: https://www.cbo.gov/sites/default/files/43741-MedicalOffsets-11-29-12.pdf.

Sanofi has spent a lot of time exploring the role of community health workers in the health care delivery system and their potential to build trusted relationships with patients that improve health outcomes. They are lay members of the community that fill a variety of public health roles, such as offering culturally appropriate health education and information, providing social support and informal counseling, and delivering certain health screening services. The Centers for Medicare and Medicaid Innovation (CMMI) has a number of ongoing projects that rely on community health workers as part of the care delivery team. We believe community health workers could play a greater role in medication adherence and suggest the Committee explore ways to encourage providers and payers to further engage these professionals. The Centers for Disease Control and Prevention (CDC) recently released a policy brief on community health workers outlining steps that state health departments and their partners may consider to better integrate community health workers into community-based efforts to prevent chronic disease.[8]

- Medicare should test a medication synchronization program for beneficiaries with chronic conditions and who are at risk of poor medication adherence. Beneficiaries with a chronic disease could take multiple medications that require numerous trips to a pharmacy each month. A medication synchronization program could provide pharmacist counseling, a comprehensive medication review, and the ability for beneficiaries to pick up all medication refills at the same time. Any medication synchronization program must be based on best practices in the commercial market and remain affordable for beneficiaries so that their copays could be staggered over the course of the month.

Strategies to increase chronic care coordination in rural and frontier areas;

- The Committee should explore ways to encourage comprehensive mobile medical care to chronically ill beneficiaries living in isolated and underserved communities. Nearly 25 percent of Americans (70 million people) live in rural areas, but only 10 percent of doctor's practice there. The Sanofi Foundation for North America has partnered with the Children's Health Fund (CHF) for several years in support of its mission to provide access to high-quality health care for underserved children in rural and urban communities across America. As part of this initiative, our foundation supports eight CHF mobile medical clinics (also known as a "doctor's office on wheels") in Austin, Phoenix, Orlando, Los Angeles, Newark, Clarksdale and in a recent expansion of services, also in Detroit and Washington, D.C. [9]

[8] The Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention, *Addressing Chronic Disease Through Community Health Workers: A Policy and Systems Level Approach*, Second Edition, April 2015, available at http://www.cdc.gov/dhdsp/docs/chw_brief.pdf

[9] The Children's Health Fund, *Medical Home Initiative*, available at http://www.childrenshealthfund.org/special-initiatives/medical-home-initiative.

Through this initiative, we have learned the importance of delivering a medical home to isolated populations. The care delivered—including in mobile clinics—must be comprehensive, culturally appropriate, and coordinated. For example, the mobile medical clinics provide children with age-appropriate immunizations, early identification and management of chronic illness, including asthma, obesity, and health education. They also assist in case management and maintain electronic health records on patients. The key learnings from this medical mobile home concept could be applicable to the delivery of care to chronically ill Medicare patients.

Options for empowering Medicare patients to play a greater role in managing their health and meaningfully engaging with their health care providers; and

- The Committee should consider ways to increase the level of patient engagement into the Medicare program. Beneficiaries with chronic conditions—such as diabetes—could benefit from a patient education and engagement programs that include regular assessments regarding knowledge, skill, and performance. After the assessments, additional education is targeted to meet the individual patient's needs. Sanofi has supported work done by the American Pharmacists Association (APhA) Foundation on a "patient credentialing program" where patients are "credentialed" at various levels depending upon demonstrated expertise and competency, which typically earns them incentives for participation. The APhA Foundation developed a psychometrically validated tool that empowers health care providers (HCPs) and patients to work together in meaningful and efficient ways to identify and address areas for improvement in the self-management of chronic diseases.[10]

- Beneficiaries in FFS Medicare should have the ability to participate in a rewards and incentives program that promotes wellness and disease management. Sanofi has a robust employee wellness and disease prevention platform. Employees are encouraged to obtain a biometric screening and a personal health assessment which leads to a customized action plan that includes recommendations for preventive screenings, good nutrition habits and exercise recommendations, as well as lifestyle and health management coaching. Upon completion of these activities, employees are offered incentives for undertaking healthy behaviors. As a result of the program, Sanofi has seen an improvement in preventive screening rates as well as a lower than average medical cost trend compared to other large employers.

[10] The American Pharmacists Association (APhA) Foundation, *Patient Self-Management Credential (PMSC)*, available at http://www.aphafoundation.org/patient-self-management-credential-project.

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Beneficiaries in Medicare Advantage plans already have the ability to participate in rewards and incentives programs that provide a variety of dedicated resources, as well as specific incentives for achievement and incentives. We recommend that the Secretary of Health and Human Services develop a similar program for beneficiaries in FFS programs.

We're grateful for the opportunity to submit comments to the chronic care working group and look forward to working with you to improve care for Medicare beneficiaries with chronic conditions. Thank you for your consideration of these important issues.

Sincerely,