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January 29, 2016

The Honorable Orrin Hatch
Chairman
Committee on Finance
United States Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Johnny Isakson
Senator
Committee on Finance
United States Senate

The Honorable Mark Warner
Senator
Committee on Finance
United States Senate

VIA ELECTRONIC SUBMISSION TO: chronic_care@finance.senate.gov

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

Sanofi U.S. ("Sanofi") appreciates the opportunity to provide comments in response to the Bipartisan Chronic Care Working Group's Policy Options Document, released in December 2015. Sanofi is an innovative biopharmaceutical research company, devoted to discovering and developing medicines supporting patients in a number of therapeutic areas including chronic care needs in the treatment of diabetes and cardiovascular diseases. Sanofi applauds the Committee for its commitment to the important issue of finding ways to improve outcomes for Medicare beneficiaries with chronic conditions.

Sanofi supports the comments on the Policy Options Document submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the Biotechnology Innovation Organization ("BIO"), the Prescriptions for a Healthier America (P4HA) and the Adult Vaccine Access Coalition (AVAC). As a stakeholder committed to improving outcomes and care for patients with chronic diseases, Sanofi would like to add our emphasis and support to several of the areas under discussion in the Policy Options Document concerning Medication Synchronization, Quality Measures for Chronic Conditions and Receiving High Quality Care in the Home and Community.

Expanding Supplemental Benefits in Medicare Advantage and Adherence in Part D Overall

Sanofi supports the proposal of the Working Group for a policy to allow MA plans to offer a wider array of supplemental benefits than they do today. Adherence support services should be considered or added as a supplemental benefit MA could offer. Studies have shown consistently that 50 percent of medications for chronic disease are not taken as prescribed and 20 to 30 percent of medication

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prescriptions are never filled.[1] Medication adherence is particularly important to a broad range of serious chronic conditions such as diabetes. The Working Group should consider enhancing adherence across in stand-alone Part D plans. We are encouraged by the previous legislative interest and the CMMI efforts to improving the Part D Medication Therapy Management (MTM) program to improve not only the medication usage among enrollees with chronic conditions but also as a component of improving adherence. As proposed, the model design of the Enhanced MTM demonstration allows PDP sponsors to work with physicians and pharmacies, but not drug manufacturers. Manufacturers have a range of materials and resources that could be used by pharmacies and plans to improve use of medicines. Additionally, various barriers and challenges exist that could be studied and improved: adequate patient eligibility criteria for the program; access to timely Part A and B data; and aligned incentives allowing PDP plans to be adequately reimbursed. We encourage the Committee to look for ways to increase medication adherence as they continue developing this paper into legislation.

Study on Medication Synchronization (p. 29)

Sanofi supports the Committee's consideration of a study to identify potential obstacles to medication synchronization under Medicare Part D. Medication synchronization is a process of consolidating a patient's refills for multiple medications to reduce the number of trips they have to make the pharmacy. Medication synchronization can be extremely important in improving the adherence for patients with multiple chronic diseases such as diabetes and elevated cholesterol. These patients can routinely be prescribed multiple medications just for diabetes, both oral and injectable, and medication synchronization has the potential to support better medication management by allowing the dispensing pharmacist to review all of the patient's medications at one time, identify any missing or duplicate therapies, and provide counseling in appropriate administration as needed. Synchronizing medications can also enable use of compliance-based packaging at the pharmacy, which packages together medications to be taken at a particular time each day.

Initial evidence about the effect of medication synchronization suggests that it can improve adherence.[2] Improved adherence has been shown to lead to reductions in medical spending for patients with many chronic conditions.[3] A study exploring current barriers to medication synchronization under Part D could help identify changes that have the potential to yield savings for the Medicare program.

We also support legislation to test medication synchronization interventions that has been introduced in the House of Representatives. The Synchronization & Non-adherence Correction (SYNC) Act of 2015 (H.R.4292) would require a demonstration testing three approaches to medication synchronization – synchronization, synchronization with compliance-based packaging, and synchronization with ongoing

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[1] Viswanathan M, Golin CE, Jones CD, et al. Medication Adherence Interventions: Comparative Effectiveness. Closing the Quality Gap: Revisiting the State of the Science. EVIDENCE REPORT/TECHNOLOGY ASSESSMENT NO. 208. (Prepared by the RTI International-University of North Carolina Evidence-based Practice Center under Contract No. 290-2007-10056-I.)

[2] D. Holdford and T Inocencio. Appointment-Based Model (ABM) Data Analysis Report. Prepared for Thrifty White Pharmacy. Virginia Commonwealth University.

[3] Roebuck MC, Liberman JN, Gemmill-Toyama M, et al. Medication adherence leads to lower health care use and costs despite increased drug spending. Health Affairs. 2011;30(1):91-99.

pharmacist counseling. This demo would offer an opportunity to formally evaluate the impact that medication synchronization interventions have on adherence – evidence that is currently lacking in the literature due to limited adoption of this promising intervention. The SYNC Act would also test 90-day fills at retail pharmacies, an intervention which shows great promise in improving adherence. Because current evidence around the effect of medication synchronization is so limited, there is need for a study testing the effectiveness of these promising interventions in the real world. We recommend and hope that in implementation of a study that focus is also given to medications that require periodic titration in order to allow for periodic synchronization updates as medication dosing and strength may be changed due to titration evaluations.

Developing Quality Measures for Chronic Conditions (p. 22)

Sanofi supports the proposal for CMS to include the development of measures that focus on health outcomes for individuals with chronic disease in its measure development plan. Currently, patients with chronic disease (especially those with multiple chronic conditions) are not well represented in care guidelines. We support the Working Group's attention to measures of patient and family engagement and shared decision making in particular as these patients have a demonstrated need for long term family support. As the health care marketplace increasingly shifts towards models that seek to reward health care value, these measures will be critical to ensuring that patients with chronic disease are receiving high quality patient-centered care that aligns with their values and preferences.

Sanofi suggests to the Working Group to consider the extent to which community-level measures are appropriate measures of the care an individual patient receives. This is an important consideration with implications since in some instances (e.g., immunization services) community-level measures may meaningfully indicate the impact of care on an individual patient, while in the case of chronic disease care, community-level measures have the potential to obscure important information about individualized care. In turn, tying provider reimbursement to the achievement of community-level measures may undermine the Working Group's broader goal of improving chronic disease care for Medicare beneficiaries by incentivizing the provision of "one size fits all" care, rather than targeting care toward the individual complexities and needs of each patient. Sanofi has commented on this same concern to CMS and we continue to urge CMS to strive to identify consensus quality measures that are both meaningful and supportive indicators of desirable patient health outcomes.

Insight to our noted concern above can be identified in quality measures for two chronic conditions, cardiovascular disease and diabetes.

For the CY2016 PQRS and MSSP quality programs, CMS will collect reporting on a new measure "Statin Therapy for the Prevention and Treatment of Cardiovascular Disease". Sanofi commented that this new measure signals a shift away from health outcomes and back toward process-oriented measures. This measure identifies three patient risk types, or denominators, but it will produce just one aggregate score or evaluation. We suggest that just one evaluation does not allow the collected data to be used as an analytic tool to determine if the measure is improving care in each of the three risk types. For this reason, we have recommended that CMS implement this measure as three distinct measures and retain

all three measures as pay for reporting until the initial measure undergoes further development and receives full endorsement from the NQF.

Additionally, for the CY2016 PQRS and MSSP quality programs, CMS retired four components of the composite measure "Optimal Diabetes Care" including the component that tracked the ratio of identified diabetics whose HbA1c levels were maintained less than 8%, a move we consider misguided, inconsistent with widely accepted treatment goals for most diabetic patients, and detrimental to Medicare patients with diabetes. We also note that the only available medication adherence quality metric (Medicare Advantage STAR program –Adherence to Anti-Diabetic Medications) specifically excludes insulin as a component. We recognize the complexity of diabetes and the need for individualized treatment for people with diabetes makes it difficult to develop one comprehensive quality measure and as stated above, we believe that population measures are not always appropriate, but we are concerned about the lack of any quality measures for diabetes. In order to truly make a dent in the trajectory of the disease and its budgetary impacts, more consideration and work needs to be placed on how to develop quality measures that are inclusive yet specific enough to allow for individual patient needs.

Receiving High Quality Care in the Home and Community

Sanofi supports the need to improve the current Independence at Home demonstration. With both the expansion of health insurance coverage under the ACA as well as the growth of the proportion of the US population with at least one chronic disease, a growing shortfall nationwide of physicians and other associated health care providers is projected.[4] The working group should also consider the broader context of overall patient home and community care through initiatives to test and pursue improving the "Point of Care" across the nation (i.e., the optimization of resources and enhanced care coordination

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[4] Tim Dall, Terry West, Ritashree Chakrabarti, and Will Iacobucci, "The Complexities of Physician Supply and Demand: Projections from 2013 to 2025," Association of American Medical Colleges, March 2015, https://www.aamc.org/download/426242/data/ihsreportdownload.pdf?cm_mmc=AAMC-_-ScientificAffairs-_-PDF-_-ihsreport ; Walt Zywiak, "U.S. Healthcare Workforce Shortages: Caregivers," CSC, May 2013, http://assets1.csc.com/health_services/downloads/CSC_US_Healthcare_Workforce_Shortages_Caregivers.pdf; "Recent Studies and Reports on Physician Shortages in the US," Center for Workforce Studies, Association of American Medical Colleges, October 2012, https://www.aamc.org/download/100598/data/; "National Center for Health Workforce Analysis," Health Resources and Services Administration, http://bhpr.hrsa.gov/healthworkforce/; Michael J. Dill and Edward S. Salsberg, "The Complexities of Physician Supply and Demand: Projections Through 2025," Center for Workforce Studies, Association of American Medical Colleges, November 2008, http://www.innovationlabs.com/pa_future/1/background_docs/AAMC%20Complexities%20of%20physician%20demand,%202008.pdf; Amy Anderson, "The Impact of the Affordable Care Act on the Health Care Workforce," The Heritage Foundation, March 18, 2014, http://www.heritage.org/research/reports/2014/03/the-impact-of-the-affordable-care-act-on-the-health-care-workforce.

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at the location where medical care is actually delivered), with a goal of addressing shortages of healthcare professionals services and incorporating a more comprehensive approach to treating chronic illness. "Point of Care" delivery focuses on optimization of resources to meet different needs in multiple patients or the same patient (especially those with multiple chronic diseases). The primary point of contact is generally the primary care or specialist healthcare professionals that see patients in the non-institutional setting on a day-to-day basis. This can include those healthcare professionals operating in physician's offices or from satellite locations as well, and it's inclusive of every touch point for the patient, i.e. the integrated loop where patients access care. Importantly, this also can include care and services from a variety of different types of providers and care givers that reach patients in their home and community, such as certified diabetes educators, community health workers and social workers.

We encourage the Committee to take a holistic view when contemplating policy options to improve the care of patients with chronic diseases, and to promote delivery and reimbursement models that coordinate care among the various healthcare professionals and healthcare settings that a patient will encounter. Chronic care patients face a complex and siloed healthcare delivery system today and Sanofi supports policies that seek to streamline the patient experience while improving the effectiveness and efficiency of healthcare delivery.

An essential element necessary to maximize success of this approach to care is recognition of the need to identify a much wider definition of the types of services necessary to support best care and patient wellness, a new acceptance of the expanded role and scope various healthcare professionals will provide in the future and a need to align reimbursement to support and incentivize these new services within an integrated delivery structure such as a medical home or medical community.

Sanofi appreciates the opportunity to engage with the Working Group as it pursues improvements in chronic care in Medicare beneficiaries.

Sincerely,