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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

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

On behalf of Novartis Pharmaceuticals Corporation (NPC), thank you for this opportunity to respond to your request for information and input on ways to improve outcomes for Medicare patients with chronic conditions. As the Committee has recognized, this is a tremendously important issue not only for the individuals who suffer from these conditions but for the long term sustainability of our healthcare system given the high costs of health care for these individuals.

We applaud the Committee for recently forming the bipartisan Chronic Care Working Group (Working Group). This Working Group is appropriate and timely given the continuing rise in prevalence of chronic illnesses such as heart disease, diabetes, chronic obstructive pulmonary disease (COPD) and cancer, which now account for almost 93 percent of Medicare spending. NPC appreciates that as one of your first steps as a working group, you have reached out to stakeholders in the private sector, for input that will guide and inform your efforts to improve care for individuals with chronic conditions.

At NPC, we aim to improve patients' lives through our research, development, manufacturing and marketing of innovative medicines for a broad range of conditions including cancer, cardiovascular disease, endocrine disease, inflammatory disease, infectious disease, neurological disease, organ transplantation, psychiatric disease, respiratory disease and skin conditions. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

We focus our recommendations on heart failure and provide examples of ways to address your goals of increasing care coordination among individual providers across care settings, streamlining Medicare's current payment systems to incentivize the appropriate level of care for

patients living with chronic diseases, and facilitating the delivery of high quality care. We believe these suggestions have the opportunity to improve care transitions, produce stronger patient outcomes, and reduce the growth in Medicare spending.

Chronic Heart Failure

Heart Failure (HF), a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's needs for blood and oxygen, is a rapidly growing public health problem in the US population, and in particular, among Medicare beneficiaries. HF prevalence increases with age and HF incidence approaches 10 in 1000 in the over-65 population.[1] With the aging of the American population, this high prevalence is expected to increase from 5.1 million in 2012 to over 8 million by 2030.[2] HF is associated with high mortality, and studies have found that roughly half of HF patients die within 5 years of diagnosis and for those with a HF hospital admission, 22% die within 1 year.[3] Moreover, this chronic condition is responsible for high medical costs primarily related to hospitalizations, and also encompassing costs for end-of-life care. In 2012, the total direct medical cost for HF was estimated at $20.9 billion, and by 2030, the cost is expected to increase to $53.1 billion.[4] For Medicare, addressing the needs of HF patients is particularly urgent -- HF contributes to 34% of the total Medicare spend, 42% of the total Medicare admissions and 55% of the total Medicare readmissions.[5]

To improve the delivery of high quality healthcare, which will in turn lead to better health outcomes for Medicare beneficiaries and lower costs for the Medicare program, NPC urges the Working Group to focus on improved transitions of care, better understanding the importance of medication adherence, and quality measurement related to heart failure. We also comment briefly on Alternative Payment Models (APMs) and express support for the detailed comments that have been submitted by the Biotechnology Industry Organization (BIO) and PhRMA.

Transitions of Care

With hospitalizations accounting for a significant portion of the high medical costs for patients with HF, having effective transitions of care can be key to improving health outcomes and reducing costs. Poorly executed transitions of care can lead to increased use of hospital and other care. One important component of care transitions includes reconciliation of discharge

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[1] Mozaffarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics-2015 update: a report from the American Heart Association. Circulation. Jan 27 2015;131(4):e29-e322.
[2] Heidenreich PA, Albert NM, Allen LA, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circulation. Heart failure. May 2013;6(3):606-619.
[3] Roger VL, Weston SA, Redfield MM, et al. Trends in heart failure incidence and survival in a community-based population. JAMA. 2004;292(3):344-350. Loehr LR, Rosamond WD, Chang PP, Folsom AR, Chambless LE. Heart Failure Incidence and Survival (from the Atherosclerosis Risk in Communities Study). American Journal of Cardiology.101(7):1016-1022.
[4] Milliman, The High Cost of Heart Failure for the Medicare Population: An Actuarial Cost Analysis. Commissioned by Novartis Pharmaceuticals Corporation, February 2015, at p. 3.
[5] Id. at 23.

medicines with other medications to ensure that patients are not taking duplicate therapies or inappropriate medications.

We would like to bring to the Working Group's attention a report prepared last May for the Agency for Healthcare Research and Quality (AHRQ) on "Transitional Care Interventions To Prevent Readmissions for People With Heart Failure" in which researchers conducted a meta-analysis to examine transitional care interventions that aim to reduce readmissions and mortality for adults hospitalized with HF.[6]

The researchers found that the two categories of interventions that reduced all-cause readmissions (focused mainly on 30-day readmissions) were the following multi-component complex interventions: home visiting programs and multidisciplinary HF clinic interventions.[7] Both of these categories of interventions included common elements of: HF education, HF pharmacotherapy emphasizing patient education about medications, adherence to medication regimens, face-to-face contact with home-visiting personnel following discharge, streamlined mechanisms to contact personnel outside scheduled visits, and mechanisms for post-discharge medication adjustment. Interventions that were successful in reducing mortality rates over 3 to 6 months shared some of the same components.

Although the AHRQ report found that there are still gaps in the evidence surrounding effective transitions, we believe that these categories of interventions show important potential for improving care and reducing costs. We would urge the Working Group focus on further research and support for effective transitions of care for patients with HF as way to bend the Medicare cost curve and positively impact patient outcomes.

Medication Adherence and Disease Management Programs

Improving medication adherence and disease management in the chronic care population – and particularly with respect to those with HF – holds exciting potential to both improve health outcomes and reduce healthcare expenditures. With the implementation of the Hospital Readmissions Reduction Program (HRRP) in 2012, which was created by section 3025 of the Affordable Care Act of 2010, there has also been an increase in efforts to develop medication adherence and disease management programs. The HRRP requires CMS to reduce inpatient prospective payments to hospitals that have excess readmissions with respect to certain conditions, one of which is HF. Providers have responded to the need to reduce readmissions or else face penalties. Despite the accelerated efforts to develop HF disease management programs to reduce readmissions, however, we believe there is room to improve.

Current clinical practice still varies greatly with respect to care for patients with HF after a hospitalization. Studies have shown that hospitalizations can be reduced through better adherence to drug regimens and simple steps such as patients taking medications in accordance with their physicians' orders. Yet efforts to improve medication adherence still face barriers to

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[6] AHRQ Publication No. 14-EHC021-EF, prepared by the University of North Carolina Evidence-based Practice Center , Transitional Care Interventions To Prevent Readmissions for People With Heart Failure (May 2014).
[7] Id. at ES-15.

widespread support and adoption. A recent study examined the impact of the drug coverage under Part D on reductions in medical expenditures among beneficiaries diagnosed with congestive heart failure (CHF) and without prior comprehensive drug coverage. The study also simulated the economic implications of improving adherence among CHF patients to 80%. The authors estimate that further improvements in adherence could potentially save Medicare another $1.9 billion annually.[8]

The FDA Office of Health and Constituent Affairs recently announced that it has teamed with the nonprofit National Forum for Heart Disease and Stroke Prevention to advance the cause of a heart-healthy and stroke-free society. The goals of the initiative are to "create recommendations to improve compliance with prescribed medical therapies and implement the recommendations to improve the lives of patients living with heart disease".[9] We suggest the Working Group follow this initiative closely to determine if best practices can be adopted for Medicare beneficiaries.

NPC believes that more can be done to tap into the potential that medication adherence has to offer. For example, the Working Group should focus on developing ways to better incorporate medication adherence into the Medicare program and to specifically draw out the impact that such efforts have on the various aspects of poor adherence such as intermittent or inconsistent use, gaps in therapy, or discontinuation of a drug and driving factors including patient attitude, access to care, affordability or lack of adherence to evidence-based treatment guidelines.[10] There is also evidence that shows as cost-sharing for patients increases, adherence to medications decreases. Therefore, we also suggest that the Working Group examine existing Part D benefit designs such as very high cost sharing for medicines to assess how they may impede patients' ability to gain access to the items and services that are most valuable to them.

Health outcomes for beneficiaries with HF could also be improved through greater use of cardiac rehabilitation (CR) services. In February 2014, CMS issued a coverage decision memorandum that expanded coverage for CR services to beneficiaries with stable, chronic heart failure.[11] These services are multi-disciplinary and address multiple factors associated with HF. Programs are required to include the following components:

- Physician prescribed exercise each day CR services are furnished;
- Cardiac risk factor modification, including education, counseling, and behavioral interventions, all tailored to the patient's individual needs;
- Psychosocial assessment; and
- Outcomes assessment.

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[8] http://www.ajmc.com/journals/supplement/2013/a460_13may_medicarepartd/A460_13May_MedicarePartD
[9] http://blogs.fda.gov/fdavoice/index.php/2015/05/fda-teams-with-national-forum-to-reduce-deaths-from-heart-disease-program-is-first-of-its-kind/?source=govdelivery&utm_medium=email&utm_source=govdelivery
[10] Ruth Lopert MD, et al, Medication Adherence and Medicare Expenditure Among Beneficiaries With Heart Failure, Am J Manag Care. 2012;18(9):556-563).
[11] CMS, Decision Memo for Cardiac Rehabilitation (CR) Programs, CAG-00437N (February 18, 2014).

A recent Brookings paper, "Treating Congestive Heart Failure and The Role Of Payment Reform", cites a New England Journal of Medicine (NEJM) study, which "estimated that lifestyle choices and behavior account for 80 to 90% of cardiovascular disease diagnoses, including diet, exercise, substance abuse, and obesity".[12] Behavioral interventions and exercise called for in CR services could play a key role in helping individuals better manage their condition.

We appreciate the CMS decision to expand CR services to beneficiaries with HF. However, despite the holistic approach to therapy and the potential for improved outcomes, utilization of these services is low among Medicare physicians and patients. A 2012 Scientific Statement from the American Heart Association (AHA) discussed a number of the barriers to CR access. According to the AHA, the benefits of CR are greatly under-appreciated in both the public and medical community.[13]

We would urge the Working Group to prioritize efforts to better incorporate medication adherence and effective disease management programs. In particular, we support the recommendations laid out by PhRMA in this important area of medication adherence. We also recommend that the Working Group examine how to optimize use of CR services.

Quality Measurement

Quality measurement programs in effect across the country in both the private and public sectors are recognized as an effective way to raise awareness about and alignment with best practices, streamline clinical care, hold providers accountable and measure standards of care and improvement. As you know, the National Quality Forum (NQF) leads national collaboration to improve health and healthcare quality through measurement and is the convener of key public and private sector leaders to establish national priorities and goals to drive healthcare forward with NQF-endorsed standards and quality improvement.

Last November, the NQF issued a technical report on measures for cardiovascular conditions.[14] The NQF portfolio of performance measures for cardiovascular conditions currently contains 63 measures: 42 process measures, 19 outcome and resource use measures, and 2 composite measures.[15] A large number of measures in this topic area, however, "require greater attention to harmonization of related measures, and consolidation of measure," and in the case of some, the measures are "'topped out' with little further room for improvement." In addition to the 17 measures which were the focus of the review in 2014, the report also identified the following areas in which additional measurement development is needed:

- measures of cardiometabolic risk factors;

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[12] Brookings, Treating Congestive Heart Failure and The Role of Payment Reform, Lessons from Duke University Health System and the University of Colorado Hospital, May 2014.
[13] http://circ.ahajournals.org/content/126/21/2535.full.pdf+html
[14] National Quality Forum, Technical Report: NQF-Endorsed Measures for Cardiovascular Conditions: 2014, Nov. 29, 2014.
[15] Id. at p. 8.

- patient reported outcome measures for heart failure symptoms and activity assessment;
- composite measures for heart failure care;
- "episode of care" composite measure for AMI that includes outcome as well as process measures;
- consideration of socioeconomic determinants of health and disparities; and
- global measure of cardiovascular care.[16]

We strongly support the continuous evolution and increased use of quality measurement in the Medicare program. For HF, we believe the use of updated and relevant quality measures is essential to improved care and care coordination for patients. To the extent that the Working Group can encourage the Secretary and NQF to prioritize development of measures for HF in a timely manner, or even accelerate such development and implementation of the measures into the Medicare program, we would urge the Working Group to do so.

Alternative Payment Models (APMs)

Going forward, APMs will have an increasingly important role in both the public and private sectors. In January the Department of Health and Human Services (HHS) announced goals to tie 30 percent of traditional, fee-for-service Medicare payments to quality or value through APMs, such as Accountable Care Organizations (ACOs) or bundled payment arrangements, and tying 50 percent of payments to these models by the end of 2018[17]. Participation in APMs will be a determining factor in extra payments that physicians may receive beginning in 2019 under the new physician reimbursement methodology[18]. As a result, it is critically important to make sure that these models are designed appropriately.

Although APMs, in theory, hold potential to improve quality of care and reduce costs, NPC also believes that such new APMs must pay particularly careful attention to incorporate adequate quality measures, safeguards for beneficiaries, transparency and stakeholder input. NPC would like to underscore the importance of how APMs are structured and the need for these new models to incorporate appropriate incentives for high quality care and to avoid perverse incentives which could lead to denying appropriate care for the most vulnerable patients, such as those with chronic conditions.

Both BIO and PhRMA, each of which NPC is a member, have commented in detail on the safeguards and criteria that APMs should meet. We voice full support for both organizations' comments, and in particular, the criteria and underlying rationale set forth by the organizations on this topic.

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[16] Id. at p. 10.
[17] HHS, Press Release, Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value (Jan. 26, 2015), available at http://www.hhs.gov/news/press/2015pres/01/20150126a.html.
[18] Medicare and CHIP Reauthorization Act, Pub. L. No. 114-10 (April 16, 2015).

We appreciate the Working Group's efforts to better understand and respond to the needs of individuals with chronic conditions. Thank you for this opportunity to submit our comments for your consideration. We welcome the opportunity to meet with the Working Group to discuss our comments in more detail.

Sincerely,

Daniel Casserly