June 22, 2015

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

The Honorable Mark Warner
United States Senator
475 Russell Senate Office Building
Washington, DC 20510

Dear Senators Isakson and Warner:

Thank you for giving us the opportunity to provide recommendations to the Senate Finance Committee Chronic Care Working Group around improving outcomes for Medicare beneficiaries with chronic conditions. Novo Nordisk applauds the Senate Finance Committee for the formation of a chronic care working group to analyze current law, discuss alternative policy options and develop bipartisan legislative solutions to help improve care for Medicare patients with chronic conditions.

Novo Nordisk is a healthcare company with more than 90 years of history in innovation and achievement in diabetes care. In addition to diabetes care, Novo Nordisk is a leader obesity, hemostasis management, growth hormone therapy, and hormone therapy for women. Novo Nordisk's business is driven by the Triple Bottom Line: a commitment to economic success, environmental soundness, and social responsibility to employees and customers. Our global headquarters are in Denmark and our US headquarters is in Princeton, New Jersey. We conduct research and manufacturing in the US, and have over 6,000 US-based employees in all 50 states. Here in the US, Novo Nordisk is also proud to be a Co-Chair of the Diabetes Advocacy Alliance, a coalition of 20 members representing patient, professional and trade associations, other nonprofit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America.

We agree that it is time to look beyond cost-shifting and think about ways to redesign and improve the program to improve the care Medicare beneficiaries with chronic conditions receive today. Specifically, we encourage the workgroup to advance policy changes encouraging better detection, prevention and care for patients with chronic conditions in the Medicare program, so that we can not only meaningfully impact the numbers of people living with these diseases, but can also improve the care and quality of life for patients with chronic conditions.

The related epidemics of diabetes and obesity are devastating our healthcare system and economy. Today, more than 29 million people in the U.S. are living with diabetes, and another 86 million are at high risk for the disease.[1] During the past 30 years, the percentage of Americans diagnosed with diabetes has more than doubled; and by 2050, one in three will be living with diabetes.[2] Similarly, one in three U.S. adults currently have obesity, and the rates of obesity

have nearly doubled since 1980. Absent change, some projections show that, by 2030, 50 percent of Americans will have obesity[3] – a staggering 180 million people.

In the Medicare population, the statistics are just as concerning. Over one quarter of the Medicare-eligible population (nearly 11 million seniors) have diabetes,[4] and more than 40 percent of adults between the ages of 65 to 74 have obesity. Furthermore, the longer people live with diabetes and obesity, the more likely it is they will suffer from the complications, including heart disease, blindness, lower limb amputations, and kidney failure, among others.[1] These largely preventable problems will add a human and economic burden not only to the individual and their families, but also to the federal government.

These chronic diseases also continue to be one of the largest healthcare threats to our nation's economy. Currently, one in three Medicare dollars is spent on people with diabetes, and the cost of diabetes has continued to increase significantly, with the true total cost of diabetes rising to $322 billion per year in 2012, up 48 percent ($100 billion) in just five years from $218 billion in 2007.[5] For individuals, the financial burden is taking a toll. People diagnosed with diabetes have healthcare costs 2.3 times higher than if they didn't have the disease.[1] Similarly, one analysis found that the annual medical costs for individuals with obesity are $2,741 higher than medical costs for a patient of normal weight. All told, direct U.S. healthcare spending attributable to obesity is over $200 billion every year.[6]

By advancing policy changes encouraging better detection, prevention and care for patients with chronic conditions in the Medicare program, we believe the workgroup can improve the cost-effectiveness and quality of care patients receive today. This is critically important given the loss to society should diabetes and obesity continue to grow at the current rate. For example, to encourage better prevention, Medicare enrollees should have access to the National Diabetes Prevention Program (DPP), which has shown remarkable success in this population and could prevent millions of Medicare beneficiaries with prediabetes from developing diabetes – preventing the costly complications of diabetes and improving the quality of life. We also believe that this workgroup can help drive optimal outcomes and better care by working with the Department of Health and Human Services (HHS) to ensure that adequate quality measures are established in the Medicare program that will encourage and reward physicians who can provide better care and deliver better patient outcomes. Finally, we believe it is imperative that the workgroup make changes that will empower Medicare patients to take control of their disease. Examples of empowerment tools that would help patients manage their diseases include diabetes self-management training and Medical Nutrition Therapy (MNT).

We also ask that the workgroup consider making changes to ensure policies are in place allowing the Medicare program to keep up with medical advances. One area where Medicare doesn't provide patients a full spectrum of treatment options is for patients with obesity, who do not have access to any of the recently FDA-approved medications that have come to the market. Allowing patients with obesity access to these medications will produce clinically significant reductions in risk factors for chronic diseases such as hypertension, arthritis, heart disease, mental illness, lipid disorders, sleep apnea, and certain cancers. The existing prohibition on weight loss medications in current law is outdated; we ask that the workgroup consider legislation to make this critical change.

Detection

Novo Nordisk believes it is essential to identify individuals with diabetes or at risk for diabetes as it can not only help prevent the disease but it can also ensure that patients get the best treatment and care for this chronic condition. Currently, Medicare provides a Diabetes Screening Benefit, which covers screening for diabetes and prediabetes with no co-pay up to two times a year for individuals with one or more risk factors for the disease. However, less than 12 percent of the Medicare population has taken advantage of this benefit.[7] We believe it is essential to raise awareness and educate Medicare providers and patients about this important screening benefit. Additionally, Medicare patients receive not only an introductory Welcome to Medicare physical but subsequent annual Wellness visits as well. Both of these instances offer other opportunities for Medicare enrollees with risk factors for diabetes to be screened and detected. Novo Nordisk believes the working group should look at ways, such as through these current benefits, to increase screening for type 2 diabetes among individuals with risk factors for the disease.

Community-Based Prevention

While diabetes and obesity are growing problems in this country, the good news is that these diseases can largely be prevented, and there are community-based examples such as the National Diabetes Prevention Program (National DPP). The National DPP is a partnership consisting of government agencies including the Centers for Disease Control and Prevention, private insurers and community organizations like the Y-USA designed to provide evidence-based community programs to prevent type 2 diabetes in individuals at highest risk – specifically, individuals with prediabetes.

The National DPP originated from the successful Diabetes Prevention Program (DPP) clinical trial carried out by the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health, which found individuals with prediabetes can reduce their risk for type 2 diabetes by 58 percent with lifestyle changes including improved nutrition, increased physical activity and weight loss of 5-7 percent. The results were even stronger for seniors. Participants over the age of 60 reduced their risk for type 2 diabetes by 71 percent. Further research translating the clinical trial to a community setting showed these results can be replicated in a group for a moderate cost. The National DPP is based on this effective low-cost community model.

The dramatic success achieved by seniors in the original clinical trial and the overall success of the intervention in the community-based setting warrants coverage of this program for our nation's Medicare population. Bipartisan legislation has been introduced in the House and Senate to prevent and/or delay the onset of type 2 diabetes in seniors at high risk for the disease. The Medicare Diabetes Prevention Act (S. 1131/HR 2102) would provide the National DPP as a covered benefit for eligible Medicare beneficiaries who are at high risk for developing type 2 diabetes.

Novo Nordisk has been a strong proponent of the National DPP for years, and believes strongly that providing coverage of this program through the Medicare program can reduce the number of beneficiaries who develop type 2 diabetes and its dangerous and costly complications, including cardiovascular disease, stroke, blindness, lower-limb amputation and kidney disease. It can also rein in long term healthcare spending by preventing or delaying the onset of type 2 diabetes and its complications. Millions of seniors are slowly, silently marching toward type 2 diabetes – even though we now have this amazing community-based tool.

The program has proven so successful that *Forbes* has described it as such: "If this diabetes prevention program were a drug, it could be a blockbuster." And the *New York Times* has reported, "(t)his may be the largest national health effort that most of us haven't heard of, and one of the most important, especially for older adults." We urge the working group to consider allowing seniors to have this important benefit, which could have an enormous impact on the health of the Medicare population and the fiscal health of our country.

In fact, a recent study by the consulting firm Avalere shows that this policy could reduce federal spending by $1.3 billion over 10 years. This amount reflects a combination of an estimated $7.7 billion in new spending on the diabetes prevention program offset by an estimated $9.1 billion in savings. Savings from preventing diabetes would likely continue to increase beyond 10 years, suggesting even greater impact on longer-term federal spending.

Medical Nutrition Therapy (MNT) offers another potential avenue for reducing the risk of progression to type 2 diabetes among individuals with risk factors for the disease. MNT is a nutritional, diagnostic therapy and counseling service for disease management. When provided by a registered dietitian nutritionist (RDN), MNT includes lifestyle, knowledge and skills assessment; negotiation of individual nutrition goals; nutrition intervention; and evaluation of clinical and behavioral outcomes. To ensure an individualized therapeutic plan, MNT is conducted through an one-on-one session, and has been proven to show successful weight loss and improved blood glucose levels. Yet, currently this treatment is only provided for those beneficiaries who already have diabetes or renal disease. While this is essential, this coverage does nothing to help prevent individuals from developing the disease. There is legislation in Congress, the Preventing Diabetes in Medicare Act (H.R. 1686), which would expand this important service to allow Medicare to reimburse RDNs to provide MNT to patients at risk of diabetes or with prediabetes, thus providing much needed access to preventative treatment and medical nutrition therapy. We are strongly supportive of this important preventative effort.

Similarly, Novo Nordisk supports efforts to ensure individuals with diabetes have access to certified diabetes educators (CDEs). CDEs are the only health professionals who are specially trained and qualified to teach patients with diabetes how to improve their health and avoid serious diabetes-related complications. However, the 1997 authorizing Diabetes Self-Management Training (DSMT) statute did not include CDEs as Medicare providers and it has become increasingly difficult to ensure that DSMT is available to patients who need these services, particularly those with unique cultural needs or who reside in rural areas. The Access to Quality Diabetes Education Act (S. 1345/ H.R. 1726) would make a technical clarification to recognize certified diabetes educators (CDE) as providers for Medicare diabetes outpatient self-management training services (DSMT).

Importance of Quality Measures

Increasingly, in our health care system, there is a focus on value driven medical care and alternative payment models. For instance, the Department of Health and Human Services (HHS) has initiated an effort to move away from a health delivery system where reimbursement is based on the volume of procedures and tests and moving toward payments tied to the quality of healthcare delivered to patients. Novo Nordisk is committed to advancing optimal outcomes for patients with diabetes. Novo Nordisk supports efforts to develop, adopt, and implement quality measures that address optimal care and outcomes for patients with diabetes. We have worked with a number of stakeholders including CMS, NQF, and members of the Diabetes Advocacy Alliance, to try to align measures and ensure they drive optimal outcomes. There are currently 97 different diabetes measures used across a variety of programs—22 just in Government programs. Despite the number of quality measures currently in use, the current diabetes medication adherence measure only tracks appropriate use of oral medications and some single-use non-insulin products. This measure does not take into account the need for intensification of therapy to insulin use, which results in penalizing a doctor for prescribing appropriate therapy for a patient who has uncontrolled diabetes.

Novo Nordisk is committed to ensuring that the right measures are being used to assess appropriate care for patients with diabetes. Diabetes is a serious, multifaceted disease, and it is important for providers to be assessed holistically on multiple components of disease management. The lack of coordination is a significant challenge for physicians who have different guidelines depending on a patient's source of coverage and health plan issuer.

As we enter the obesity space, the importance of having quality measures to drive optimal outcomes has become clearer. While for our patients with diabetes the challenge is that there are far too many measures with different guidelines, there are few quality measures currently established to drive optimal outcomes for our patients with obesity. Without standards and incentives to achieve optimal outcomes, physicians treating patients with obesity won't be able to measure and improve patient outcomes. We urge the Senate Finance Committee to think about potential ways to ensure adequate quality measure exist for all chronic conditions.

Novo Nordisk supports efforts to promote care coordination through quality measurement. Effective care coordination in the treatment of chronic disease patients such as those with diabetes and obesity is essential to ensure patients receive appropriate care when moving across various treatment settings and are prepared for self-management. Poor care transitions and a lack of provider communication can result in negative patient outcomes that may increase the likelihood of costly disease complications and readmissions.

Access

With a majority of Americans affected by excess weight or obesity and at risk for chronic diseases, obesity has become a healthcare and financial epidemic requiring access to a full range of safe and effective treatment options. Yet, under Medicare, current treatment options only

include behavioral counseling and surgery. FDA approved medications for obesity are not covered, providing no lower-cost, middle ground for patients with moderate needs.

When Part D was enacted 10 years ago, not only were there no widely-accepted, FDA-approved obesity drugs on the market, but Congress also had just witnessed the controversy around fen-phen. Thus, Congress did not want to cover non-prescription treatments and nutritionals for weight loss. However, due to significant medical advances resulting in the development of weight-loss drugs and the current and growing epidemic, the Part D statute has quickly become out of date. Commercial payers and Medicare Advantage plans can, and many do, now cover these products. In fact, the Federal Employee Health Benefit Plan recently removed a barrier to access of obesity drugs by prohibiting its plans from barring obesity therapy coverage. For this reason, Novo Nordisk supports the Treat and Reduce Obesity Act (S. 1509/ H.R. 2404), which would correct this outdated provision in Medicare Part D by allowing the Centers for Medicare & Medicaid Services (CMS) to provide coverage of prescription drugs under Medicare Part D for chronic weight management to individuals who are affected by obesity, or excess weight (classified as "overweight" according to body mass index) with one or more co-morbidities.

The bill also requires CMS to highlight and provide additional information regarding Medicare coverage of intensive behavioral counseling for the disease of obesity for seniors and their doctors, and gives CMS the authority to enhance beneficiary access to the new Medicare benefit for intensive behavioral counseling services by allowing additional types of health care providers to offer these services.

Evidence-based literature clearly demonstrates that people affected by obesity can substantially improve their health and quality of life when they have access to a continuum of medically necessary treatment – including behavioral, nutritional, psychosocial, surgical, and pharmaceutical treatment. Even a 5 percent weight loss produces clinically significant reductions in risk factors for chronic diseases such as hypertension, arthritis, heart disease, mental illness, lipid disorders, sleep apnea, and certain cancers. Similar to many other medical conditions, obesity is a complex, multifactorial chronic disease, requiring a multidisciplinary treatment approach. This approach must encompass the best standards of care, both in terms of the treatments chosen, and the care coordination and clinical environment in which they are delivered. Effective treatment of obesity requires the coordinated services of providers from several disciplines and professions (both physician and non-physician) within both of these treatment areas.

Furthermore, you may be interested to know that Novo Nordisk is committed to research and development in the field of obesity. Globally, we have over 300 employees working on obesity research and development, and we recently opened a new obesity research unit in Seattle. The main task of the Novo Nordisk Research Center in Seattle will be to identify novel approaches and targets for obesity treatments while increasing the scientific understanding of obesity.

Hemophilia

Novo Nordisk is committed to working on more rare chronic conditions, which also create challenges for the Medicare population, specifically hemophilia. Through Novo Nordisk's

global research initiative HERO (Hemophilia Experiences, Results, and Opportunities), we have gathered unique data about the immense psychosocial issues that people with hemophilia live with daily.

For instance, from the HERO study we have learned that persons living with hemophilia not only struggle with access to optimal care and treatment, but also face unique challenges, including difficulties in the workplace, challenges in relationships, and the need for counselling and support services. This valuable insight provides a strong platform for us to advocate about the needs for improved access to care. Specifically, we know that preventative therapy started early in childhood, as compared to on-demand treatment, reduces total bleeds, bleeding into joints, resulting in a decrease in overall joint deterioration and a vast improvement in patient quality of life in the short and long term. A cost-benefit analysis of such appropriate access to care indicates that this approach reduces overall factor use and significantly reduces morbidity, preserves mobility, and therefore ability to participate in normal family, work and social activities. For this reason, there are certain proposals that we believe the workgroup can focus on to improve the lives of people living with hemophilia.

Specifically, Medicare currently pays for services of a Skilled Nursing Facility (SNF) for a patient in a Medicare Part A stay using a prospective payment system (PPS) that pays facilities a predetermined daily rate for each day of care. However, since the PPS payment is based on the cost of care that is typically provided, it does not accurately reflect the cost of infrequently used, often higher-cost therapies such as chemotherapy and treatments for rare conditions. As a result, there is a concern that the SNF PPS provides a disincentive from appropriate use of orphan products (other than those that are already designated for separate payment, e.g., specified chemotherapy drugs, radioisotopes, and EPO for dialysis patients). There are other drugs for rare diseases, such as clotting factor therapies for patients with hemophilia, which would greatly benefit from exclusion from the prospective bundled SNF payment rate. Many patients are being denied access to SNF services because of the current SNF payment policy.

This proposal is intended to correct that situation and provide separate payment, using otherwise applicable payment rules under Medicare Part B, for clotting factor therapies and orphan drugs when used to treat the rare disease – such as hemophilia – for which they are indicated. This change will make Medicare payment for these products, when delivered to SNF patients in a Medicare Part A stay, comparable to Medicare's payment for chemotherapy when provided to SNF patients. The proposed change would be budget neutral. Medicare Part A payments to SNFs would be reduced in order to cover the separate payments made for SNF patients using these products, just as is now done for chemotherapy and other excluded items and services.

Additionally, Medicare's Local Coverage Decision (LCD) process is important in determining the clinical circumstances and services covered for beneficiaries' healthcare in a timely manner. However, improvements are needed to improve transparency and understanding throughout the LCD process. Given the importance that LCDs have on patient access to innovative therapies, it is critical that stakeholders are aware of and have opportunities to comment throughout the process.

Specifically, Novo Nordisk urges the Senate Finance Committee to consider an LCD reform proposal similar to, but one that goes further than, Section 3081 of the 21st Century Cures legislation (H.R. 6) passed out of the House Energy and Commerce Committee. Specifically, a proposal is needed that directs CMS to incorporate certain transparency requirements before the LCD has been made final, such that stakeholders: (1) know about proposed LCDs; (2) have ample opportunity to work with clinicians and other scientific and technical experts to develop comments on those proposed LCDs; and (3) are able to submit comments and, if requested, meet with Medicare administrative contractors to discuss LCDs under review. A final LCD that is not a "logical outgrowth" of the proposed LCD should be required to be resubmitted through the public comment process before becoming effective. Additionally, any proposed LCD that would result in restricting beneficiary access should be subject to additional time and consideration within the notice-and-comment process.

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According to the Novo Nordisk Way, our contribution to society comes from having a patient-centered approach. We look forward to working with you on these important issues during future deliberations of this working group. If you have any questions or need any further information relating to our comments, please do not hesitate to contact Curt Oltmans at 609.987.5800 or cuot@novonordisk.com.

Sincerely,

Curtis G. Oltmans
Corporate Vice President & General Counsel
Novo Nordisk Inc.

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