

January 29, 2016

By Electronic Delivery

The Honorable Orrin Hatch
The Honorable Ron Wyden
The Honorable Johnny Isakson
The Honorable Mark Warner
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

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

On behalf of AstraZeneca, I am writing to commend the Senate Finance Committee's Chronic Care Working Group ("Working Group") for the development of its Policy Options document ("document"). We are pleased with the options included in the document and thank the Working Group for its consideration of the recommendations we submitted in June and for inviting us to meet with the Working Group to discuss our suggestions. We were particularly encouraged to see the Working Group's inclusion of medication synchronization and transitions of care in the context of quality measure development.

We thank the Working Group for its continued commitment to improving care for Medicare patients with chronic conditions and for the significant time and effort it has devoted to this initiative.

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development, and commercialization of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection, and neuroscience diseases. Given our strong focus on chronic conditions, we are committed to continuing to work with the Working Group to develop robust policy options that will improve care for Medicare patients with chronic conditions. We hope that our significant experience with this patient population will remain helpful to the Working Group as it further deliberates on solutions to improve outcomes for these vulnerable patients.

We strongly believe that innovation in the biopharmaceutical sector is critical to improving outcomes for Medicare patients with chronic conditions. It is therefore of paramount importance that beneficiaries have access to the drug therapies they need. To that end, our additional proposed policies and comments to the policy options included in the document focus on how new and existing policies and programs can improve use of and access to medicines. Medicare policy should encourage, and not impede, innovation in the development of new drug therapies. Specifically, models, demonstrations, and permanent payment and delivery reforms should preserve market-based competition in Medicare. Additionally, allowing manufacturers to explore innovative ways to price medications should be encouraged. We urge the Working Group to keep these concepts in mind as it further develops policies as part of the Chronic Care initiative.

We begin with a discussion of additional policy options the Working Group should consider including in its efforts moving forward. We then offer comments on specific policy options presented in the document. We would welcome the opportunity to discuss in further detail with the Working Group.

I. Additional Policy Options for Committee Consideration

As the Working Group continues to develop policy options for inclusion in future legislation, we urge you to consider additional options not directly addressed in the document: namely, the creation of alternative payment and pricing models for drug therapies, improvements to the Medicare Part D Medication Therapy Management (MTM) program, and modernization of existing laws and regulations to encourage private sector participation in patient engagement efforts.

A. Alternative Payment and Pricing Models for Drug Therapies

As we discussed with the Working Group in our in-person stakeholder meeting last summer, AstraZeneca is keenly interested in pursuing innovative payment and pricing models for drug therapies in the public sector. We therefore urge the Working Group to develop policies, including encouraging the development of one or more models by the Center for Medicare & Medicaid Innovation (CMMI), that allow stakeholders, including biopharmaceutical manufacturers, to explore innovative ways to price and pay for drug therapies used by Medicare patients. Such models should recognize the importance of innovation by appropriately reimbursing innovative drug therapies. Additionally, any model should provide the legal and regulatory flexibility required to allow manufacturers to robustly and thoroughly engage in these innovative pricing and payment models.

Under the current drug pricing and reimbursement system, contracts between manufacturers and payers often focus on per unit prices and discounts. However, innovative payment and pricing arrangements, which are currently being tested in the commercial market, offer the potential to increase efficiency in the Medicare program. For example, contracts between manufacturers and payers could focus on a fixed course of therapy for a patient, in which the total cost to a payer for a patient is the same regardless of the length of the patient's course of therapy. Under another alternative pricing model, costs to a payer for a patient with a certain chronic condition- such as type 2 diabetes- would not vary based on the type or amount of drug therapies prescribed. Such models could help reduce financial uncertainty for payers as well as patients.

Unfortunately, legal challenges and other risks may impede the development of such arrangements in Medicare as well as Medicaid and the Exchange market. Government price reporting requirements, the antikickback statute, and Food and Drug Administration (FDA) promotional requirements, among others, pose challenges to the vigorous implementation of these arrangements. In order to fully and robustly evaluate innovative ways to pay for and price drug therapies in the public sector, manufacturers and other stakeholders should be able to test such arrangements in the context of a carefully designed CMMI model that addresses challenges to implementation through the exercise of CMMI's waiver authority. We believe alternative payment and pricing models for drug therapies hold incredible promise as the healthcare system moves from volume to value based payments. We would be happy to discuss this suggestion with the Working Group as it continues to develop its policy options.

B. Strengthening the Part D Medication Therapy Management Program

Non-adherence to medication therapies is a critical public health issue that results in substantial costs to the healthcare system. Medication non-adherence is of particular concern in patients with chronic conditions; studies indicate that 50-60% of drug therapies used to treat chronic conditions are not used as prescribed.¹ Non-adherence has significant impacts on patient health as well as healthcare spending. Researchers estimate that as

¹ National Council on Patient Information and Education, "Accelerating Progress in Prescription Medicine Adherence: The Adherence Action Agenda" (2013), available at http://www.bemedicinesmart.org/A3_Report.pdf

many as two out of three medication-related admissions² and 125,000 deaths per year³ are attributable to non-adherence. A recently released study found that the estimated direct and indirect costs of non-adherence totaled \$337 billion in 2013.⁴

As you may know, Medicare Part D Prescription Drug Plans (PDPs) are required to offer MTM services to certain enrollees.⁵ When properly designed and implemented, MTM programs can improve medication adherence for patients with chronic conditions.⁶

As the Working Group evaluates potential policy options, we urge you to consider ways in which the Part D MTM program can be strengthened. Two specific proposals are discussed below: modifying eligibility requirements for MTM services and allowing manufacturer participation in future iterations of CMMI's Part D MTM model.

1. Modifying Eligibility Requirements

The Centers for Medicare & Medicaid Services (CMS) has set minimum standards with respect to the beneficiaries that PDPs are required to "target" for MTM programs. To summarize, PDPs must target beneficiaries with three or more chronic conditions who are taking multiple Part D drugs.⁷ MTM beneficiaries must also have drug costs anticipated to meet a minimum annual threshold.⁸

The current eligibility criteria may not target beneficiaries most in need of MTM services. For example, patients who have fewer than three chronic conditions but have recently transitioned from the hospital to home may be at significant risk of non-adherence yet not qualify for MTM services. While we support the Part D MTM program, we agree with the statement made by our trade association PhRMA in its June submission to the Working Group that there are inadequate data on which enrollees are most likely to benefit from the program. We therefore encourage the Working Group to require CMS to perform a study evaluating how eligibility standards could be modified so that enrollees who are most in need of MTM services qualify. The study should also compare the effectiveness of different elements of the MTM program on medication adherence and patient outcomes. This study would help ensure that the right patients have access to MTM services and would inform future policies designed to improve the benefits offered by the MTM program.

2. Manufacturer Participation in CMMI's Part D MTM Model

In late September 2015, CMMI announced a five-year model to test approaches to improve Medicare Part D beneficiary medication use. The "Part D Enhanced MTM" model will look at the effect of providing selected PDPs additional incentives and flexibilities to improve beneficiary medication adherence and health outcomes while,

² Osterberg L, Blaschke T. Adherence to Medication. *New Engl. J. Med.* 2005;353(5):487-497.

³ McCarthy R. The price you pay for the drug not taken. *Bus Health.* 1998;16:27-28,30,32-33.

⁴ Express Scripts, "The Costs of Nonadherence," available at <http://lab.express-scripts.com/insights/adherence/the-high-price-of-low-adherence-to-medication>

⁵ According to CMS, "In general, each [MTM program] should include prescriber interventions to promote coordinated care, an interactive comprehensive medication review and discussion with the beneficiary to assess their medication therapies which results in the creation of a written summary in CMS' standardized format, and frequent monitoring and follow-up of the beneficiary's medication therapies." CMS, CY 2016 Medication Therapy Management Program Guidance and Submission Instructions (April 7, 2015).

⁶ Acumen, LLC (prepared for CMS), "Medication Therapy Management in Chronically Ill Populations: Final Report" (August 2013).

⁷ Plans can choose to target enrollees with two or more chronic conditions.

⁸ CMS, CY 2016 Medication Therapy Management Program Guidance and Submission Instructions (April 7, 2015); Section 1860D-4(c)(2)(A)(ii)(I) of the Social Security Act.

in turn, reducing costs. The model is meant to foster more meaningful investment in MTM by allowing PDPs more flexibility in the beneficiaries they target and the services they provide.

While AZ strongly supports strengthening the MTM program and the model's goals, the model includes a funding exclusion that prohibits participating plans from receiving support from manufacturers in connection with the model, including educational materials. There are already laws in place that prohibit manufacturers from interacting with payers in ways that would result in fraud, waste and abuse. By excluding manufacturer participation, we believe CMMI may be missing opportunities to include the key learnings and experience of manufacturers in developing programs to improve medication adherence and chronic care management. We therefore request that the Working Group consider ways to ensure that future iterations of the model, or changes to the MTM program based on learnings from the model, recognize the important contributions of manufacturers and allow them to participate in ways that comply with existing law.

C. Challenges to Private Sector Participation in Patient Engagement Efforts

AstraZeneca and other stakeholders in the private sector are deeply interested in contributing knowledge and experience with issues central to chronic care management, such as medication adherence and transitions of care, to public sector efforts to improve care. However, providers, payers, manufacturers and other stakeholders may be discouraged from testing and implementing innovative programs due to risk of Federal antikickback liability, privacy concerns, and government price reporting concerns, among others. We encourage the Working Group to assemble stakeholders to identify these challenges and ways to overcome them in a manner that ensures the integrity of federal healthcare programs and protects patients.

Manufacturers and other stakeholders have significant experience in developing and implementing programs designed to improve outcomes for patients with chronic conditions, and these programs could serve as models for many of the policy proposals listed in the document. For example, in our June submission to the Working Group, we highlighted an AZ program called Fit2Me, a free diet and lifestyle support program that allows people with type 2 diabetes to create a customized wellness plan to support healthy choices that work best for them. We have also established a team of Respiratory Care Specialists (RCS) who work with patients and providers to improve care for patients suffering from asthma and Chronic Obstructive Pulmonary Disease (COPD) by delivering general respiratory disease management education and/or product-support and training. We also support adherence efforts through Cardiovascular Nurse Consultants (CNC) who are available to educate various allied healthcare professionals within hospitals and pharmacies on the need for oral antiplatelet therapy (OAP) and patient education post discharge after an admission for acute coronary syndrome (ACS). These are examples of programs that AstraZeneca has designed to help improve patient engagement and outcomes across disease states that could serve as models for the patient engagement proposals included in the document.

II. Comments on Specific Policy Options

In this section of our comment letter, we provide feedback on many of the specific policy options discussed by the Working Group in the document. We begin with two options that most directly relate to the comments AZ submitted in June: the "Study on Medication Synchronization" proposal and the "Developing Quality Measures for Chronic Conditions" proposal. The remainder of the proposals are discussed in the same order as they are presented in the document. Again, we would be happy to discuss these comments in more detail with the Working Group.

A. Study on Medication Synchronization

AstraZeneca is pleased that the Working Group addresses medication synchronization. As we stated in our June submission to the Working Group, we support testing the medication synchronization concept in Medicare to assess the intervention's efficacy in improving adherence, lowering costs, and improving outcomes for stand-alone PDPs and Medicare Advantage Prescription Drug Plans (MA-PDP).

We would encourage the Working Group to take additional steps to ensure that the study it proposes results in a tangible plan for the implementation of medication synchronization in Medicare. Specifically, we make the following recommendations:

- The report/study on medication synchronization should be developed in the context of a model or demonstration that tests use of medication synchronization by PDPs and MA-PDPs. A demonstration is necessary to develop data and recommendations on how medication synchronization could be implemented across the Part D program;
- The Working Group should require CMS to develop the demonstration within a specified timeframe (i.e., to begin within one year of enactment of the relevant legislation) and to issue the report within a specified timeframe after completion of the demonstration;
- In addition to identifying challenges to potential implementation in Medicare, the report should also suggest ways in which those challenges could be addressed, including changes to existing laws and regulations that would be necessary for successful implementation;
- The report should include a plan and timeline for implementation of medication synchronization across PDPs and MA-PDPs.

Again, we thank the Working Group for its attention to this important policy proposal. We hope that our suggestions will help ensure that medication synchronization is adopted across PDPs.

B. Developing Quality Measures for Chronic Conditions

The Working Group is considering requiring that CMS include in its quality measures plan the development of measures that focus on the health care outcomes for individuals with chronic conditions. AstraZeneca supports this proposal, and encourages the Working Group to require CMS to include more robust transitions of care measures in its plan.

Transitions of care are of paramount importance to patients with multiple chronic conditions; only 3% of Medicare fee-for-service beneficiaries overall were hospitalized more than three times in 2010, compared to 16% of patients with six or more chronic conditions.⁹ In our work with a variety of patient populations, we are aware of the significant challenges that patients face once they are discharged from the hospital setting. Patients often do not remain adherent to their medication therapies after discharge and many fail to seek the proper follow-up care from a primary care physician or appropriate specialist.

Because of these challenges, AstraZeneca is a strong advocate for policies that strengthen transitions of care. For example, in our comments to the 2016 Medicare Inpatient Prospective Payment System (IPPS) proposed rule,¹⁰ we commended CMS for proposing to include the Three-Item Care Transition Measure (CTM-3) in the

⁹ Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition. Baltimore, MD. 2012.

¹⁰ 80 Fed. Reg. 24324 (April 30, 2015).

Hospital Value Based Purchasing Program (VBP)¹¹ in fiscal year 2018 and recommended strengthening the CTM-3 to ensure even more robust transitions of care.

The CTM-3 is a three item survey instrument given to patients when they are discharged from the hospital that asks about the patient's discharge experience, whether they understand what they must do after discharge, and whether they understand the purpose for taking each of their medications. In our comments to the 2016 IPPS proposed rule, we recommended that CMS strengthen the CTM-3 by including a question asking whether patients were satisfied with the assistance of the hospital in making prescriptions available immediately after discharge (either through transition supplies or working with the patient's pharmacy). We also suggested that CMS update the existing medication-related question in the CTM-3 to ask if the patient understood the duration of use of their medications. In the final rule, CMS stated that it would share our comments with the CTM-3 measure developer;¹² while we appreciate CMS's statement, we believe more can be done to strengthen this measure. We therefore suggest that the Working Group require CMS to consider ways that the CTM-3 can be updated as part of its quality measures plan.

Additionally, AstraZeneca recently submitted comments to CMS's proposed rule updating the hospital discharge planning conditions of participation.¹³ While the proposed updates were a significant improvement over existing regulations, AstraZeneca made a number of recommendations to further bolster the proposed requirements. Those suggestions included a recommendation that hospitals be required to provide discharge instructions in a culturally competent manner and that the hospital allow the patient an opportunity to identify a caregiver to also receive discharge instructions. We believe that these and other suggestions made by AstraZeneca in our comment letter to CMS could serve as the basis for the development of additional measures relating to transitions of care. We therefore recommend that the Working Group encourage CMS to consider the feedback provided to it through comments to the discharge planning proposed rule when developing and considering additional transitions of care measures.

C. Expanding Access to Home Hemodialysis Therapy

AstraZeneca thanks the Working Group for its consideration of policies that would allow dialysis patients greater flexibility in where they receive their monthly clinical assessment. We support the proposed policy of allowing patients to go to a free-standing renal dialysis facility to have their monthly visit with their clinician via telehealth. However, we believe it is extremely important that the beneficiary retain the choice to receive an in-person monthly visit with their clinician and that an in-person visit occur at least once every six months.

We also support allowing the home to be considered an originating site for the limited purpose of allowing dialysis patients to receive their monthly clinical assessment via telehealth. Again, we encourage the Working Group to require an in-person visit at least once every six months and to continue to allow the patient the choice to receive their monthly visits in-person.

Finally, the Working Group should require CMS to track the clinical outcomes of patients who receive their monthly visits via telehealth from the home or free-standing dialysis center to measure the impact that this policy has on patients. The Working Group could consider temporarily enacting this policy and make its

¹¹ The VBP program ties Medicare reimbursement to hospitals for inpatient care to performance on a number of quality measures. See <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing/> for more information.

¹² 80 Fed. Reg. 49326, 49552-53 (Aug. 17, 2015).

¹³ 80 Fed. Reg. 68126 (Nov. 3, 2015) (proposed). Please note that the final rule is still pending. Conditions of Participation are standards that healthcare organizations must meet in order to participate in the Medicare and Medicaid programs.

permanent adoption contingent on a report from CMS finding that it does not have a negative impact on patient care. We urge the Working Group to require CMS to closely monitor the use of telehealth and the quality of care provided to ensure that patients continue to have access to the range of services they need.

D. Improving Care Management Services for Individuals with Multiple Chronic Conditions and Establishing a One-Time Visit Code Post Initial Diagnosis of Alzheimer's/Dementia or Other Serious or Life-Threatening Illness

The Working Group is considering establishing a new high-severity chronic care management code that clinicians could bill under the Medicare Physician Fee Schedule for managing patients with multiple chronic conditions, and is soliciting feedback as to the patient criteria for this potential new code. The Working Group is also considering requiring CMS to implement a one-time payment to clinicians to recognize the additional time needed to have conversations with patients who have received a diagnosis of a serious or life-threatening illness, including Alzheimer's/Dementia.

We support ensuring that providers are adequately reimbursed for the time they spend managing highly severe patients and counseling patients who have received a serious or life-threatening diagnosis. However, we urge the Working Group to consider the unique and individualized needs of patients with chronic conditions when determining which patients should qualify for these codes. Instead of restricting use of these codes to a limited number of conditions, we urge the Working Group to require CMS to allow their use across a range of chronic conditions (including diabetes, asthma, COPD, chronic kidney disease and cardiovascular disease) in combination with one or more risk factors that render the patient "high severity" or the diagnosis serious or life-threatening.

Poor prognosis, comorbidities, impact on functional status, and stage of disease at diagnosis are among many factors that could render the use of these codes appropriate. For example, patients with end stage renal disease (ESRD) have a high prevalence of depression, fatigue, pain, muscle cramps, and difficulty sleeping.¹⁴ Additionally, severe COPD is characterized by increased difficulty in breathing during normal activities of daily life or even at rest. Loss of energy, weakness, weight loss and insomnia, among other symptoms, often present as well.¹⁵ It is a particularly complex disease which requires that clinicians consider multiple treatment options, including not just medications, but rehabilitation approaches as well as adjunct therapies such as oxygen, ventilator support, and even surgical approaches in select patients. It is also associated with multiple comorbidities that need to be addressed in association with COPD, including heart failure, coronary artery disease, lung cancer, loss of muscle mass and cachexia leading to progressive disability.¹⁶

Clearly, patients with diseases that have such a devastating impact on their daily lives should be encouraged to have conversations with their providers about disease progression, treatment options, and resources and may require more intense management by providers. Therefore, the conditions and risk factors that qualify patients for these codes should be developed by CMS through a formal notice and comment rulemaking to ensure that the patient population qualifying for the payment is appropriately defined.

¹⁴ Abdel-Kader K, Unruh ML, Weisbord SD. Symptom burden, depression, and quality of life in chronic and end-stage kidney disease. *Clinical Journal of the American Society of Nephrology*. 2009 Jun 1;4(6):1057-64.

¹⁵ Guarascio AJ, Ray SM, Finch CK, Self TH. The clinical and economic burden of chronic obstructive pulmonary disease in the USA. *ClinicoEconomics and Outcomes Research: CEOR*. 2013;5:235-245. doi:10.2147/CEOR.S34321.

¹⁶ Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: Revised 2016. Global Initiative for Chronic Obstructive Lung Disease (GOLD). www.goldcopd.org; *European Respiratory Review* 2015; 24: 159–172.

E. Adapting Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees

The Working Group is considering giving MA plans the flexibility to establish a benefit structure that varies based on the chronic conditions of individual enrollees. While AstraZeneca is generally supportive of granting MA plans greater flexibility to tailor benefit designs, we encourage the Working Group to consider the following suggestions.

First, we recommend that the Working Group test this policy through a targeted CMMI model before granting all or a subset of MA plans this flexibility. Evaluation of the model will allow the Working Group to understand if and how flexibility improves care and how access to care is impacted before it is implemented nationwide. We recommend that the model design go through formal notice and comment rulemaking to ensure that the evaluation methodology is sufficiently robust.

Second, the model must be carefully designed to ensure that beneficiaries continue to have access to the innovative items and services they need. It will be extremely important to incorporate protections in the model design to ensure that increased flexibility is not used to reduce benefits, increase cost-sharing, or discriminate against beneficiaries with certain diseases or conditions. Additionally, patients without chronic conditions should not face reductions in benefits to pay for the additional benefits offered to those with chronic conditions.

AstraZeneca is particularly concerned with ensuring patient and provider access to and choice of drug therapies. Current CMS standards with respect to PDP formularies, including the prohibition on discriminatory formularies and the requirement that multiple strengths and dosage forms of drugs be included on formulary,¹⁷ should be robustly enforced to protect beneficiaries whether their MA-PDP or standalone PDP is part of an innovative model/demonstration or not.

For example, patients with COPD should have access to a range of delivery device types to ensure the best possible outcomes for this vulnerable patient population. COPD is the third leading cause of death in the United States and COPD-related medical costs were estimated to be \$32 billion in 2010.¹⁸ The burden of this disease is both widespread and significant, making it particularly important that COPD patients can access the most appropriate treatment therapies. Physicians consider many factors when selecting delivery devices for COPD patients, including patient age; the ability to use the selected device correctly; and patient and physician preference.¹⁹ Dry powder inhalers (DPI) and pressurized metered dose inhalers (pMDI) are two key inhalation device types used to deliver COPD medications and there are advantages and disadvantages to each device type depending on the patient's needs.²⁰ It is therefore of paramount importance that patients and providers have choice of a range of device types to ensure access to the most appropriate treatment option.

¹⁷ CMS, Medicare Prescription Drug Benefit Manual, Ch. 6.

¹⁸ CDC. MMWR Morb Mortal Wkly Rep. 2015; 64:1-24.

¹⁹ Dolovich MB, Ahrens RC, Hess DR, Anderson P, Dhand R, Rau JL, Smaldone GC, Guyatt G; American College of Chest Physicians; American College of Asthma, Allergy, and Immunology. Device selection and outcomes of aerosol therapy: evidence-based guidelines: American College of Chest Physicians/American College of Asthma, Allergy, and Immunology. *Chest*. 2005;127:335-71.

²⁰ *Id.* To correctly use DPIs, patients need to inhale deeply and rapidly to deliver the medication, which may be difficult for certain patients who cannot generate adequate inspiratory flow rates due to advanced disease or other factors. In contrast, effective use of pMDIs is not dependent on achieving a certain inspiratory flow rate, suggesting that they are more appropriate for certain patient types. However, to correctly use pMDIs, patients are required to coordinate pressing the canister and timing their breathing, which may be difficult for certain patient types. See Laube et al. ERS/ISAM Task Force. What every pulmonology specialist should know about inhalation devices. *Eur Respir J* 2011;37:1308-1331; Myrdal PB, Sheth P, Stein SW. Advances in Metered Dose Inhaler Technology: Formulation Development. *AAPS PharmSciTech* 2014;15:434-455; *Respiratory Medicine* (2013) 107, 1817e1821).

Additionally, in type 2 diabetes, early intensive treatment may result in sustained A1C goal attainment.²¹ Evidence from real-world data showed that an early approach to management can help patients reach and sustain their glycemic goals.²² It is therefore extremely important that diabetes patients can access a wide range of antidiabetic agents early in their disease progression.

We recommend that the Working Group prohibit plans granted this flexibility from increasing cost-sharing on covered items or services or reducing the number of medicines on the plan's formulary. Again, we suggest that the model design go through the formal notice and comment rulemaking process to ensure that stakeholder feedback on adequate beneficiary protections is considered.

Finally, we note that the Working Group is considering allowing MA plans to offer care improvement and/or wellness programs tailored for patients with chronic conditions. As discussed in section I.C, manufacturers and other members of the private sector have a great deal of experience in developing and implementing such programs. We encourage the Working Group to specifically promote private sector involvement in the development of patient engagement programs offered by MA plans. Leveraging the knowledge and experience of external stakeholders would result in a robust and efficient mechanism for delivering these programs to MA beneficiaries.

F. Expanding Access to Prediabetes Education

AstraZeneca supports efforts that would expand access to prediabetes education. The likelihood of developing diabetes over five years for people with prediabetes is high (up to 30%)²³ and lifestyle changes can reduce conversion from prediabetes to diabetes by up to 58%.²⁴ Given the substantial burden that diabetes places on the Medicare budget- it is estimated that one in three Medicare dollars is spent caring for patients with diabetes²⁵- interventions targeting beneficiaries with prediabetes could offer cost-savings to Medicare,²⁶ in addition to reducing the risk that patients develop this potentially devastating disease.

In our work with the type 2 diabetes patient population, we focus on patient education and engagement to help support patients in reaching their treatment goals. In 2014, AstraZeneca launched Fit2Me,²⁷ a free diet and lifestyle support program that allows people with type 2 diabetes to create a wellness plan that is custom fit to their likes and dislikes. Again, diet and lifestyle modifications reduce the likelihood that patients with prediabetes will develop diabetes. We therefore believe many of the tools included in the Fit2Me program would be informative as CMS develops a program for prediabetes patients. We urge the Working Group to

²¹ Abdul-Ghani MA, Puckett C, Triplitt C, et al. Initial combination therapy with metformin, pioglitazone and exenatide is more effective than sequential add-on therapy in subjects with new-onset diabetes. Results from the Efficacy and Durability of Initial Combination Therapy for Type 2 Diabetes (EDICT): a randomized trial. *Diabetes Obes Metab.* 2015;17:268-275.

²² *Id.*

²³ Centers for Disease Control and Prevention. A Snapshot: Diabetes in the United States, *available at* <http://www.cdc.gov/media/dpk/2014/images/diabetes-report/Infographic1-web.pdf>

²⁴ Diabetes Prevention Program Research Group, Knowler WC, Fowler SE, et al. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. *Lancet.* 2009;374:1677-1686; Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002;346:393-403.

²⁵ American Diabetes Association, "The Staggering Cost of Diabetes," <http://www.diabetes.org/diabetes-basics/statistics/infographics/adv-staggering-cost-of-diabetes.html>

²⁶ See Anderson JM. Achievable cost saving and cost-effective thresholds for diabetes prevention lifestyle interventions in people aged 65 years and older: a single-payer perspective. *J Acad Nutr Diet.* 2012 Nov;112(11):1747-54. doi: 10.1016/j.jand.2012.08.033; Diabetes Prevention Program Research Group. The 10-Year Cost-Effectiveness of Lifestyle Intervention or Metformin for Diabetes Prevention An intent-to-treat analysis of the DPP/DPPOS. *Diabetes Care.* 2012 Apr 1;35(4):723-30.

²⁷ www.fit2me.com

request that CMS solicit feedback from manufacturers and other stakeholders when developing the prediabetes education benefit.

G. Expanding Access to Digital Coaching

AstraZeneca supports the Working Group's proposed policy to require CMS to provide medically-related information and educational tools on its website to help beneficiaries learn more about their health conditions and how to manage their own health.

Again, the private sector could play an instrumental role in the development of digital coaching services offered to Medicare patients. For example, many of AstraZeneca's own patient engagement programs include a counseling or "coaching" component. AZ recently announced the creation of the Day-by-Day program, the first AZ program to utilize a live digital coaching approach designed to provide heart attack patients and caregivers after hospital discharge with knowledge and tools to make and sustain healthy lifestyle changes. Through a partnership with Vida Health, Day-by-Day combines high-quality digital content with a personal touch, providing patients and caregivers their own health coach from Vida's expert, national network, as well as an extensive library of relevant articles, activities and patient videos.

AstraZeneca also offers SteadySTART™, a diabetes education program that focuses on helping adults with type 2 diabetes by offering them access to Clinical Educators, who provide participants education focused on healthy eating and being active, as well as treatment support. SteadySTART has both full-time and on-demand Clinical Educators available to help in face-to-face meetings or over the phone. For those patients who prefer group support, the program offers educational sessions, where educators provide resources and lead discussions and activities.

AstraZeneca has significant experience in developing and implementing patient education and disease self-management programs, and we believe that this experience would be extremely valuable to CMS as it develops educational tools for its website. If the Working Group pursues this proposal, we urge it to ask CMS to solicit external stakeholder participation in the development of this website and its content.

III. Conclusion

AstraZeneca greatly appreciates the opportunity to provide these comments. We look forward to continued engagement with the Working Group to explore ways to improve the health of Medicare beneficiaries with chronic conditions, and find ways to address growth in total Medicare spending. If you have any questions or would like additional information on these or any other related topics, please contact Christie Bloomquist at 202-350-5542 or via e-mail at Christine.Bloomquist@astrazeneca.com.

Sincerely,



Christie Bloomquist
Vice President of Federal Government Affairs & Policy
Corporate Affairs