Johnson & Johnson
WORLDWIDE GOVERNMENT AFFAIRS & POLICY

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BY ELECTRONIC DELIVERY TO: chronic_care@finance.senate.gov

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The Honorable Orrin Hatch
Chairman, U.S. Senate Finance Committee
104 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member, U.S. Senate Finance Committee
221 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Johnny Isakson
U.S. Senate Finance Committee
131 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Mark R. Warner
U.S. Senate Finance Committee
475 Russell Senate Office Building
Washington, D.C. 20510

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

This letter is in response to the Bipartisan Chronic Care Working Group's Policy Options Document, released in December 2015. Johnson & Johnson fully supports the efforts by the Working Group to address the challenges of chronic conditions in the Medicare population. We submitted a comment letter in June 2015 supporting access to digital health coaching for Medicare fee-for-service beneficiaries, and we are pleased to see this included in the Policy Options Document.

In this comment letter we are providing further details about digital health coaching, and we outline our proposal for Congress to expand access for Medicare beneficiaries. In addition, our comments align with the recommendations in the Policy Options Document calling for:

- expanded quality measures for patients with chronic conditions, particularly with regard to patient-reported outcomes and the utilization of shared decision-making tools;
- addressing the need for behavioral health among chronically ill beneficiaries;
- expanded access to diabetes prevention services; and
- greater utilization of technology to improve care coordination.

Expand Access to Digital Health Coaching

The proposal to expand access to digital health coaching would require the Centers for Medicare & Medicaid Services to "provide medically-related information and educational tools on its website to help beneficiaries learn more about their health conditions and help them in the self-management of their own health." The Policy Options Document refers to the usefulness of information about chronic diseases and how to manage them. The proposal is to rely upon the Medicare.gov website as a trusted source for this important information and it stops there.

We are very concerned that the proposal to provide access to online information about chronic diseases and their management falls far short of the potential benefits for Medicare beneficiaries from digital health coaching. As an example, Johnson & Johnson's Health and Wellness Solution's digital health coaching programs combine expertise from the fields of human behavior, medicine, and digital content development so that our digital health coaching emulates the interaction that a beneficiary would have in a live session, either face-to-face or over the phone, with a health coach. Digital health coaching combines technology and behavioral science to help empower individuals to build and sustain healthy behaviors with the same individualized guidance and encouragement that you would get from a live coach, but in a more scalable digital solution.

The digital health coaching experience starts with an online consultation where the digital coach learns about the individual and their chronic condition(s). This consultation allows the digital coach to then be able to recommend a sequence of skills and action steps that are tailored (personalized) specifically to the beneficiary. Simply providing online access to disease information, as described in the Policy Options Document, does not distill down the volume of digital health information to the most important and relevant topics for the individual to maximize health improvement outcomes. This is accomplished through digital health coaching programs. The individually tailored feedback of digital health coaching recommends concrete, personalized and manageable action steps that each patient with one or more chronic conditions can take to improve their health. The personalized feedback the beneficiary gets from the program may then be easily transmitted electronically to their treating physician or non-physician practitioner, thus facilitating improved care coordination.

We are concerned because we believe the proposal may miss a real opportunity to provide access to the type of digital health coaching programs that are being offered to tens of millions of commercially insured people currently, including Medicare Advantage enrollees. A published review of the use of a digital health coaching program in a population with chronic disease for a Blues Plan found average year-over-year cost savings of $382 in actual medical expenses for every program participant.[1] These savings came primarily from a reduction in hospital admissions. Other published articles are available at: http://www.jjhws.com/insights/white-papers.

Therefore, we respectfully urge the Working Group to consider a proposal that CMS be given authority to contract directly for digital health coaching programs to be made available to traditional Medicare beneficiaries (as well as those covered under alternative payment models) at no cost to the beneficiaries. This would enable Medicare to take allow its beneficiaries access to these programs in the same way that it is provided by commercial insurers (e.g., Kaiser Permanente, a number of Blue Cross Blue Shield

[1] Steven M. Schwartz, Brian Day, Kevin Wildenhaus, Anna Silberman, Chun Wang, and Jordan Silberman (*2010*) The Impact of an Online Disease Management Program on Medical Costs Among Health Plan Members. American Journal of Health Promotion: November/December 2010, Vol. 25, No. 2, pp. 126-133.

health plans, and Aetna). Here are the key features of the proposal to expand access to digital health coaching:

- The Secretary would enter into agreements with one or more eligible entities with demonstrated experience in the design, implementation, and operation of digital health coaching programs that reduce health care expenditures and improve health outcomes in patients with chronic conditions;
- The Secretary shall include requisite Internet links to the Internet website of the digital health coaching programs involved on the relevant Internet websites of the Centers for Medicare & Medicaid Services, and other appropriate Internet websites of the Department of Health and Human Services.
- The Secretary shall include information on the availability of digital health coaching programs as part of the information and services furnished to applicable beneficiaries.
- The Secretary shall not impose cost-sharing (including deductibles, coinsurance, or copayments) in any form on an applicable beneficiary for access to, and use of, digital health coaching programs.
- The Secretary shall negotiate an annual payment amount for the provision of digital health coaching programs to applicable beneficiaries. Such payment amount may not vary by the number of times applicable beneficiaries access and use such programs, but may be determined on a per-beneficiary basis that takes into account an estimate of the number of applicable beneficiaries involved.
- In no case may the aggregate payment amounts under a 5-year agreement exceed $25,000,000 for the provision of digital health coaching programs to applicable beneficiaries during such 5-year period.
- The Secretary may renew an agreement under this section if the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that a new or renewed agreement for such programs would reduce program spending.

The attached document describes in more detail how our digital health coaching programs work, the range of chronic conditions for which programs are available, and the published evidence demonstrating their efficacy. In short, digital health coaching aligns perfectly with the Triple Aim goals that are helping improve health care delivery in the US.

- *Better outcomes* are achieved through providing tailored information specifically designed to help patients better manage their chronic condition(s).
- *Better patient experiences* are achieved as a result of helping people feel they are more actively engaged in their health and better informed about it.
- Finally, *cost savings* occur as a result of better decisions being made about one's chronic condition and overall health.

Developing Quality Measures for Chronic Conditions

We appreciate that the Chronic Care Working Group recognizes gaps in existing quality measures. Patient-centered outcomes measures and specialty-specific measures are lacking, especially for complex

chronic conditions, such as inflammatory bowel disease (IBD), psoriasis, rheumatoid arthritis, behavioral health and cancer. These conditions inflict chronic debility in realms not presently measured. Better measures offer opportunities for better outcomes and lower costs through streamlined care coordination and personalized disease management.

In summary, we recommend: 1) the consideration of Patient Reported Outcomes Measurement Information System (PROMIS) developed by National Institution of Health to measure general health based on patient reported data; 2) disease specific patient-reported outcomes (PROs) to measure disease progress and treatment outcomes; 3) shared decision-making measures for all different specialties; and 5) a national standard for shared decision-making tools.

In addition to the measure gap areas identified in the Policy Options Document, the Working Group should consider recommending treatment adherence measures and non-medical switching measures. Studies show increased adherence is highly correlated with positive patient outcomes.[2] Non-medical switching- defined as the substitution of a therapy on which a patient is already stable with another treatment option in the same therapeutic class on the basis of a non-clinical rationale (e.g., cost)—can impact adherence to treatment, especially in cases in which the new therapy is less effective for the individual patient and/or results in increased negative side-effects.

Implement PROMIS and Clinically Meaningful PROs

Chronic autoimmune diseases, such as IBD and rheumatoid arthritis, affect many people in the U.S, and are well-suited to PROs. For example, approximately 1.6 million Americans currently have IBD.[3] Rheumatoid arthritis impacts about 1.3 million adults.[4] One study found PROMIS PROs are valid in measuring general health status for patients with autoimmune diseases.[5] Providers will also benefit from disease specific outcomes measures to measure clinically meaningful sign/symptoms of specific disease. For example, stool frequency, rectal bleeding and abdominal pain are important PROs for IBD These measures have been validated and included as part of clinical outcome assessment in clinical studies.[6]

The PROMIS tools can be used across a wide variety of chronic diseases and conditions for general health status as well as specific symptom (like depression and fatigue) or functional well-being.[7] We recommend the Working Group consider both general health measurement based on PROMIS and disease specific clinical measures.

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[2] Robinson, J. H., Callister, L. C., Berry, J. A., & Dearing, K. A. (2008). Patient-centered care and adherence: Definitions and applications to improve outcomes. Journal of the American Academy of Nurse Practitioners, 20(12), 600-607.

[3] The Facts About Inflammatory Bowel Diseases, Chron's & Colitis Foundation of America, Accessed on January 18, 2016 http://www.ccfa.org/assets/pdfs/updatedibdfactbook.pdf

[4] Helmick CG, Felson DT, Lawrence RC, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States-Part I. Arthritis & Rheum. 2008: 58(1):15-25. - See more at: http://www.rheumatology.org/Learning-Center/Statistics/Prevalence-Statistics#sthash.CFGqxEoD.dpuf

[5] Snyder, C. F., Aaronson, N. K., Choucair, A. K., Elliott, T. E., Greenhalgh, J., Halyard, M. Y., ... & Santana, M. (2012). Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations. *Quality of Life Research*, 21(8), 1305-1314.

[6] Exploring Key Signs and Symptoms of the Crohn's Disease Activity Index: FDA analyses of data from six randomized, controlled trials. The GREAT 3 Workshop, March 30, 2015. Accessed on January 18, 2016 http://www.great3.org/wp-content/uploads/2015/04/Exploring-Key-Signs-and-Symptoms-of-the-Crohn%E2%80%99s-Disease-Activity-Index-Insook-Kim-Ph.D.pdf

[7] http://www.nihpromis.org/about/overview

There is an increasing amount of health-related data being generated by patient-centered technologies (e.g., such as through mobile apps[8]). These data sources have great potential to improve communication and coordination with healthcare providers or to capture performance measurement. We encourage the Working Group to strongly recommend that these patient-centered technologies connect with provider electronic health records, and determine their potential future applicability for Medicare beneficiaries with chronic conditions.

We also want to make sure the benefits of collecting data through appropriate PROs should outweigh the burdens. Obtaining PRO data is not merely a process to collect data for performance measurement. Rather, providers should be able to use the appropriate PRO measures to assess patient status or response to intervention, plan and manage care or services, provide feedback for self-management, and engage patients in share-decision making.

Develop More Shared Decision-Making Measures

Quality measurement on utilization of shared decision-making arrayed around treatment options should exist for all complex chronic conditions. Many shared decision-making tools exist and have been incorporated into some clinical guidelines. For example, in collaboration with the Informed Decision Foundation, the American College of Cardiology (ACC) developed a decision tool to assess each patient's risk of stroke and guide them through the decision process on anticoagulation treatment for atrial fibrillation.[9] This shared decision-making tool was incorporated into the 2014 American Heart Association/ACC/Heart Rhythm Society Guideline for the Management of Patients with Atrial Fibrillation.[10]

Other medical societies encourage the use of shared decision-making tools through quality measurement. The 2016 CMS Physician Quality Reporting System includes a shared decision-making quality measure for physicians managing hepatitis C: "Measure #390: Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Option."[11] As maintained by the American Gastroenterological Association, this measure examines the documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient, including all of the following: treatment choices appropriate to genotype; risks and benefits; evidence of effectiveness; and patient preferences toward treatment" [12,13]

In contra-distinction to the above example, shared decision-making quality measures are lacking for other complex disease, such as psoriasis, IBD, rheumatoid arthritis and cancer. We look forward to working with medical societies, National Quality Forum, patient advocacy groups, healthcare providers and the Working Group on this topic.

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[8] http://www.healthline.com/health/crohns-disease/top-iphone-android-apps#2

[9] The ACC continues focus on "The Year of the Patient". Informed Medical Decisions Foundations. http://www.informedmedicaldecisions.org/tag/atrial-fibrillation/Assessed December 29, 2015.

[10] 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation: Executive Summary. Journal of American College of Cardiology. http://content.onlinejacc.org/article.aspx?articleid=1854230. Accessed on December 29, 2015

[11] http://www.mdinteractive.com/files/uploaded/file/CMS2016/2016_PQRS_Measure_390_11_17_2015.pdf

[12] https://www.gastro.org/practice-management/quality/400-1683302_PQRS_and_VBM_for_HCV_Flashcard.pdf Accessed December 29,2015

[13] The American Medical Association (AMA) and Physician Consortium for Performance Improvement (PCPI) made great contributed to the development of this measure and American Gastroenterological Association maintains the measure.

Addressing The Need For Behavioral Health Among Chronically Ill Beneficiaries

We appreciate the consideration of the Working Group for developing policies that improve the integration of care for individuals with a chronic disease combined with a behavioral health disorder. We would specifically call attention to the success of a program in southern California to House Calls, an in-home program that provides, coordinates, and manages care primarily for recently discharged high-risk, frail, and psychosocially compromised patients.[14]

It would be helpful to have the Government Accountability Office conduct a study on the current integration of behavioral health and primary care, not only among accountable care organizations (as suggested in the Policy Options Document, but more broadly. We especially encourage a study of the benefits of home-based mental health services for complicated behavioral health conditions (including severe depression).

Support for the Medicare Diabetes Prevention Act

We support the request by the American Diabetes Association (ADA) for the Working Group to incorporate in its legislative proposals of the Medicare Diabetes Prevention Act (MDPA). Johnson & Johnson's diabetes care companies Animas and LifeScan are dedicated to serving the needs of the diabetes community. In addition, our Diabetes Institute is a unique training program designed to improve diabetes care for people living with diabetes.

A key driver in moving Medicare from a fee-for-service payment system toward a value-based model is to establish incentives to prevent illness and avoid chronic diseases and costly complications where possible. By providing access to proven interventions to prevent and/or delay the onset of type 2 diabetes in many cases, the MDPA lays out a pathway forward for Medicare to begin to turn the tide on the diabetes epidemic. According to the ADA's analysis, this policy will improve patient health outcomes, facilitate the delivery of high quality care to individuals at risk of developing diabetes, and reduce the growth in Medicare spending – all stated goals of the Working Group.

Greater Utilization of Technology to Improve Care Coordination

We support the proposal under consideration by the Working Group to clarify that remote patient monitoring may be furnished by accountable care organizations even though payment for these services is not made under Medicare fee-for-service. Johnson & Johnson offers and is developing a number of technologies that enable patients to record data about their health and medication adherence. These technologies can help Medicare beneficiaries share this information with their doctors and lead to better coordinated care.

The Clinical Opportunities for Novel and Necessary Effective Care Technologies (CONNECT) for Health Act would further promote the use of these technologies in the care provided to Medicare beneficiaries. We encourage the Working Group to consider including the provisions of this legislation as it develops its proposals to improve care for Medicare beneficiaries with chronic conditions.

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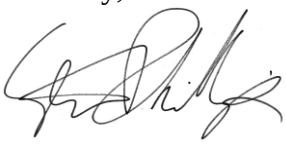
[14] *Health Affairs*, 35, no.1 (2016):28-35 "House Calls: California Program For Homebound Patients Reduces Monthly Spending, Delivers Meaningful Care."

Thank you for the opportunity to provide input into your process. We would welcome the opportunity to discuss this in greater detail.

Sincerely,



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Attachment: 1