



Eli Lilly and Company

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The Honorable Orrin Hatch  
Chairman, Senate Finance Committee  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Ron Wyden  
Ranking Member, Senate Finance Committee  
219 Dirksen Senate Office Building  
Washington, DC 20510

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

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

Dear Senators Hatch, Wyden, Isakson and Warner:

Eli Lilly and Company (Lilly) appreciates the opportunity to provide input into the Senate Finance Committee's chronic care working group, as it seeks to develop policy options and potential legislative solutions to improve care for Medicare beneficiaries with chronic conditions. Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

We wish to provide a number of principles that we believe would help guide your effort, and provide input on two of the issue areas upon which you have solicited comment.

**Issue Area 2: Transformative policies that improve outcomes for patients living with chronic diseases through Alternative Payment Models (APMs)**

Several payment and delivery system reform models have developed in the public and private sector, including medical homes, accountable care organizations (ACOs), bundled payments, and others, as part of efforts to increase efficiency and care coordination for patients with chronic diseases. Payment reforms generally seek to incentivize providers to improve or maintain quality while containing costs. They are often accompanied by delivery system reforms, such as ACOs or medical homes, in order to transform the delivery of care to support the goals of improved quality and lower costs. While these models have the potential to generate health system savings while improving or maintaining the quality of care provided to patients, there is also the risk that they could narrowly focus on reducing the cost of care, be based on static definitions of best clinical practice and not include adequate patient protections. For this reason, we suggest the following "guardrails" or principles for APMs and similar payment and delivery system reforms:

- The development, implementation and assessment of payment reforms should be grounded on a system-wide perspective in setting cost containment and quality outcome goals, in order to capture savings and efficiencies that benefit the broader system, as well as to account for improved long-term patient outcomes. They should be developed and applied through a transparent process that is predictable and includes input from a range of stakeholders, including patients, providers and the biopharmaceutical industry.
- Alternative payment models should support patient-centered care and reflect patient needs and values.
- Payment reforms should support patient access to the full range of treatment options and medical advances, choice of providers, as well as the prescriber's role in selecting the best treatment for an individual patient. This includes ensuring access to new-to-market therapies. Reform should also support a competitive, market-based reimbursement system.
- Any clinical guidelines, pathways and protocols used in alternative payment models should be grounded in well-researched, methodologically rigorous evidence from a range of sources and study designs and this evidence base should be transparent and kept up-to-date. It will be important to maintain clinical flexibility and the ability of health care providers and patients to make decisions based on the situation and needs of each individual patient.
- Payment reforms should not sacrifice quality of care for the sake of cost containment.
  - APMs must avoid establishing unintended incentives to encourage underutilization of care or the selection of healthier patients. Conversely, incentives, such as adequate risk adjustment, should be in place to minimize discrimination against sicker patients.
  - Payment reforms must include robust and meaningful quality metrics that measure patient health outcomes, quality-of-life and functional status. They should be able to capture the full range of benefits and side-effects of available treatment options for the relevant population.
  - The development of additional quality measures are needed to support broad payment reform, recognizing gaps in measures of clinical and patient-reported outcomes.

#### **Issue Area 4: The effective use, coordination and cost of prescription drugs**

- Lilly has long supported policies that increase patient adherence to therapies, and believes that improved adherence can have a significant positive impact on patient care and reduce costs over the long term. As recognized in a study from the Congressional Budget Office (CBO), adherence to, and appropriate utilization of,

prescribed therapies could result in a reduction in Medicare's spending on medical services.<sup>1</sup>

- To support quality and cost-containment goals, the Federal government should clarify that it is permissible for biopharmaceutical manufacturers to participate in arrangements designed to improve the quality and value of patient care, such as activities that improve adherence to prescribed medication regimens or facilitate patient education regarding disease states or the appropriate use of medicines. For example, federal policy should support the potential for pharmaceutical manufacturers to collaborate with the sponsors of Part D prescription drug plans (PDPs), as well as Medicare Advantage (MA) plan sponsors, by offering financial or programmatic support to sustain or expand upon a sponsor's medication adherence programs. This type of partnership could reduce or eliminate current financial disincentives and administrative expenses for PDP and MA plan sponsors, while allowing manufacturers the opportunity to contribute to an important public health imperative for our patients. In order for such arrangements to go forward, the Federal government should provide assurances that manufacturer support for MTM Programs would not implicate either the anti-kickback statute or a manufacturer's government price reporting obligations.
- The Federal Government should also support additional approaches to improve the financial incentive for Medicare plan sponsors to engage in adherence-related activities. For various reasons, such as lack of accountability for medical costs among PDPs and the longer time horizon typically required for the benefits of prescription drug adherence to be realized in the form of improved health outcomes, plan sponsors may view adherence activities as costly investments. The federal government should consider a full range of new approaches, such as cross-industry collaborations, the development of improved adherence-related quality measures, and other financial incentives and bonuses for plan sponsors to enable optimal investment in patient interventions designed to promote better adherence to prescribed therapies and improved health outcomes.
- Patients should have access to the full range of available therapies so that they can work with their provider to ascertain that which is most appropriate for their particular situation.
- In order to promote adherence as part of the effective use of prescription drugs, it will be important to study the role and impact of out-of-pocket costs and cost-sharing in current chronic disease management. Mechanisms should be developed to mitigate the negative impact of these costs on patients, with input from diverse

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<sup>1</sup> Congressional Budget Office. "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services," November 2012, p.1. CBO's study estimated that a one percent increase in the number of prescriptions filled by beneficiaries would cause Medicare's spending on medical services to fall by about one-fifth of one percent.

stakeholders. This could include consideration of ways to lessen the burden of out-of-pocket costs borne by Medicare beneficiaries with chronic conditions, such as through new private supplemental insurance mechanisms. In addition, one might look at policy solutions to reduce the impact upon Medicare beneficiaries of the absence of an out-of-pocket maximum under the Medicare Part D program.

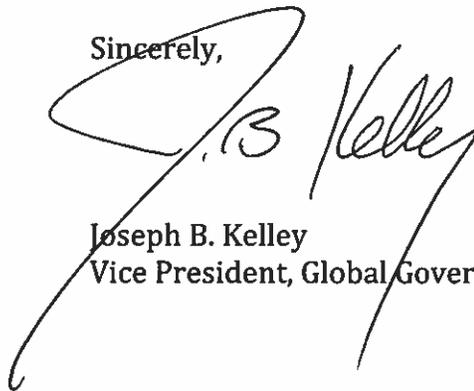
- An improved health care infrastructure can play an important role in the coordination of prescription drugs for those with chronic diseases. It will facilitate improved and efficient communication and help ensure that providers recommend treatments based on the same health care data.

In addition, Lilly would like to express its support for the input provided to the working group by the Pharmaceutical Research and Manufacturers of America (PhRMA) as well as by the Biotechnology Industry Organization (BIO).

Lilly looks forward to the possibility of working with the working group and the Senate Finance Committee as it moves forward to develop policy and legislative options to help the Medicare program improve the care provided to Medicare beneficiaries with chronic conditions.

If you have any questions, please do not hesitate to contact Sean Donohue at [SDonohue@lilly.com](mailto:SDonohue@lilly.com) or at 202-434-1015.

Sincerely,

A handwritten signature in black ink that reads "J.B. Kelley". The signature is written in a cursive style with a large, sweeping initial "J" and "K".

Joseph B. Kelley  
Vice President, Global Government Affairs