do more
feel better
live longer

June 22, 2015

The Honorable Orrin Hatch
Chairman
Committee on Finance
United States Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Johnny Isakson
Senator
Committee on Finance
United States Senate

The Honorable Mark Warner
Senator
Committee on Finance
United States Senate

RE: Request for Information (RFI) on Ways to Improve Outcomes for Medicare Patients with Chronic Conditions
Via electronic submission: chronic-care@finance.senate.gov

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

On behalf of GlaxoSmithKline (GSK), I am pleased to express our support for the Senate Finance Committee's (the Committee) chronic care reform initiative and to submit our comments on innovative policies to improve outcomes for Medicare patients with chronic conditions. GSK is a science-led global healthcare company that researches and develops a broad range of innovative medicines, vaccines and consumer healthcare products that are used by millions of patients around the world.

GSK supports the comments that the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO) have submitted on this initiative. Below, GSK submits additional comments that demonstrate our long term leadership, support and engagement in implementing patient-centered solutions to strengthen chronic care coordination with the goal of improving quality of care and health outcomes while lowering overall healthcare costs.

Our comments illustrate why prescription drugs should not be considered in a silo, separate and apart from other programs and services covered by the Medicare program. When medications are managed appropriately as part of a coordinated, patient-centered comprehensive care plan, patient outcomes improve and overall healthcare costs, including emergency room and hospitalizations, decrease. To support this point, we offer you examples of two successful patient-centered approaches: improving health of those with chronic disease via Comprehensive Medication Management (CMM) and our active engagement with Community Care of North Carolina (CCNC), the state's widely recognized innovative statewide Medicaid medical home and care management system. We will also comment on the ongoing importance of healthcare quality in improving healthcare outcomes for Medicare beneficiaries living with chronic disease.

Comprehensive Medication Management (CMM)

Recommendation:

GSK recommends the introduction of bi-partisan legislation that integrates and provides funding for CMM as a key service for Medicare fee-for-service beneficiaries in Part B (legislative language attached), Medicare Advantage, and an essential element in advanced payment models.

Background:

Absent the integration of a patient-centered systematic approach to medication management such as Comprehensive Medication management (CMM), our healthcare system will remain financially unsustainable and result in poor outcomes for patients. CMM is distinctly different from the traditional Medication Therapy Management (MTM) program administered through the Medicare Part D program.

CMM is an approach to drug therapy that has been shown to help optimize clinical and patient goals of therapy in a safe and effective manner, improving clinical outcomes and quality while reducing overall health care costs. As defined by the Patient-Centered Primary Care Collaborative (PCPCC), CMM is the standard of care that ensures each patient's medications (whether they are prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements) are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended. All medicines are assessed and drug therapy problems are identified and resolved. The evaluation results in a personalized care plan that aims at achieving the intended goals of therapy with appropriate follow-up to track actual outcomes and make adjustments as needed. The patient and, when needed, caregivers are engaged and armed with the knowledge needed to enable them to successfully adhere to the care plan and achieve health goals.[1]

As opposed to some medication therapy management (MTM) strategies that can mean anything from a letter or automated call reminding a patient to fill a prescription or reconciling a medication list to more comprehensive approaches, CMM relies on a collaboration of people and systems including clinical pharmacists, the patient's physician, other health care providers and caregivers who work together with the patient and are supported by health information technology (HIT) tools.

The currently used medication reconciliation and adherence efforts alone continue to fall short because they view medications in a silo and are not embedded into a systematic frame-work. CMM, however, provides a systematic frame-work that focuses on closing gaps in therapy, which is necessary to significantly reduce acute care services and reach quality outcomes in high-risk patient populations. Having clinical pharmacists capable of delivering CMM as integrated core team members (enabled by collaborative practice agreements) with physicians and other providers is key to not only successfully managing the medications for patients, but also to greatly increasing access to providers within the teams and addressing physician workforce shortage needs.[2]

Recent and growing evidence on CMM demonstrates its value for improving patient outcomes. A 3-year Center for Medicare and Medicaid Services (CMS) grant, ending this year, was awarded to the University of Southern California (USC) School of Pharmacy collaborating with AltaMed Health services to provide CMM for patients with poor chronic disease control in primary care teams (Patient-Centered Medical Homes- PCMHs- and Programs for the All inclusive Care

---

[1] McInnis T, Webb E, Strand L. The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. Washington, DC: Patient Centered Primary Care Collaborative, June 2012. https://www.pcpcc.org/guide/patient-health-through-medication-management

[2] We recommend an excellent recent article on the importance of CMM's patient-centered approach to medications by CMM expert Terry McInnis, which can be found online at http://www.pharmacytimes.com/publications/Directions-in-Pharmacy/2015/March2015/Medication-Underuse-The-Most-Underappreciated-Quality-of-Care-Gap?utm_source=GoogleNews&utm_medium=GoogleNews&utm_campaign=PharmacyTimesNews

of the Elderly-PACE clinics). In 10 clinics with more than 6,000 patients, this project is revealing strong preliminary results, which build upon overwhelming evidence that high-risk patients have many medication related problems (an average of 10 per patient) which when resolved result in vastly improved quality, lower acute care utilization, and extremely high patient and physician/provider satisfaction.[3]

CMM ensures patients are utilizing the most effective treatments for the desired outcome. Over 50% of drug therapy problems are related to underuse of appropriate medications including untreated conditions, doses too low and nonadherance.[4] As an example of how underuse of medications impacts outcomes and cost, consider the third leading cause of death, Chronic Obstructive Pulmonary Disease (COPD).[5] COPD is associated with multiple co-morbidities as well as increases in healthcare resource utilization and spending.[6] Inpatient care accounted for approximately 80% of excess costs for COPD patients in a matched comparison of Medicare beneficiaries with and without COPD in 2004.[7] The appropriate use of maintenance therapy has been shown to reduce the incidence of exacerbations and has the potential to reduce overall costs associated with the management of patients with COPD. Despite this evidence maintenance therapy remains underutilized for COPD with only 30% to 35% of publicly insured patients in both private and public health plans receiving prescriptions for maintenance treatment of their COPD.[8]

Another example of the underuse of appropriate medications resolved by CMM integration includes ensuring that patients have received recommended vaccines. Depending on one's age or risk factors, there are 11 vaccines recommended for adults by the Advisory Committee for Immunization Practice (ACIP).[9] Despite the ACIP recommendations and Healthy People 2020 targets, adult immunization rates remain low. In 2013, 24.2% of adults aged ≥60 years reported receiving herpes zoster vaccination to prevent shingles. Between 2005-2013, 11.9% of survey respondents ≥65 years received a Tdap vaccine.[10] GSK encourages the Committee to support CMM as a key new service in Medicare Part B together with improved policies in Medicare Part D to ensure Medicare beneficiaries receive these important preventative services.

Targeting Medication Management to the Right Patient- the CCNC Model

Recommendation:

GSK recommends that the Committee consider a "small data" approach to identify patients at risk of negative health outcomes and provide guidance around medication management services to healthcare providers.

Background:

Through collaboration with North Carolina Community Care Networks (NC3N), an affiliated company of Community Care of North Carolina, Inc. (CCNC), GSK co-developed a health information technology tool that uses "small data" to identify patients at risk for drug therapy problems and provides guidance around medication management services to healthcare providers. NC3N has piloted the tool across various healthcare settings to demonstrate the value in analyzing a smaller set of data, inclusive of prescription fill history, to predict potential negative outcomes and efficiently deliver

---

[3] http://www.careinnovations.org/knowledge-center/facilitating-care-integration/integrating-primary-care-and-pharmacy-care /innovator-highlight-integration-of-pharmacy-teams-into-primary-care. Webinar and download of slides- http://www.careinnovations.org/knowledge-center/care-integration-webinar-4-integrating-pharmacy-care-and-primary-care

[4] http://www.pharmacytimes.com/publications/Directions-in-Pharmacy/2015/March2015/Medication-Underuse-The-Most-Underappreciated-Quality-of-Care-Gap?utm_source=GoogleNews&utm_medium=GoogleNews&utm_campaign=PharmacyTimesNews

[5] Centers for Disease Control and Prevention. National Center for Health Statistics. National Vital Statistics Report. Deaths: Final Data for 2010. May 2013; 61(04).

[6] Dalal AA, Shah M, Lunacsek O, Hanania NA. Clinical and economic burden of patients diagnosed with COPD with comorbid cardiovascular disease. Respiratory Medicine, 2011. 105:10:1516-1522

[7] The economic burden of chronic obstructive pulmonary disease (COPD) in a U.S. Medicare population.Menzin J, Boulanger L, Marton J, Guadagno L, Dastani H, Dirani R, Phillips A, Shah HRespir Med. 2008 Sep; 102(9):1248-56

[8] Blanchette C. "Rising Costs of COPD and the Potential for Maintenance Therapy to Slow the Trend" Am Health Drug Benefits. 2014 Apr; 7(2): 98–106

[9] MMWR, February 6, 2015/64(04);91-92

[10] MMWR, February 6, 2015/ 64(04); 95-102

comprehensive medication management (CMM) services to high risk patients, and targeted interventions throughout the continuum of services to appropriate patients at the right time with the right interventions.

Through the example described above, Medicare could use predictive and prescriptive analytics to better understand a beneficiary's medication challenges, determine effective ways to overcome barriers and deliver quality services. The generated information could assist pharmacists and care team members in determining – and responding to – medication-related problems that often lead patients to use their medicine incorrectly, or to not adhere to the treatment regimen prescribed by their doctor. This approach combined with medication management services, such as CMM discussed above, could improve clinical goals of therapy and result in overall cost reductions.

In fact, a CMS Healthcare Innovation Award (Round 2) was awarded to the NC3N and the UNC Eshelman School of Pharmacy for the project entitled "Optimizing the Medical Neighborhood: Transforming Care Coordination through the North Carolina Community Pharmacy Enhanced Services Network." The project will test a model focused on community based pharmacists who will deliver medication management services to patients with at least one chronic condition and have more than 80% of their medications filled within the last 100 days at a specific pharmacy. Participating pharmacists will aim to optimize patients' medication use and provide care management in collaboration with other health care providers to reduce hospital readmissions and visits to the emergency department.[11]

While not involved in the implementation of the grant, GSK is collaborating with NC3N and the UNC Eshelman School of Pharmacy to develop, implement and test new approaches to care delivery through the pharmacist (whether that pharmacist is embedded in a primary care practice, working in a community pharmacy, or providing care in a hospital setting) with the goal of providing a model for payers and healthcare providers interested in optimizing medication use as part of a holistic approach to managing patients' health and lowering overall healthcare costs.[12]

Please view the attached GSK Policy Document on Collaboration for a Healthy America for more information on our work in advancing collaboration and care coordination.

Improving Quality in Healthcare

Recommendation:

Developing and implementing new payment and delivery models are crucial steps in identifying innovative ways to deliver high quality, efficient care to patients. GSK supports value-based delivery models where there is accountability for both the delivery of quality and efficiency. We recommend that the Committee ensure quality and accountability measures maximize clinical health improvements within evaluation of ACOs, PCMHs, and alternative payment models (APMs).

Background:

GSK has had a long history of leading with a wide range of stakeholders to improve healthcare quality through use of performance measures that will advance high-quality care through adherence to clinical guidelines, improvements to care coordination and care transitions, and a focus on patient decision making and patient experience of care. We support quality measures that: (1) have been endorsed by multi-stakeholder, evidence-based quality organizations, such as the National Quality Forum (NQF); (2) reflect higher performance in helping to achieve patient-centered outcomes; (3) are based on evidence-based processes; and (4) are aligned across multiple care settings and providers to harmonize the use of measures in various reporting programs to help reduce reporting burden and accelerate improvement.

GSK is very encouraged by the Committee's focus on improving care coordination for Medicare patients with chronic disease. Provisions in the Affordable Care Act (ACA) as well as private market forces and HHS' recently announced timeline for moving to a value –based system in Medicare are facilitating a shift in focus in healthcare from the volume of services to

---

[11] CMS.gov, Health Care Innovation Awards Round Two: North Carolina, http://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards-Round-Two/North-Carolina.html

[12] GSK Press Release, North Carolina-based collaboration takes on medicine management challenge, October 30, 2014. http://us.gsk.com/en-us/media/press-releases/2014/north-carolina-based-collaboration-takes-on-medicine-management-challenge/

the value of services provided. The goal of this shift is to help lower healthcare costs while improving patient safety and quality of care. As these changes take place, an evidence-based, patient-centered approach to improving healthcare quality is critical to transforming the U.S. healthcare system.

An important part of the care coordination is medication management. Proper use of medications can lead to improved health, enhanced quality of life, and increased productivity. GSK supports implementation of quality measures that encourage coordination between various aspects of an episode of care, including patient transitions between providers and from provider care to home health and post-acute care -- times that are prone to medical misadventures due to lack of care coordination and continuity.

An example of how value-based programs that include appropriate quality metrics can improve patient outcomes and encourage care coordination can be found in HIV. A key to effectively managing HIV as a chronic disease is to maximally suppress a patient's viral load. Reduced viral load has been linked with improved quality of life and survival, delay or the prevention of the emergence of drug-resistance, and decreased risk of HIV transmission.[13] [14] [15] Encouraging the adoption of the Viral Load Suppression measure into Medicare-related measure sets can stimulate focused practice change towards improved clinical care and outcomes for patients with HIV. We urge the Committee to support programs that measure critical aspects of patient care and encourage providers/healthcare stakeholders to focus on improving patient outcomes, such as HIV care viral load suppression.

For more information on Quality, please view the attached GSK US Public Policy Position paper on Recommended Quality Measures.

GSK appreciates the opportunity to share with the Committee our ideas and innovative solutions for chronic care reform. We are encouraged by Congressional efforts to address chronic conditions holistically while also supporting the needs of complicated chronic diseases such as COPD, diabetes and heart disease. We support the Committee's chronic care reform legislative initiative and other legislative proposals addressing chronic disease currently underway. We look forward to working with the Committee's chronic care working group and staff members as you move forward on this very important initiative. In the meantime, please do not hesitate to contact me if you have questions or would like to further discuss any of the items raised in our letter.

Sincerely,

William J. Schuyler
Vice President
Government Relations

---

[13] D. Donnell, et al., *Heterosexual HIV-1 Transmission After Initiation of Antiretroviral Therapy: A Prospective Cohort Analysis*, 375 The Lancet 2092, 2095 (Jun. 2010)

[14] Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, NIH, http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf

[15] World Heath Organization (WHO). Adherence to long term therapies—evidence for action. 2003. Available at http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf