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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

VIA ELECTRONIC SUBMISSION TO: chronic_care@finance.senate.gov

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

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments in response to your request for ideas on ways to improve outcomes for Medicare patients with chronic conditions. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Consistent with that mission, PhRMA applauds the Committee for its commitment to addressing this issue.

Continued advances in biopharmaceutical innovation will be critical in addressing future health care challenges and improving health outcomes for patients with chronic conditions in Medicare. Currently, biopharmaceutical research companies are developing 435 medicines targeting 15 leading chronic conditions affecting seniors,[1] and the pipeline has never been more promising for conditions such as Alzheimer's and dementia, arthritis, chronic kidney disease, chronic obstructive pulmonary disease (COPD), diabetes, cardiovascular conditions, and obesity. It is imperative to provide Medicare beneficiaries with the highest quality care available and help them get access to the medicines and treatments they need to prevent, treat and cure disease.

With advances in current treatment and the promise of future innovation, better use of medicines is an integral part of the solution to improve outcomes for Medicare beneficiaries with chronic conditions. The Committee's effort presents a clear opportunity to leverage evidence about the impact of improved medication use and how investments in these efforts can benefit both beneficiaries and the Medicare

[1] Pharmaceutical Research and Manufacturers of America. "Medicines in Development for Older Americans: 2014 Report." http://www.phrma.org/sites/default/files/pdf/2014-meds-in-dev-older-americans.pdf

program more broadly over time. There is strong evidence in the peer-reviewed literature that improving patient adherence offers one of the best opportunities to achieve better results and greater value from our health care system. In fact, in 2012, the Congressional Budget Office (CBO) announced that going forward it will reflect offsetting savings in medical spending associated with use of prescription drugs. This decision was based on extensive research showing that improved use of recommended medications is associated with improved health and productivity as well as reduced total health care costs.[2] For example:

- Improved medication adherence following the enactment of the Medicare Part D program has been linked to reduced spending for nondrug medical care. Following Part D implementation, beneficiaries in traditional Medicare with limited prior drug coverage experienced a reduction in non-drug medical spending of about $1,200 per year in the first two years of the program.[3] This resulted in an overall savings of $13.4 billion in 2007, the first full year of the Part D program.[4]

- Enrollment in Part D improved access to medications recommended to treat congestive heart failure (CHF) for beneficiaries with limited or no prior drug coverage. The resulting increase in adherence among Part D enrollees with congestive heart failure led to over $2.3 billion in annual savings to Medicare, driven by reductions in Parts A and B expenditures. Over the next 10 years, further improvement in adherence among Part D enrollees with CHF could yield an additional $22.4 billion in federal savings.[5]

A guiding principle of the Committee's effort should also be to preserve successful aspects of the Medicare program, including market-based competition in Medicare Part D. With this principle in mind, PhRMA recommends that the Committee pursue the following actions:

- Improve medication adherence, including strengthening the Part D Medication Therapy Management (MTM) program and requiring CMS to test new innovations, such as medication synchronization and comprehensive medication management (CMM).
- Improve transitions across Part D plans for beneficiaries who have already completed step therapy protocols in another plan, while also preserving beneficiary choice.
- Improve beneficiary experience with the Part D exceptions and appeals process.
- Better align benefit design with the clinical value of items and services for beneficiaries with chronic conditions.
- Study how to eliminate barriers to better alignment between Medicare Part D prescription drug plans (PDPs) and other parts of the Medicare program.

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[2] Congressional Budget Office. "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Service." November 2012.
[3] J.M. McWilliams, et al, "Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults With Limited Prior Drug Coverage," *JAMA* 306, no. 4 (2011): 402-409.
[4] Afendulis CC and Chernew ME, "State-level impacts of Medicare Part D," *American Journal of Managed Care* 17, no. 12, sup. (2011).
[5] T.M. Dall, et al, "The Economic Impact of Medicare Part D on Congestive Heart Failure," *American Journal of Managed Care* 19 no. 6, sup. (2013).

- Ensure that alternative payment models (APMs) meet the unique needs of patients with chronic disease by directing CMMI to develop quality outcome measures, protect access to innovation, and follow a more transparent process.
- Direct CMS to facilitate a stakeholder discussion on Medicare Advantage and Part D Star Ratings and the low-income subsidy (LIS) and dual eligible populations.
- Improve quality measurement and chronic disease management under traditional fee-for-service Medicare.
- Maintain strong protections for commercially sensitive data.

Specific recommendations for the Committee are laid out in more detail below.

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Improving Medication Adherence

Increasing medication adherence in the United States, so that patients take their medications in accordance with their physicians' directions, is an important opportunity to improve outcomes while also reducing healthcare costs. As mentioned above, there is strong evidence in peer-reviewed literature that improving patient adherence offers one of the best opportunities to achieve better results and greater value from our health care system.

This is an issue that impacts seniors and those with chronic illnesses and lower incomes disproportionately. The vast majority of Medicare beneficiaries have at least one chronic condition and most have multiple comorbidities. More than two-thirds of all Part D enrollees with heart failure also suffer from diabetes and/or COPD.[6] Additionally, disease burden disproportionately affects individuals with low incomes or of minority race/ethnicity. For example, Part D LIS enrollees are shown to have more severe cases of diabetes than enrollees without LIS. Additionally, LIS enrollees exhibited greater comorbidity, experience more hospital and skilled nursing facility stays, physician visits, and higher Part A and B spending than non-LIS enrollees.[7]

Medication use is suboptimal among Medicare beneficiaries, a population that can significantly benefit from preventive care, specifically prescription drugs. A University of Maryland analysis reported that less than 45% of beneficiaries with diabetes and heart failure and six in ten beneficiaries with COPD did not fill a prescription to treat their condition. In these populations adherence was also poor, with rates varying between 25% and 73% over three years.

[6] Stuart B, Loh E, Xu J, Roberto P, Dougherty JS. "Chartbook: Medication Utilization Patterns and Outcomes among Medicare Part D Enrollees with Common Chronic Conditions." 2014

[7] BC Stuart et al. Why Do Low-Income Subsidy (LIS) Recipients Have Higher Part D Drug Spending? Poster presentation at AcademyHealth Annual Research Meeting, June 2014 San Diego.

Poor medication adherence results in 33 to 69 % of medication-related hospital admissions in the United States at a cost of roughly $100 to $300 billion per year.[8] A recent Health Affairs study reported that the Medicare costs associated with poor medication adherence among beneficiaries with diabetes, heart failure, and COPD reach up to $840 per month.[9] PhRMA has identified several suggestions that have the potential to improve the use of medicines in Medicare, and may lead to system-wide cost savings. These suggestions include strengthening the existing Part D Medication Therapy Management (MTM) program by addressing the challenges and barriers identified below, and requiring CMS to test new innovations, such as medication synchronization and comprehensive medication management, also described in further detail below.

Medicare Part D Medication Therapy Management Program

PhRMA appreciates the potential the Part D Medication Therapy Management (MTM) program has to improve medication use among enrollees with chronic conditions who take multiple drugs. PhRMA has met with the Centers for Medicare and Medicaid Innovation (CMMI) and found the agency to be receptive to ideas for improving the MTM program. However, there are a number of challenges within the current MTM program that limit the MTM program's effectiveness. Our industry has significant experience with MTM program development and thus, ways to optimize its effectiveness.

PhRMA has identified several barriers to implementing effective Part D MTM programs, and below suggests ways in which CMS could use its demonstration authority to conduct a Phase I model that provides incentives for plans to conduct MTM and sufficient flexibility to target those beneficiaries most in need of MTM. The barriers and challenges identified include:

- *Inadequate eligibility criteria.* PhRMA recommends modifying the eligibility criteria for the MTM program so that individuals at high risk for non-adherence, such as beneficiaries with high medical costs, or beneficiaries who have recently undergone a transition from one setting of care to another, are targeted. Current MTM eligibility criteria are not sufficiently targeted towards those beneficiaries most in need of MTM services. For example, there are many Part D enrollees who are non-adherent to medications or whose medication regimen is not clinically appropriate who would not meet current eligibility requirements (because by definition non-adherent individuals have lower drug utilization and therefore may not meet the annual drug cost threshold or number of medications). The current criteria also permit plans to use unnecessarily restrictive MTM eligibility criteria.

- *Inability to identify beneficiaries most likely to benefit from MTM.* PDPs are limited in their ability to identify enrollees who are most likely to benefit from MTM interventions, because the PDPs do not

[8] Osterberg L, Blaschke T, "Adherence to Medication," New Engl. J. Med., 2005;353(5):487-497.
[9] Stuart, B., et al. (2013). "Increasing Medicare Part D enrollment in medication therapy management could improve health and lower costs." Health Aff (Millwood) 32(7): 1212-1220.

have visibility into Medicare Parts A and B data which provide critical information about enrollees' health status and risk for adverse health events. PhRMA recommends that CMS should provide these data to PDPs on a regular basis in a format that is readily accessible to PDPs (e.g., flags indicating beneficiaries who recently experienced a hospital readmission).

- *Limited emphasis on medication adherence.* PhRMA recommends exploring interventions that are targeted at improving medication adherence in beneficiaries. Currently, MTM program interventions primarily focus on Comprehensive Medication Reviews (CMRs) CMRs for beneficiaries, and many programs do not include interventions that aim to improve adherence and/or identify omissions in care (e.g. determining that an enrollee has not filled any prescriptions that are clinically appropriate given his or her diagnosis).

- *Misaligned incentives.* Many industry stakeholders have long recognized that PDPs have less incentive to invest in their MTM programs than Medicare Advantage Prescription Drug Plans (MA-PDs) because they are unable to realize savings from reductions in Medicare Parts A and B services. In addition, under current rules, the cost of MTM programs is considered an administrative cost and increases plan bids and premiums. One modification that would better align incentives would be to define all MTM activities, including efforts to expand such activities beyond the regulatory minimum, as a 'quality improving activity' for the purpose of calculating the Medical Loss Ratio (MLR) and bidding for Part D plans.

- *Inadequate data on program effectiveness.* CMS, plans, and MTM providers are all limited in their ability to optimize the Part D MTM program because there is limited availability of Part D-specific data. PhRMA was encouraged by CMS's recent announcement that it will permit broader access to claims data by external researchers. In that spirit, CMS should ensure that data on future adherence-related programs and services provided to Medicare beneficiaries are available to researchers, so they have the opportunity to evaluate the programs and services, and can identify ways to improve quality of care and efficiency. To facilitate better evaluations of the program and program components the Secretary should be directed to:

    (a) Collect and release data for analysis of MTM across all parts of Medicare (e.g. ACOs, PDPs)

        (i) The MTM data file should include identifiers that allow direct linkages to CMS beneficiary administrative records, Part A and B claims, Part D PDE data, and plan characteristics files. To conduct rigorous MTM program evaluations, researchers must have access to beneficiary-level utilization and spending data for Parts A, B, and D, diagnosis data, and information on Part D plan benefit design. Data on medical services should also be made available for Medicare Advantage enrollees. In particular, data elements should include: indicators for eligibility and

participation in MTM and receipt of a CMR, characteristics of the MTM services provided (e.g. setting, mode of delivery, date and duration of service, initial vs. follow up), provider characteristics (e.g. pharmacy identifier, provider profession, geography), and characteristics of outreach efforts (e.g. frequency, method). All qualified researchers in the private or public sectors should be permitted access to maximize research opportunities.

(b) Analyze current MTM services to identify best practices

(i) CMS should compare the effectiveness of components of MTM services being delivered to beneficiaries at increasing enrollee adherence with medications. Components of MTM should include but not be limited to comprehensive medication reviews and targeted medication reviews. As part of this study, CMS should also study how often these components of MTM services are provided to beneficiaries, in which setting and by which type of professional. The study shall also consider the impact of providing MTM services in alternative settings, such as through the patient's medical home or by the patient's physician or the physician's staff.

(ii) CMS should also evaluate which Part D enrollees are most likely to benefit from MTM, including beneficiary populations who are not currently eligible for MTM, in order to inform CMS requirements and PDP decisions about eligibility criteria

Medication Synchronization

For many beneficiaries, complex medication regimens are associated with poor medication adherence and adverse clinical outcomes. A key contributor to adherence complexity is the asynchronous refilling of prescriptions, which requires patients to make multiple trips to the pharmacy throughout the course of a given month. Consequently, many pharmacy chains have implemented programs in the commercial market that synchronize medication refills to be processed for pick up at the same time. In addition to synchronizing the dates for pick up that make these programs beneficial, in advance of each fill, patients receive phone calls to remind and receive authorization for filling the medications. They also receive, if desired, an opportunity to have a pharmacist conduct a face-to-face comprehensive review of the patient's medications and deliver medication management services.

Congress should direct the Secretary to test a program to synchronize medication refills for beneficiaries on the same date every month that is practical, affordable and efficient. The program should be based on current commercial best practices and test the impact on adherence, health outcomes, and total healthcare costs. Med sync programs should be conducted in coordination with the beneficiary's provider(s). Research is needed to advance adoption of this intervention to demonstrate the benefits of synchronizing medications but also the value of pharmacist counseling and oversight provided during a pharmacy visit.

Comprehensive Medication Management

Comprehensive medication management is a standard of care requiring individual assessment of each patient's medications to ensure that the medication is: 1) appropriate, 2) effective for the medical condition, 3) safe given the comorbidities and other medications being taken, and 4) able to be taken by the patient as intended. The provision of CMM services by a pharmacist, physician, or eligible professional with prescribing authority should include: an assessment of a patient's health status, patterns of medication use, documentation of the patient's current clinical status and goals, assessment of each medication for appropriateness, effectiveness, safety, and adherence, identification of all drug regimen problems or modifications, development of a written comprehensive medication care plan, and follow-up evaluations.

The Secretary should conduct a pilot to test Comprehensive Medication Management (CMM) in Medicare Part B to complement MTM efforts in Part D. PhRMA has previously commented that incorporating CMM as a required element of the new complex chronic care management service established in the 2014 Medicare Physician Fee Schedule would promote more effective management of chronic disease. A pilot program to test CMM would help to demonstrate its potential to improve the clinical goals of therapy and reduce overall health care costs through better medication management. The pilot should evaluate the effect of CMM on quality of care, patient outcomes, program costs and potential for downstream savings, and perceived patient and provider value.

Transitions in Care

PhRMA recommends ensuring that patients who are undergoing a transition of care have access to services that will ensure that their health care providers and facilities are coordinated, including a comprehensive medications management plan. Nearly one in five Medicare patients discharged from a hospital, or 2.6 million beneficiaries, are readmitted within 30 days, which costs over $26 billion every year.[10] Ensuring that a comprehensive medications management plan is in place will help beneficiaries and their providers better navigate care transitions, and are a key component of reducing unnecessary hospital readmissions, and lowering Medicare Parts A and B costs.

Improving Plan Transition Process & Preserving Beneficiary Choice in Part D

Beneficiary choice and robust competition among Part D plans are critical aspects of the program. Broad choice helps beneficiaries find a plan that meets their individual health and financial needs, and available evidence demonstrates that the program overall benefits from this competition. In a recent analysis, CBO found that, between 2007 and 2010, lower bids were submitted in regions with more plan sponsors and thus more competition.[11]

[10] CMS, "Community-based Care Transitions Program."
[11] CBO, "Competition and the Cost of Medicare's Prescription Drug Program," July 2014.

While evidence shows that more beneficiaries are switching plans each year during open enrollment relative to the early years of the program,[12] one barrier that beneficiaries may face in contemplating a plan switch may be the prospect of repeating a step therapy protocol under a new plan, even if there are other advantages to switching to a new plan. Step therapy is a process by which a plan may require beneficiaries to try and "fail" on lower tier medications before progressing to other therapy options. Having to repeat step therapy could also have critical health implications if a beneficiary is currently stable on a medication for his or her condition.

As a result, Congress should consider new requirements that would prohibit Part D plans from requiring a beneficiary to repeat step therapy in a new plan if completion of a step therapy protocol has been documented in another plan such that a beneficiary has demonstrated a clinical need for his or her specific medication. In order to accomplish this, Congress would also need to ensure that CMS facilitates better data sharing across Part D plans so that plans can verify this information. PhRMA believes that this simple step would go a long way to improve continuity of care for beneficiaries, particularly those with chronic conditions, and reduce the risk of disruptions in care if and when a beneficiary chooses to switch plans in order to better meet their individual needs.

Improve Beneficiary Experience with the Part D Exceptions and Appeals Process

Medicare beneficiaries with chronic conditions often take multiple medications and therefore may be more likely than other beneficiaries to face coverage restrictions or utilization management (e.g., prior authorization, step therapy), and also may need to use their plan's exceptions and appeals process in order to access needed medicines. Recent analysis from MedPAC,[13] CMS,[14] and others suggests that the Part D appeals process may not be working as intended for beneficiaries, which can cause unnecessary barriers to access, and that there is still significant room for improvement.

Recognizing these concerns, CMS addressed this issue in the CY 2016 Call Letter earlier this year and plans to pursue improvements to the Part D appeals process, including providing beneficiaries with better information in denial notices when they are rejected at the pharmacy counter, conducting a pilot program to streamline the beneficiary experience at point-of-sale, and improving data collection for every stage of the appeals process.[15] PhRMA strongly supports these efforts. We urge the Committee to also support and encourage CMS' efforts on this issue and explore other potential opportunities to improve the Part D appeals process that will complement CMS' existing initiatives.

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[12] MedPAC, "Report to the Congress: Medicare Payment Policy," Chap. 15, March 2013.
[13] See Medicare Payment Advisory Commission, Public Meeting, September 12-13, 2013; MedPAC, "Report to the Congress: Medicare Payment Policy," Chap. 14, March 2015.
[14] CMS, "The 2013 Part C and Part D Program Annual Audit and Enforcement Report," Oct. 16, 2014.
[15] CMS, "Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 6, 2015.

Allowing for Value-Based Insurance Design

Value Based Insurance Design (VBID) has the potential to improve the quality of care for patients with chronic conditions—by reducing or eliminating cost-sharing for medications and other services to increase patient utilization of beneficial services and improve medication adherence. With certain safeguards in place, VBID models may be used to support patient access to much needed treatments and medications by better aligning benefit design with the clinical value of items and services for beneficiaries with chronic conditions. In particular, VBID may address barriers in existing benefit designs that impede patients' ability to gain access to the items and services that are most valuable to them, such as very high cost sharing for clinically indicated medicines.

Below are several key considerations that would be critical for the Committee to address as it considers encouraging further testing or use of VBID:

- Medicare Advantage and Part D plans should maintain responsibility for VBID and assessment of clinical evidence.
- VBID should reduce beneficiary cost-sharing for targeted items and services without increasing cost-sharing for other items and services, or overall cost-sharing.
- VBID should be accompanied by meaningful, relevant measures of clinical quality and patient satisfaction to ensure they achieve their goals of incentivizing patient choice and improving health outcomes.
- In designing VBID, plans must adhere to a robust and transparent process to determine which benefits are deemed "high value" in such programs—including being open to the public, providing appropriate opportunities for stakeholder input, ensuring that input from medical experts and patients are included whenever appropriate, clearly explaining the basis of decisions, and making publicly available the evidence used in assessments. The plans should also use appropriate processes for notifying enrollees and providers about the incentives the benefit seeks to create.
- VBID should assure patients and providers have access to a broad choice of care services and treatment options and allow for tailoring of care to meeting patients' specific needs based on varying clinical circumstances, comorbidities, genetic variations, and patient preference.

It is critical for the Committee to ensure that VBID would not undermine Medicare Part D and its competitive benefit design which has been integral to the program's success. Part D plans, including Medicare Advantage prescription drug plans (MA-PDs), already have significant flexibility in designing their prescription drug benefits, such as the ability to use tiered formularies and designate certain "Select Care" tiers with low or $0 beneficiary cost-sharing for drugs targeting specific conditions. Given this existing flexibility, initiatives to give MA-PDs more flexibility for Parts A and B benefits should not change or undermine the operation of the Medicare Part D drug benefit. Any future legislative effort should require that the Part D program continue to operate as it would otherwise, keeping intact important aspects of the

Part D program such as the competitive bidding process and important beneficiary protections such as out of pocket limits and other limits on beneficiary costs (e.g. low premiums and deductibles).

Eliminating Barriers to Better Alignment between PDPs and Other Parts of Medicare

PhRMA recognizes that PDPs may lack appropriate incentives to improve medication adherence and may be constrained by existing Part D MTM program requirements. However, at this time, there are also significant barriers to comprehensive integration of Part D benefits into other parts of the Medicare program, such as Accountable Care Organizations (ACOs). Moving forward with new programs or models too quickly could jeopardize the success of the Part D program for the beneficiaries it serves. For example, a recent survey of ACOs found that "critical gaps remain before [ACOs] can become fully accountable" for appropriate medication use.[16] Additionally, there are substantial challenges related to enrollment and attribution of beneficiaries to the various Medicare programs. Beneficiaries are attributed to an ACO retrospectively at the end of each calendar year, whereas beneficiaries select and enroll in a Part D plan prior to the start of the plan year. It is critically important to maintain beneficiary choice and competition among plans in Part D, protect the integrity of the Part D bidding process, preserve important beneficiary protections, and ensure that quality of care is not compromised under any new models.

Given these challenges, Congress should direct CMS to conduct an in-depth study of the current barriers to better alignment. Additionally, CMS should make these findings available publicly and open to comment, engaging relevant stakeholders in a robust collaborative process to discuss how to better align incentives and enable partnerships between PDPs and other entities in the health care delivery system. We believe this will result in a thoughtful process that will help to shed light on some key challenges facing the program.

Ensure APMs Developed by CMMI Meet the Unique Needs of Patients with Chronic Disease

Recently the Administration has announced the "Better, Smarter, Healthier" initiative and Health Care Payment Learning and Action Network (HCPLAN) to accelerate delivery reform by linking more payment to health care value. PhRMA is participating in the HCPLAN and is working to ensure that new payment and delivery models advance high quality care and provide appropriate incentives to balance cost control efforts.

There are significant and unique challenges to designing alternative payment models (APMs) to help address chronic disease. First, there is great heterogeneity within the population of patients with one or more chronic conditions. By definition, these patients have complex health needs that require individualized treatment and a high degree of care coordination. The two-thirds[17] of Medicare beneficiaries

[16] Dubois, RW et al., "Are ACOs Ready to Be Accountable for Medication Use?" *Journal of Managed Care Pharmacy*, Vol. 20, No. 1, January 2014

[17] Chronic Conditions among Medicare Beneficiaries, Chart Book, Baltimore, MD: Centers for Medicare & Medicaid Services, 2011.

who have more than one chronic disease typically receive care from multiple providers and take multiple prescription medications that require enhanced management.

While the Center for Medicare and Medicaid Innovation (CMMI) has largely focused on opportunities to pilot episode-based payments for chronic conditions,[18] the varying care needs of patients with chronic disease pose a challenge to defining and pricing episodes of care because the cost of care can vary significantly.[19] In contrast to episode-based payment models, APM designs, such as medical homes and ACOs, may be better suited to serve the needs of the chronically ill population because of their emphasis on care coordination.

It is important that APMs are appropriately structured to give participating providers both the incentive and the flexibility to adopt models of care that have the potential to improve effectiveness and efficiency for this population. PhRMA recommends that Congress require that APMs include robust quality measures, strong safeguards to monitor for changes in quality and access to care, and greater transparency and stakeholder input in the process of designing and implementing new models. More specifically, PhRMA recommends the following policies (which are described in more detail below):

- Focus CMMI efforts on developing and piloting robust quality measures to support APMs that improve care for patients with chronic disease.
- Require that APMs tested by CMMI include safeguards to protect patient access to innovative medicines.
- Require CMMI to develop APMs through an open and transparent process that includes stakeholder input.

<u>Focus CMMI efforts on developing and piloting robust quality measures to support APMs that improve care for patients with chronic disease.</u>

Developing APMs that improve care for patients with chronic disease is challenging in part because these patients are not well represented in care guidelines. For example, a recent study conducted by the Agency for Healthcare Research and Quality examined 28 clinical guidelines on treating Type II diabetes and found that "[m]ost diabetes guidelines are lacking in the extent to which they explicitly take into account the

[18] Center for Medicare and Medicaid Innovation. Request for Information on Specialty Practitioner Payment Model Opportunities. February 2014.

[19] A recent analysis by CMS demonstrates this point. Using two different episode-creation algorithms for two common chronic conditions (diabetes and coronary artery disease), the researchers found that the two algorithms identified different patients and generated significant differences in the episode-based payment estimates. Notably, for both conditions, the researchers excluded 21 percent of diabetics (accounting for 34 percent of the total payments) and 16 percent of the CAD patients (accounting for 32 percent of the total payments) from their analysis "due to complex comorbidities." See Thomas J. O'Byrne, Nilay D. Shah, Douglas Wood, Robert E. Nesse,
Patrick J. F. Killinger, William J. Litchy, Robert J. Stroebel, Amy E. Wagie, James M. Naessens. "Episode-Based Payment: Evaluating the Impact on Chronic Conditions," *Medicare and Medicaid Research Review.* 2013: Volume 3, Number 3.

context of patients with multiple chronic conditions."[20] This lack of representation in guidelines also translates to a dearth of quality measures addressing patients with multiple chronic conditions. Congress should direct CMMI to devote resources to developing and testing measures that address Medicare patients with multiple chronic conditions, with an emphasis on patient-reported outcome measures (e.g., quality of life, functional status, and patient experience of care). Increased emphasis in this area will help to build the evidence base needed to improve care and manage costs. Further, an emphasis on outcome measures is consistent with the measurement priorities established by Congress in the Medicare Access and Children's Health Insurance Program Reauthorization Act (MACRA).[21] With this infrastructure in place, CMMI could begin to test and evaluate a range of practices in the care of people with complex health needs, particularly those with multiple chronic conditions.

Require that APMs tested by CMMI include safeguards to protect patient access to innovative medicines.

In order to support patient access to treatment advances and continued medical progress, APMs must include mechanisms allowing for the standard of care to evolve alongside medical science. Presently, many of the payment models being tested in Medicare and in the commercial sector rely on definitions of value based on the current, not the future, standard of care. A report from the California Healthcare Institute concludes that, "Without appropriate guardrails or guiding principles, payment and delivery reforms that build on a 'rear-view mirror' approach could hinder patients from receiving medical innovations that improve health and reduce morbidity and mortality. In turn, this poses a risk of discouraging investment in the next generation of drugs, devices and diagnostics." Similarly, a paper released last month by the Personalized Medicine Coalition concludes that, "If structured inappropriately and without the necessary safeguards to ensure high quality care, APMs could lead to unintended consequences that could limit access to vital services and medicines." Accordingly, PhRMA recommends that APMs account for advances in biomedical science and clinical practice through mechanisms that may include: rebasing APM spending benchmarks to account for new treatments, meaningful incentives for care quality and patient outcomes, adequate risk adjustment, and outlier adjustments, along with other tools available to CMMI.

Require CMMI to develop APMs through an open and transparent process

Currently, CMMI's process to develop and implement new models provides limited transparency, predictability and openness for stakeholders. Developing APMs for patients with chronic conditions is a technical process that can involve complex, highly-variable patient populations and rapidly changing standards of care. A more transparent process for the development of all CMMI models, including those testing APMs, would provide an opportunity for multiple stakeholders – including patient advocates, researchers, policy experts, and pharmaceutical and device manufacturers – to bring forward promising APM designs for CMMI's testing. Increased transparency would also benefit CMMI by affording

[20] K Wyatt, L Stuary, et al., "Out of Context: Clinical Practice Guidelines and Patients with Multiple Chronic Conditions: A Systematic Review," Med Care. 2014: 52; S92-100.
[21] Medicare Access and CHIP Reauthorization Act, Public Law 114–10—April 16, 2015

stakeholders and external experts the opportunity to review model designs and provide additional feedback before models are implemented. For these reasons, CMS should issue a proposed notice for CMMI models to solicit stakeholder input before moving forward with a request for application. Such notice should provide a minimum 30 day comment period and be issued to the general public, not just potential participants in the models.

Driving Improvements in Medicare Advantage and Part D Star Ratings

The Star Ratings program has been an important force for improving standards of care in the Medicare Advantage and Part D programs. Given the importance of the Star Ratings program both as a model for quality measurement and as a driver of plan reimbursement, it is crucial that it accurately reflects quality of care delivery on measures that health plans can improve upon. For PDPs, the measure set includes medication adherence, appropriate use of medications, medication safety, delivery of comprehensive medication reviews for beneficiaries eligible for medication therapy management, as well as good plan operation measures. For Medicare Advantage plans, the measure set includes the same medication measures, along with measures of disease screening, proper chronic disease control, and vaccination rates, among others. By grading plans on the measures, publicly displaying the results, and assigning ratings as stars to aid in the plan selection process, the program has prompted plans to improve their service and offerings. In order to continue driving improvements, it is important to identify more rigorous measures, identify new sources of data that can be used for measurement, and eventually measure health outcomes.

More rigorous measurement does not come without challenges. One challenge is the potential risk of disincentivizing plans from enrolling vulnerable populations such as the dual eligible and low-income subsidy (LIS) populations, who are more likely to suffer from multiple chronic conditions. Plans with high dual/LIS enrollment may be disadvantaged in their performance on some of the measures. In the draft 2016 Call Letter, CMS detailed initial findings that suggest a relationship between high enrollment of vulnerable populations and poorer performance on certain measures. Simply risk adjusting or lowering expectations is not an ideal or acceptable solution to this particular issue, though improving risk adjustment itself is another important effort. To appropriately balance incentives and encourage high performance, CMS should facilitate a discussion among the full range of stakeholders wherein they collectively share the available evidence, discuss the underlying challenges, and identify solutions.

Our shared goal must be not only to assure a fair and accurate quality rating system but to develop a better understanding of what it will take to eliminate persistent disparities in chronic disease outcomes for these groups of beneficiaries.

Improving Quality Measurement and Chronic Disease Management under Traditional Medicare

As described above, the Star Ratings program is an important component of the Medicare Advantage and Prescription Drug Programs. The bonuses plans can earn under this program create some important

incentives for improved management of chronic diseases; these incentives could be enhanced by increasingly focusing these measures on health outcomes, rather than processes of care. There is also potential to improve care coordination for patients in Traditional Medicare by implementing a measurement program similar to the Star Rating Program for those patients. This would complement existing provider-level measurement programs by looking at care at a population level.

This idea has also been recommended by MedPAC, which suggested that population level quality measures for FFS could be used for quality reporting as well as for benchmarking performance by Medicare Advantage plans and Accountable Care Organizations. [22] We suggest starting with currently available measures that have been endorsed by the National Quality Forum (NQF) for reporting at a plan-level and moving toward broader population-level health outcome measures over time. It will be important that such measures incorporate multi-stakeholder input by going through validation, testing and endorsement by an organization like NQF notice and comment before being finalized by CMS.

In addition to quality reporting, the Committee might consider requiring the Secretary to develop a strategic plan to improve treatment of chronic disease among Medicare fee-for-service beneficiaries. As part of the strategic plan, the Secretary could identify chronic diseases that would benefit from improved treatment and prevention and also lead to short or long-term Federal savings.

Maintain Strong Protections for Commercially Sensitive Data

As policymakers seek to improve care and outcomes for Medicare beneficiaries with chronic conditions, it is critically important that Congress maintain strong existing protections for commercially sensitive data, the release of which would undermine our competitive market-based system and incentives for innovation.

It is essential to continue protecting commercially sensitive drug cost data (including "data on bids, rebates and other price concessions"),[23] as outlined in the confidentiality provisions of the Trade Secrets Act (18 U.S.C. § 1905) and SSA § 1927(b)(3)(D). Disclosure of these sensitive data would undermine the competitive negotiations between health plans and manufacturers, which could result in higher prescription drug costs. This is evident in the findings of the Federal Trade Commission (FTC), which has consistently stated over many years and across different Administrations that requiring disclosure of manufacturer-PBM negotiated price information can "undercut vigorous competition on drug pricing"[24] and "undermine competition … between pharmaceutical manufacturers to offer discounts," which could "raise prescription drug prices for consumers."[25]

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[22] Medicare Payment Advisory Commission, "Measuring Quality of Care in Medicare," June 2014 Report to Congress.
[23] 79 Fed. Reg. at 1989.
[24] FTC Letter to Terry G. Kilgore, Member, Virginia House of Delegates, re: H.B. 945 (Oct. 2, 2006); FTC Letter to Representative Patrick McHenry, re: North Carolina Bill 1374 (July 15, 2005); FTC Letter to California Assembly Member Greg Aghazarian, re: AB 1960 (Sept. 7, 2004).
[25] FTC Letter to The Honorable Mark Formby, Mississippi House of Representatives, re: SB 2445 (March 22, 2011). See also J. Shepherd, "Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market," *Cornell Law Review Online*. 2013; 99(1):1-22: "[N]umerous empirical studies have also established that the disclosure of competitively

Likewise, confidential negotiations between payers and manufacturers have been a key factor in driving lower drug spending growth and are foundational to the success of the Medicare Part D program. The Congressional Budget Office (CBO) has stated, "the revelation of [manufacturers'] rebates to PDPs would create pressure to reduce those rebates, which would tend to increase costs for both the Medicare program and, on average, for enrollees."[26] CBO has estimated the impact of such disclosure as costing the program up to $10 billion over a 10 year period.

Strong protection of commercially sensitive data is fundamental to preserving our competitive market-based system and incentivizing the research and development of innovative new medicines. Therefore, we would oppose any efforts that call for the public release or dissemination of proprietary data, such as confidential data regarding pricing, rebates, and the cost of drug development.

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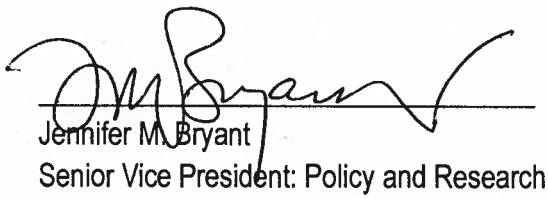
PhRMA appreciates the opportunity to submit comments in response to your request for ideas on ways to improve outcomes for Medicare patients with chronic conditions. Better use of medicines is a critical part of the solution to improve care for these beneficiaries. It is also imperative to preserve market-based competition in Part D program, which has been essential to the program's successful track record and will also help sustain long-term innovation. PhRMA is committed to working with you on these important issues and welcomes the opportunity to discuss our recommendations in more detail.

Sincerely,



Jennifer M. Bryant
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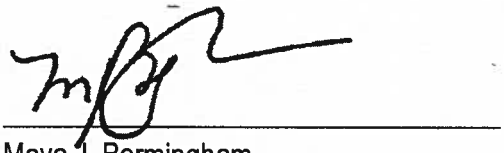

Maya J. Bermingham
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sensitive information is associated with higher prices. As firms learn of their rivals' cost structures, their willingness to bid aggressively disappears." (citations omitted)

[26] Letter from CBO to Congressman Barton and Congressman McCrery (Mar. 12, 2007).