March 5, 2018

Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Submitted via: www.regulations.gov

Re: Comments on Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the 2019 Advance Notice and draft Call Letter (the draft Call Letter). 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 and its companies are committed to the continued success of the Medicare Prescription Drug Benefit Program (Part D).

PhRMA's comments on specific provisions in the draft Call Letter are provided below.

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Attachment II, Section H, CMS-HCC Risk Adjustment Model for CY 2019

Description:

CMS proposes several changes to the CMS-HCC Part C risk adjustment model, as required by the 21st Century Cures Act, aimed at aligning risk adjustment payments to the actual costs of providing beneficiary care. Among other things, the 21st Century Cures Act directs CMS to evaluate adding diagnosis codes related to mental health or substance use disorder (SUD) and new factors (including severity) for the impact on payment for MA enrollees with chronic kidney disease (CKD) and end-stage renal disease (ESRD).

Comments:

As directed by the 21st Century Cures Act, the Centers for Medicare & Medicaid Services (CMS) evaluated mental health, SUD, and chronic kidney disease condition categories to determine if additional disease categories should be added to the model for payment. We applaud CMS' ongoing evaluation of underrepresented clinical categories in the HCC Model to eliminate the risk of disincentives among plans from enrolling patients with certain chronic conditions due to costs. Indeed, a well-structured risk adjustment program can be complimentary to the agency's enforcement of Medicare's nondiscrimination provisions in the Medicare Advantage program. In the context of this evaluation process for CY 2019, we believe that CMS has missed an opportunity to consider the ramifications of the ongoing exclusion of Alzheimer's disease (AD) and dementia in the HCC Model for payment purposes. The field has evolved to recognize that AD exists on a continuum and that early subtle cognitive impairment precedes dementia. Until recently, a formal diagnosis of AD was not made until the later stages of disease, making

study of patients in the earlier stages very difficult.[1] With more recent recognition that underlying changes in the brain begin long before the appearance of clinical symptoms, efforts have been made to develop diagnostic criteria for earlier stages of AD and refine existing criteria for later stages. Alzheimer's disease is associated with considerable burden to the healthcare system and often remains undiagnosed or diagnosed years after symptom onset. Despite these efforts, it has been estimated that less than 50% of individuals with symptomatic AD are told of their diagnosis, and diagnostic criteria and subsequent medical coding are inconsistently applied in practice.[2] The US reimbursement system provides little financial incentive for coding AD as the primary diagnosis, and a recent analysis suggests this may lead to distorted incentives to code for related comorbidities of AD, rather than the disease itself. These actions undermine efforts to accurately quantify the disease prevalence and prioritize timely diagnoses.[3] The inclusion of Alzheimer's disease and Related Dementias (ADRD) into CMS-HCC risk adjustment modeling supports the development of a healthcare ecosystem that facilitates a timely, accurate diagnosis that will enable optimal care management.

Attachment II, Section N, Encounter Data as a Diagnosis Source for 2019 and Attachment III, Section B, Encounter Data as a Diagnosis Source for 2019

Description:

For CY 2018, Part C and Part D risk scores were determined by adding 15% of the risk score calculated from encounter data with 85% of the risk score calculated using RAPS (risk-adjustment processing system) and FFS diagnoses. For CY 2019, CMS proposes to increase the share of encounter data used to determine Part C and Part D risk scores to 25%, with the remaining 75% calculated using RAPS and FFS diagnosis data.

Comments:

PhRMA appreciates CMS' continued efforts to improve the risk score calculation methodology for Part C and Part D plans. While we agree that encounter data hold great promise for improving risk score calculations, we remain concerned that these data are not yet of sufficient quality to warrant their increased use. Analyses by CMS and other organizations support these concerns. For example, during the fall briefing in 2017, CMS presented data showing that inpatient and outpatient claim counts derived from their encounter data were significantly lower than FFS claim counts, even after adjusting for expected utilization differences between the two populations. Avalere, Milliman, and the Government Accountability Office (GAO) have also released studies calling into question the accuracy and completeness of encounter data.[4]

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[1] Knopman D, Donohue JA, Gutterman EM. Patterns of care in the early stages of Alzheimer's disease: Impediments to timely diagnosis. *Journal of the American Geriatric Society.* 2000;48:300–304.

[2] Fillit H, Geldmacher DS, Welter RT, Maslow K, Fraser M. Optimizing coding and reimbursement to improve management of Alzheimer's disease and related dementias. *Journal of the American Geriatric Society*. 2002;50:1871-1878.

[3] Lin PJ, Neumann PJ. The economics of mild cognitive impairment. *Alzheimer's & Dementia.* 2013;9(1):58-62.

[4] Avalere. Impact Evaluation: Medicare Advantage Transition from RAPS to EDS. October 25, 2017 http://avalere.com/expertise/managed-care/insights/impact-evaluation-medicare-advantage-transition-from-raps-to-eds; Milliman. Impact of the Transition from RAPS to EDS on Medicare Advantage Risk Scores. January 13, 2017. http://us.milliman.com/insight/2017/Impact-of-the-transition-from-RAPS-to-EDS-on-Medicare-Advantage-risk-scores/ ; Government Accountability Office. Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments. January 19, 2017. https://www.gao.gov/assets/690/682145.pdf

In the Fact Sheet CMS issued along with the Call Letter, the agency notes that the quality of encounter data has improved, and that CMS believes it is therefore appropriate to go forward with including more of these data in the calculation of risk scores.[5] However, in light of ongoing quality concerns, we support GAO's January 2017 recommendation that CMS should fully assess the quality of the encounter data before moving forward with implementation and we urge CMS to publicly release the results of these validation studies before moving forward with incorporating additional encounter data into the risk adjustment methodology.

Attachment VI, Section I, Enhancements to the 2018 Star Ratings and Future Measurement Concepts

Description: The draft Call Letter outlines several proposed ways to improve the Part C and D quality performance measurement system, including additions and proposed changes to current measures, measures to add or retire from the Display Page, and measures to potentially include in future years. The draft Call Letter also describes CMS' proposal to adjust several measures for the effect of dual eligible/LIS and disability status using a categorical adjustment index.

Comments:

Support for Annual Call Letter Process for Enhancements to Star Ratings Program

PhRMA supports CMS' continued commitment to improving the MA and Part D quality performance measurement system. In addition to proposed measure changes put forth in this draft Call Letter, there is a proposal by CMS currently under consideration that would require that additions to the Star Ratings measures for the MA and Part D programs go through a formal rulemaking process.[6]

Consistent with our comments submitted on January 16, 2018, PhRMA believes the current Annual Call Letter process appropriately balances opportunities for comment and adequate lead time to gain experience with new measures while keeping measure sets current. Given the time-intensive nature of measure development, endorsement and adoption, we strongly believe that CMS should retain the flexibility to make changes through sub-regulatory action and do not believe it is appropriate to require rulemaking for measure additions or substantive measure changes.

Compared to other quality payment programs, the Star Ratings program is unique in that CMS has typically provided a separate solicitation and comment period regarding the Star Ratings and display measures to review and evaluate comments prior to the Call Letter process. This has been done to ensure that the Agency has time to review and consider input from stakeholders on proposed methodology changes for measures, and to provide advanced notice of potential changes to the Star Ratings and display measures. There is another opportunity to comment in response to the draft Call Letter each year, and prior to addition to the Star Ratings, measures under consideration for addition are placed on the Display page for plans to gain familiarity with the measure before they are moved into the performance ratings.

[5] CMS. 2019 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter. February 1, 2018. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf

[6] Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. [CMS–4182–P].

PhRMA appreciates the ample opportunities and the transparent process CMS has created for interested parties to review the measures and provide comment, and we believe these mechanisms in place through the Annual Call Letter process are sufficient. The advanced notice provided by CMS regarding measures considered for implementation in either the Star Ratings or display measures, additional comment opportunities and the incremental, stepwise process to measure addition should provide all stakeholders with adequate time to prepare without the need for formal rulemaking.

2019 Star Ratings Measure Additions and Removals

Statin Use

CMS is proposing to add the Statin Therapy for Patients with Cardiovascular Disease and Statin Use in Persons with Diabetes (SUPD) measures to the 2019 Part C and Part D Star Ratings, respectively. PhRMA supports the inclusion of a statin therapy measures that align with the 2013 ACC/AHA blood cholesterol guidelines. In addition, we are encouraged to see that the SUPD measure is being considered as an intermediate outcome measure, and support the move to a higher weight in subsequent years to reflect the measure's role in improving patient care and overall health status.

The inclusion of these measures to the Star Ratings is an important start, however we remain concerned that these measures are not sufficient to address the gap created by retirement of the previous cholesterol screening and control measures for persons with diabetes, nor do they provide a complete reflection of current treatment recommendations. Cholesterol screening and ongoing monitoring of low density lipoprotein (LDL) levels for patients receiving treatment continue to be important aspects of the ACC/AHA guidelines, but these aspects of care are not captured in current measures. We encourage CMS to work with measure developers to enhance their measures that also evaluate screening, monitoring, and recommended treatment goals in accordance with the guidelines and evidence demonstrating the cardiovascular benefits of LDL-C lowering and managing LDL-C to a target goal.[7,8]

Beneficiary Access and Performance Problems

Over the past several Call Letter comment periods and in open CMS forums, the Agency has proposed several potential options to address sanctions, audits, and civil monetary penalties for the Part C and D Star Ratings Program.[9,10] After consideration of the comments received, CMS is implementing the changes finalized in the CY2018 Call Letter, by retiring the current Beneficiary Access and Performance Problems (BAPP) measure for the 2019 Star Ratings, and introducing a modified measure that will only include Compliance Activity Module (CAM) data to the display page. CMS is seeking input on the utility of this measure that is solely comprised of CAM data.

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[7] Stone, Neil J., et al. "2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines." *Journal of the American College of Cardiology* 63.25 Part B (2014): 2889-2934.

[8] Wadhera, Rishi K., et al. "A review of low-density lipoprotein cholesterol, treatment strategies, and its impact on cardiovascular disease morbidity and mortality." *Journal of Clinical Lipidology* 10.3 (2016): 472-489.

[9] MA & PDP Fall Conference: Options for Adjusting Star Ratings for Audits and Enforcement Actions: Listening Session. September 8, 2016. https://www.cms.gov/Outreach-and-Education/Training/CTEO/Downloads/2016-Medicare-Advantage-and-Prescription-Drug-Plan-Fall-Conference/MA-PDPFall2016AgendaFinal08172016.pdf

[10] Request for Comments: Enhancements to the Star Ratings for 2018 and Beyond: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Request-for-Comments-2018-Stars.pdf

We appreciate the methodical and transparent process CMS has undertaken to gather stakeholder feedback as it considered the Agency's approach to revising the BAPP measure. Ensuring that beneficiaries receive high quality customer service while minimizing access barriers to care should be a top priority of the program. CMS notes that it received comments from advocates who had concerns with decoupling the BAPP measure from audit results, and we agree it is important to ensure that beneficiary protections are not weakened as a result of the measure change. We are concerned about the impact of removing all enforcement actions and reductions for plans under sanction due to audit findings from the BAPP measure, and are also concerned that removing these actions from the measure could dilute the seriousness of audit findings. CMS has cited concerns with the subjective nature of audits, and absence of audit information for each plan every year. Moving forward, we encourage CMS to examine whether there are more reliable data sources that could better inform the BAPP measure.

In the absence of including audit data from the BAPP measure, we encourage CMS to ensure that the measurement domains, *Member Complaints and Changes in the Drug Plan's Performance* and *Health Plan Customer Service* include measures that maintain strict standards for plan accountability. One such example is strengthening quality measures on timely decisions made by plans about appeals, to include cases dismissed by the IRE that is being proposed for addition as a display measure for 2019. Data integrity and completeness of appeals information is essential to ensuring that beneficiary access to high quality care is not hindered.

Categorical Adjustment Index

PhRMA appreciates CMS' attention to the potential impact of DE/LIS and disabled beneficiary enrollment on Star Rating performance and commitment to an open process as it carefully evaluates this issue and considers long-term solutions. In particular, we appreciate CMS' work with measure developers, including National Committee for Quality Assurance (NCQA) and Pharmacy Quality Alliance (PQA), to assess the need for additional adjustments to the Star Ratings measures and develop adjustments as appropriate.

CMS notes that application of the Categorical Adjustment Index (CAI) for the Star Ratings has resulted in modest improvements, and that it plans to continue applying the same methodology for select measures to the 2019 Star Ratings. PhRMA supports the approach of applying the CAI as an interim adjustment, and would emphasize that within-contract differences should be the area of focus. Adjusting for any between contract differences could have the unintended effect of masking real differences in plan quality. Further, such adjustments should only be applied to measures where there is evidence of a meaningful within-contract disparity. As CMS continues to examine this issue, it is also critical for the Agency to closely monitor the effect of any adjustment to the Star Ratings for potential unintended consequences—such as declining quality of care for LIS/DE and disabled enrollees, or the potential risk of incentivizing plans from enrolling these populations.

PhRMA believes that the best approach to risk adjusting the Star Ratings measures is to facilitate rigorous analysis, development, and testing of measure-specific adjustments by the PQA and the NCQA. It is important to maintain fair and accurate reflections of performance, without introducing bias, inadvertently masking disparities or compromising the integrity of the measures. As CMS notes, both PQA and NCQA are in the process of developing measure-specific risk adjustment strategies for several measures. Both measure developers have included stratified reporting as part of their overall strategy, consistent with the recommendations of the National Quality Forum (NQF) trial.

PhRMA continues to believe that it is important that CMS approach risk adjustment for sociodemographic status with caution in order to avoid creating a double standard of care or inappropriately lowering standards for chronic disease management. As CMS considers future adjustments to the Star Ratings methodology, other interim approaches could include use of structural measures in the Star Ratings program to evaluate if plans have appropriate supports in place for DE/LIS and/or disabled beneficiaries to achieve optimal outcomes. Additionally, for measures where the steward has recommended reporting a stratified rate, CMS could consider constructing an improvement measure to encourage plans to address health care disparities.

We are pleased that CMS will continue to work closely with the stewards of these measures, as well as the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and take their recommendations under careful considerations before developing or finalizing any future specification changes.

2019 Display Measures

Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP)

After consideration of stakeholder feedback from previous Call Letters, CMS is proposing to add a PQA measure examining high dosage opioid use from multiple providers among individuals 18 or older without cancer to the 2019 Part D display page. PhRMA believes that medications should be used appropriately and safely, and we support quality measures, whether structural, process or outcome, that aim to support these goals. However, CMS should use caution to ensure that evaluation of opioid overutilization does not lead to limitations on access to needed pain medication. To balance this concern, we are encouraged to see that CMS is considering additional measure concepts that are not based on claims data, that assess optimal use of pain treatment (whether through prescription medicines or other available non-pharmacologic treatment options).

Concurrently, CMS is also charged with working with Plan Sponsors and stakeholders on the development of drug management programs for at-risk beneficiaries within the MA-PD and PDP programs, scheduled to go into effect in CY2019. As CMS is engaged in multiple efforts to ensure the proper balance between beneficiary access to needed medications and potential overuse, we urge the Agency to continue to take a coordinated and thoughtful approach with measure stewards regarding the potential impact of such opioid-related quality measures and implementation of lock-in criteria to ensure program goals are aligned and met. Additionally, as the Agency evaluates and implements measure changes related to high risk medications and opioid use, we urge CMS to do so in concert with the National Action Plan for Adverse Drug Event Prevention (ADE Action Plan), as there are likely to be synergies created amongst affected medications and drug classes to better safeguard the interests of patients.

Measure Removals

Due to measure specification changes in which the Medicare cohort has been removed by the measure steward, CMS proposes to retire several Part C measures from the display page in 2019, including Appropriate Monitoring of Patients taking Long-Term Medications, and Asthma Medication Ratio. PhRMA is concerned that such important clinical measures are being proposed for removal, without indication from CMS on how it will continue to evaluate plans on management of chronic disease, patient safety and appropriate medication use through other quality measures.

Timely and continuous use of prescription medicines as recommended by a healthcare provider is key to effective disease management, particularly for chronic conditions. Yet, medicines are frequently not used as directed, leading to poor clinical outcomes. For elderly patients, medication adherence can be challenging due to regimen complexity, or cognitive decline, making it especially important that appropriate monitoring is in place for patient safety. Proactive monitoring of patients and closing the adherence gap can encourage better chronic care management, and lead to a reduction in complications arising from the lack of communication, monitoring and follow-up of patients on long-term medications.[11] This should continue to be a priority for CMS with adequate quality measures in place to monitor and evaluate plan performance.

The removal of the Asthma Medication Ratio measure marks the retirement of another asthma-related display measure. CMS recently retired the Medication Management for People with Asthma from the display page as well. PhRMA had previously supported NCQA's expansion of its asthma measures to include older adults. Although this population is being removed from the measure, we still believe that it is important to include older adults in such measures to ensure that their conditions are also being adequately managed and complications are thus avoided. If finalized, the retirement of this measure would represent a critical measure gap in older adults with such respiratory conditions, with over 3 million beneficiaries potentially affected.[12] We encourage CMS to engage in further dialogue with measure developers to address the concern that asthma and COPD might be difficult to delineate among patients 65 and older and identify solutions to move forward with quality measures that address proper management of asthma in older adults.

Forecasting to 2020 and Beyond – Potential Changes to Existing Measures

PhRMA commends CMS for closely working with NCQA and PQA to ensure that the Star Ratings measure specifications reflect recent updates by the measure developers. By keeping pace with specification updates initiated by the developer, CMS ensures that the Star Ratings measures reflect changes in clinical evidence and stakeholder consensus. Use of measures consistent with the recommendations of the steward also ensures that measurement in the Star Ratings is methodologically sound. By working concurrently with measure developers, CMS can forecast measures to ensure they are being updated or added to the Star Ratings program in a timely manner, while maintaining a transparent, consensus-based process for stakeholder input.

Telehealth and Remote Access Technologies

CMS is also seeking feedback to share with NCQA regarding feasibility of and strategies for addressing telehealth services as eligible encounters in quality measures, particularly for several measures reported by Medicare contracts in managing certain chronic conditions. Recent advances in health care delivery incorporate the use of mobile health or remote monitoring technology as a complementary component to aid beneficiaries and their providers in shared decision making, or better manage their disease. PhRMA supports exploring incorporating aspects from these technologies in current or future quality measures, as determined appropriate by the measure developers and through public comment.

[11] Marcum, Z. A., Hanlon, J. T., & Murray, M. D. (2017). Improving medication adherence and health outcomes in older adults: an evidence-based review of randomized controlled trials. *Drugs & Aging*, *34*(3), 191-201.
[12] Centers for Disease Control (CDC) Most Recent Asthma Data: https://www.cdc.gov/asthma/most_recent_data.htm

CMMI Model Tests

There are currently two model tests underway at the Center for Medicare and Medicaid Innovation (CMMI) that provide plan sponsors with additional regulatory flexibilities to develop and evaluate certain programmatic changes in Medicare Advantage and Part D. CMS is considering the option of excluding CMMI participant data from the calculation of relevant Star Ratings measures. While PhRMA appreciates CMS' approach and intention not to penalize participants or non-participants in either model, we would strongly urge that participant data continue to be collected for model evaluation purposes outside of the Star Ratings.

PhRMA appreciates that CMS has continued to use the Call Letter to provide advance notice and updates to existing CMMI models in Medicare Advantage and Part D programs. We have consistently advocated for an open, transparent and accountable process for the development and testing of new models of care that include opportunities for public comment. Seeking and responding to stakeholder feedback while models are in the development or testing stages is essential to the long-term success of alternative payment models and ensure a robust dialogue on the key elements of these models, including quality measures and evaluation methods.

Potential New Measures Under Consideration, Additional Measurement Concepts for 2020 and Beyond

PhRMA is supportive of several measures and measure concepts under consideration and the strides the Agency is taking to address beneficiary health outcomes and making their care safer, including care coordination measures, addressing the needs of beneficiaries with multiple chronic conditions, and mental health screenings. We also appreciate the responsiveness of the Agency in addressing public health needs, such opioid-use or immunizations, and look forward to future inclusion of these quality measures.

As CMS considers potential new measures for 2019 and in future years, we encourage the Agency measure stewards to prioritize and focus on measure gaps, including the development of patient-centered, outcomes measures. Inclusion of more granular measures that address a broad range of conditions, coupled with metrics evaluating appropriate medication management will strengthen the Star Ratings program and help assure that it achieves its goals. Measure types such as quality of life and patient-reported outcomes, provide important patient perspective on care, and should be included as additional outcome measures. As an interim step, CMS could consider the addition of adherence measures in clinically relevant areas, and placing greater weight on current outcomes measures, while scaling back on process measures.

CMS has also noted interest in measurement concepts such as functional status, and use of non-pharmacologic pain management interventions, which PhRMA supports. This presents opportunities to develop complementary measures that address gaps in currently available measures related to cancer treatment and symptom management, as well as pain management. While these measures will generally require collection and reporting of non-claims data, it is critically important to capture and convey the patient's care preferences, goals and experience of care through the use of consensus-driven, validated quality measures. In the future, we encourage CMS to also consider development of comprehensive measure sets that include a mix of measure types—i.e. outcomes and processes, disease-specific and cross-cutting; and clinical and patient-reported data sources—to ensure that measure sets provide a complete picture of the quality of care.

Additional Adherence Measures

PhRMA encourages the development of clinically relevant measures in therapeutic areas that are representative of the Medicare population to appropriately assess the quality of care provided. CMS has already noted the importance of adhering to these therapies, some of which are especially critical for life-threatening conditions. Adherence measures serve as important proxies of clinical progression of a disease and we strongly urge CMS to continue working with measure developers to address these challenges of small denominators to find solutions that will work for a measure across a population. Furthermore, we encourage CMS to consider enhancing current adherence measures by capturing additional guideline-recommended therapies to provide a more comprehensive reflection of care quality.

There are currently three medication adherence measures included in the Part D Star Ratings, one of which is for diabetes medications. However, this set of medications does not include the use of insulin, which is recommended, either alone or in combination with antidiabetics to achieve improved glycemic control.[13] This presents a measure gap, as some form of combination therapy or multi-drug regimen that includes insulin is important to managing the disease to prevent further complications. Current methods to measure patient adherence, such as proportion of days covered, are not applicable for insulin products due to varying factors associated with dosing and titration. While there are complexities in developing a standardized measure for insulin adherence, the PQA has convened clinicians, researchers, and other stakeholders to closely examine the issue and identify evidence-based, methodologically sound solutions to overcome measurement challenges. PhRMA encourages CMS to closely monitor these developments and consider future inclusion of such adherence measures.

CMS has considered and evaluated two additional PQA-endorsed medication adherence measures within the Medicare Part D population, specifically for non-warfarin oral anticoagulants and non-infused disease modifying agents used to treat multiple sclerosis (MS). These measures fill important gaps in care quality as they represent clinical areas of need where adherence to therapy is critical, and yet is often suboptimal. Improved adherence in both MS and atrial fibrillation (AF) is associated with significant reduction in inpatient service use and total health care costs.[14]

MS is a highly heterogeneous disease, with no clear-cut treatment pathway. While the course of the disease and how it will progress in any individual patient may be challenging to predict, what is known is that initiation and adherence to disease modifying therapy (DMT) is associated with significant reductions in non-prescription medical costs.[15] Early diagnosis and continuous management with DMTs is critical to preventing the irreversible damage the disease causes to the immune system, and slowing disease

[13] Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes – 2018. American Diabetes Association. *Diabetes Care*. 2018;41(Supplement 1): S73-S85.
[14] Casciano, Julian P., et al. "The costs of warfarin underuse and nonadherence in patients with atrial fibrillation: a commercial insurer perspective." *Journal of Managed Care Pharmacy* 19.4 (2013): 302-316.
[15] Nicholas J et al. Comparison of Disease-modifying Therapies for the Management of Multiple Sclerosis: Analysis of Healthcare Resource Utilization and Relapse Rates from US Insurance Claims Data. *PharmacoEconomics*. 2017. Available at: https://link.springer.com/article/10.1007/s41669-017-0035-2

progression to disability. Furthermore, adults with MS that improved medication adherence by 10 percentage points decreased the likelihood of an inpatient or emergency room visit by 9% to 19%.[16]

AF is a serious, potentially life-threatening condition. Although clinical guidelines recommend oral anticoagulant therapy in patients with AF at moderate or high risk for stroke but not at high risk for bleeding, evidence shows consistent suboptimal use of such therapy, including within the Medicare population.[17,18,19] Gaps in dosing or medication nonadherence leave patients vulnerable to blood clots and further complications.[20] Non-Vitamin K antagonists have emerged as an alternate to warfarin, offering patients convenience with less frequent monitoring, drug- or food-interactions. Given the importance of adherence to anticoagulants for stroke prevention, medication adherence to non-warfarin anticoagulants may be more critical to assess because there is not routine monitoring nor a surrogate lab value, such as the international normalized ratio (INR) that accompanies warfarin.

The data from CMS' evaluation of both adherence measures indicates there is room for plan sponsors to improve on adherence rates, and that it is important to identify solutions to the noted measurement challenges. At the very least, we believe this information should be provided to plans in the Patient Safety reports, along with beneficiary-level data so contracts can appropriately target and apply adherence improvement efforts. Anticoagulants have been identified as priority area in the National Action Plan for Adverse Drug Event Prevention.[21] However, the given the critical importance of medication adherence to successful outcomes in these conditions, we believe these measures, which have been developed by clinicians and endorsed by the PQA are worthy of consideration as the reporting improves for inclusion in future display measures or Star Ratings.

Adult Immunization Measure

There is strong alignment and clinical evidence that supports the need for quality measures that address adult immunization status. The Measures Application Partnership (MAP) has recently recognized the importance of adult immunizations, and emphasized the need for such a composite measure.[22] As CMS has noted and is aware, NCQA is examining the feasibility of such a composite measure that would assess the receipt of four routine adult vaccinations, the same vaccinations which have recommended by the Advisory Committee on Immunization Practices (ACIP).[23] PhRMA supports the inclusion of this composite

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[16] S Yermakov et al. Impact of Increasing Adherence to Disease-Modifying Therapies on Healthcare Resource Utilization and Direct Medical and Indirect Work-Loss Costs for Patients with Multiple Sclerosis. *Journal of Medical Economics*. 2015;18(9):711-20.

[17] January, Craig T., et al. "2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society." *Journal of the American College of Cardiology* 64.21 (2014): e1-e76.

[18] Kimmel, Stephen E., et al. "The influence of patient adherence on anticoagulation control with warfarin: results from the International Normalized Ratio Adherence and Genetics (IN-RANGE) Study." *Archives of Internal Medicine* 167.3 (2007): 229-235.

[19] Fitch, Kate, et al. "Utilization of anticoagulation therapy in medicare patients with nonvalvular atrial fibrillation." *American Health & Drug Benefits*. 2012;5(3):157-168.

[20] Noseworthy, Peter A., et al. "Direct comparison of dabigatran, rivaroxaban, and apixaban for effectiveness and safety in nonvalvular atrial fibrillation." *Chest* 150.6 (2016): 1302-1312.

[21] https://health.gov/hcq/pdfs/ADE-Action-Plan-Anticoagulants.pdf

[22] National Quality Forum Measures Application Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: MIPS and MSSP. Draft Report for Comment. December 2017.

[23] Kim DK, Riley LE, Hunter P. Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults 19 Years or Older – United States, 2018. *MMWR Morbidity and Mortality Weekly Report*. 2018;67158-60.

measure to the display page and Star Ratings in the near future, with the consideration as an improvement measure to acknowledge this as an area of development for plans.

While additional immunization measures are under development and consideration, we stress that these measures should be viewed as complementary to current measures so as not to inadvertently create any measure gaps. The potential new measures should not diminish the importance of, nor be intended as a substitute for existing immunization measures in the Medicare Part C and D programs, such as the annual influenza vaccine in the Star Ratings and pneumonia vaccine on the display page. PhRMA continues to be concerned with the removal of the Part C Pneumonia Vaccine measure from the Star Ratings and placement on the Display Page and previously provided recommendations on alternate measures primarily based on claims data.[24] While there may be concerns with data reliability of these measures because the information is collected from patient surveys, these remain fundamental quality measure concepts from a public health standpoint, as the prevalence of illnesses attributable to vaccine-preventable diseases remains higher in adults than children due to low vaccine uptake.[25]

A robust quality measure set for routinely recommended adult vaccinations in the Star Ratings program will create provider accountability and incentive mechanisms for plan sponsors to ensure beneficiaries are receiving the appropriate immunizations. Therefore, we strongly encourage CMS to take swift action to accelerate the inclusion of the new HEDIS composite measure in the Star Ratings, while not losing sight of the improvement of existing immunization measure to continually elevate the standard of care for beneficiaries.

Opioid Measures

In order to holistically address opioid misuse and abuse, there also needs to be adequate quality measures in place that address the application of non-addictive alternatives to pain management, whether in the form of pharmacotherapeutics or non-pharmacological options. A substantial unmet need exists in the treatment of acute and chronic pain. Looking ahead as new treatments become available, we encourage CMS to explore quality measures that support the use of new non-opioid pharmacologic therapies and other treatment modalities which contribute meaningfully to better patient outcomes.

PhRMA also believes that Medicare Advantage plan sponsors have a different perspective and greater insight into beneficiary utilization of both health care and prescription services, and therefore there should be similar opioid use measures in Part C. In particular, we urge consideration of measure concepts seeking to improve the care of patients struggling with both opioid use disorder and mental or behavioral health issues. There are 8.2 million adults in the U.S. with co-occurring substance use disorder and mental illness, providing significant opportunity for Medicare Advantage plan sponsors to improve care among this population.[26]

With respect to polypharmacy measures addressing concurrent use of opioids and benzodiazepines, we appreciate the steps CMS has taken to ensure plan sponsors perform appropriate due diligence and assure

[24] PhRMA Comments on Advance Notice of Methodological Changes for Calendar Year (CY) 2013 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2013 Call Letter. March 2, 2012.
[25] Williams, Walter W. "Surveillance of vaccination coverage among adult populations—United States, 2015." *MMWR. Surveillance Summaries* 66 (2017).
[26] Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Health Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration

patient safety in the program while also ensuring that legitimate patient access to needed medicines is not impeded. We believe a focused case management approach is critical to ensuring plans make appropriate clinical contact with prescribers to determine appropriate levels of utilization and/or concurrent use. Likewise, we appreciate that CMS' flags concurrent opioid and benzodiazepine use in Overutilization Monitoring System (OMS) and we support plans to begin reporting concurrent use in the Patient Safety reports for the 2018 plan measurement year.

Technical Expert Panel

PhRMA appreciates CMS' commitment to continual enhancements to the Part C and Part D Star Ratings program by seeking new measures and methodological enhancements, as well as the close collaboration the Agency shares with measure developers to keep the quality measures relevant for beneficiaries. We are interested to learn that CMS will be working with RAND Corporation to establish a Technical Expert Panel (TEP) later this year to gather feedback from stakeholders on the Star Ratings Framework, methodology, and operational measures. PhRMA believes it is critically important to continually engage in programmatic quality improvement, and look forward to providing input and assistance throughout the process.

Quality measure development and maintenance is a dynamic process that evolves with the science and discovery of new therapeutics, as well as improved technology and data collection capabilities to support these measures with a greater focus on patient outcomes. The measure development process itself, when thoughtfully conducted through a patient-centered, clinically-driven and validated process that is transparent and accountable, can take several years. Additionally, there is time lag in the data collection periods to any corresponding performance year, so measures are not a current reflection or representation of plan performance. Stakeholders should strive to reduce this delay without compromising the measurement development process so patients can make the best decisions about their care. As CMS considers further measurement and methodological enhancements to the Star Ratings, we encourage the Agency and the TEP to explore ways to shorten the timeframe between measure development and adoption in the Star Ratings in order to further speed inclusion of evidence-based quality measures as they are endorsed by a multi-stakeholder, consensus-based organization.

Attachment VI, Section II, Part C Cost Sharing Standards

Description:

For CY 2019, CMS will continue the current policy of affording MA plans greater flexibility in establishing Parts A and B cost-sharing by adopting a lower, voluntary maximum out-of-pocket (MOOP) limit than is available to plans that adopt the higher, mandatory MOOP limit. MA plans that adopt a voluntary MOOP are allowed greater flexibility for individual service category cost-sharing, within limits set by CMS to ensure that cost-sharing is not discriminatory (e.g., Part B prescription cost-sharing is currently limited to 20% or $50/$75). For CY 2020, CMS is considering changes to its policies related to service category cost-sharing limits and is soliciting comment on whether CMS' interpretation of cost-sharing limits is impacting plans' ability to offer more flexible benefit designs that would provide beneficiaries with valuable plan options.

Comments:

The Part A/B MOOP is a critical feature of the MA program that helps to protect patients against excessive annual cost-sharing and to ensure that MA benefit designs do not discourage sicker Medicare patients from enrolling. The MOOP also helps to improve enrollees' adherence to treatment regimens and, thus, to improve their health, as studies have repeatedly shown that higher cost-sharing leads to reduced or delayed initiation of treatment[27] and lower adherence rates,[28] which, in turn, may result in worse outcomes for patients as well as higher overall Medicare spending.[29]

Given the important functions the MOOP performs, we urge CMS to extend the MOOP to Part D to protect MA patients against annual excessive cost-sharing across the breadth of benefits and services covered by MA-PD plans. Extending the MOOP to all benefits offered by MA-PD plans could improve adherence to Part D prescribed drug regimens; curb spending on many Part A and B services, including hospitalizations, the use of which increases with poor adherence to drug regimens; and help MA-PDs better coordinate Part A, Part B, and Part D-covered care for their enrollees.

From a legal and healthcare policy perspective, a MOOP that includes Part D services would be an appropriate and sound strategy offering substantial benefits to the MA program and its enrollees and prospective enrollees. Given the flexibility of its SSA § 1860D-21(c)(2) authority,[30] CMS could either establish a separate Part D MOOP that would apply in addition to the MOOP for Part A/B services, or (if operationally feasible) could consider a single unified MOOP that applied to all Part A, B, or D services covered by an MA-PD plan (e.g., a MOOP that set at the projected 95th percentile of Part A, B, and D spending, mirroring the current A/B MOOP model). We encourage CMS to include a MOOP on Part D

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[27] See, e.g., Doshi JA, Li P, Huo H, et al. High Cost-sharing and Specialty Drug Initiation under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia. *American Journal of Managed Care*.2016;22(4 Suppl):s78-86.

[28] See, e.g., Doshi JA, Takeshita J, Pinto L, et al. Biologic Therapy Adherence, Discontinuation, Switching, and Restarting Among Patients with Psoriasis in the US Medicare Population. *Journal of the American Academy of Dermatology*. 2016;74(6):1057-1065.e4.; Doshi JA, Hu T, Li P, Pettit AR, Yu X, Blum M. Specialty Tier-Level Cost-sharing and Biologic Use in the Medicare Part D Initial Coverage Period Among Beneficiaries with Rheumatoid Arthritis. *Arthritis Care Research*. 2016; 68(11):1624-1630; Gibson T et al., Cost-Sharing Effects on Adherence and Persistence for Second-Generation Antipsychotics in Commercially Insured Patients. *Managed Care*. 2010; 19(40):40-47. Iuga AO, McGuire MJ. Adherence and Health Care Costs. *Risk Management and Healthcare Policy*. 2014;7:35-44. doi:10.2147/RMHP.S19801 (literature review finding that "Reducing out-of-pocket costs leads to better medication adherence across many diagnoses. There is a linear relationship between the magnitude of patient cost-sharing and the level of adherence. This relationship persists from low to higher income levels")(citation omitted).

[29] See, e.g., Eaddy MT, Cook CL, O'Day K, Burch SP, Cantrell R. How Patient Cost-Sharing Trends Affect Adherence and Outcomes. *P&T*. 2012;37:45–55. [PubMed] (literature review concluding that "increased patient cost-sharing was associated with declines in in medication adherence, which in turn was associated with poorer outcomes"; the authors found that 85% of the articles that evaluated the relationship between changes in cost-sharing and adherence found that an increasing patient share of medication costs was significantly associated with a decrease in adherence, and that the majority of the articles that investigated the relationship between adherence and outcomes found that increased adherence was associated with a statistically significant improvement in outcomes); MacEwan JP, et al. The Relationship Between Adherence and Total Spending Among Medicare Beneficiaries with Type 2 Diabetes. *American Journal of Managed Care*. 2017; 23(4):248-252. Stuart B, Davidoff A, Lopert R, Shaffer T, Shoemaker JS, Lloyd J. Does Medication Adherence Lower Medicare Spending among Beneficiaries with Diabetes? *Health Services Research*. 2011;46(4):1180-1199. doi:10.1111/j.1475-6773.2011.01250.x.

[30] Please see our comment letter on the proposed Medicare Advantage and Part D rule for 2010 for a detailed discussion of section 1860D-21(c)(2) of the Social Security Act's waiver authority and the reasons it would permit a Part D or Part A-B_D MOOP.

spending in its next MA rulemaking and would welcome the opportunity to work with CMS on further developing this approach in the interim.

Lastly, as CMS considers allowing plans more flexibility to change their cost-sharing limits for individual service categories in exchange for reduced MOOP limits, we urge CMS to maintain the current upper limits for Part B prescription cost-sharing to ensure that cost-sharing is not discriminatory. CMS established the specific cost-sharing limits for individual service categories based on concern for particular beneficiaries who might be impacted by cost-sharing in excess of the amounts established for the original Medicare program. PhRMA believes that the concern for these beneficiaries remains valid, and CMS should not allow additional flexibility for cost-sharing limits for Part B prescription cost-sharing.

Attachment VI, Section II, Medicare Advantage (MA) Uniformity Flexibility

Description:

CMS has determined that it has the authority to permit MA plans to reduce cost-sharing and deductibles and/or offer supplemental benefits for enrollees that meet certain medical criteria (provided all enrollees who meet those criteria are treated the same). In implementing any changes to their benefit designs, MA plans may not deny, limit, or condition the coverage or provision of a service or benefit based on health-status related factors. CMS states that this flexibility will help MA plans better manage healthcare services for particularly vulnerable enrollees.

Comments:

PhRMA supports CMS proposal to expand flexibility under the uniformity requirements. We agree with CMS' new interpretation that the MA uniformity of benefit requirements generally do not preclude offering enrollees who meet specific medical criteria tailored supplemental benefits or reduced deductibles as long as all similarly situated individuals (i.e., all enrollees who meet the specified medical criteria) are treated the same and the MA benefit package does not violate MA nondiscrimination principles by discouraging enrollment by Medicare beneficiaries with higher-cost health conditions (e.g., a plan would not be permitted to offer targeted cost-sharing reductions and supplemental benefits for large number of disease conditions while excluding other, higher-cost conditions). The new flexibility could offer plans the opportunity to better align patient incentives with health care financing and delivery designed to both encourage value-based care and improve patient access to necessary services like medicines used to treat chronic diseases. The new flexibility, with the appropriate safeguards, also complements health plans' interest in exploring value-based arrangements, because value-based arrangements also encourage value-based care and better patient access.[31]

PhRMA appreciates and supports efforts to ensure the overall impact of this change is non-discriminatory. PhRMA also recommends that CMS develop a set of guardrails to test the non-discrimination of benefit designs for MA plans opting to adjust cost-sharing according to these new flexibility standards. These protections are critical to ensuring that MA plans opting into this flexibility do not discriminate against or discourage enrollment of beneficiaries with certain conditions. PhRMA suggests that CMS ensure that plan

[31] PhRMA, Delivering Results for Patients: The Value of Value Based Contracts (Feb. 2018), available at https://www.phrma.org/report/value-of-value-based-contracts.

changes to cost sharing or supplemental benefits conform to the following principles, intended to safeguard against differential cost-sharing being used as a mechanism to discriminate against beneficiaries with particular conditions, whether by design or by effect:

- Ensure that benefit flexibility is used in a way that improves, rather than harms patient affordability
- Safeguard against plan actions to discriminate against or discourage enrollment of certain beneficiaries, including higher cost patients or those with certain diseases
- Confirm that plans do not discriminate against patients in certain geographic regions (e.g., as a proxy for regions with lower socioeconomic status) by offering supplemental benefits in some regions and not others
- Ensure that plans using the new flexibility to reduce cost-sharing or provide supplemental benefits make such changes based on quality and outcomes of care, not just the cost of items or services provided by the plan.
- Make sure that as plans rely on a broad range of relevant, timely, and accurate evidence in designing benefits that reduce cost-sharing or provide supplemental benefits.

To monitor compliance with these principles, we suggest that CMS consider additional data that it might need to collect from plans, such as beneficiary-level cost-sharing and utilization information, rationale for any enhanced benefits, as well as information about how enhanced benefits are expected to, and actually do, affect beneficiary outcomes and costs. CMS may also need to conduct additional analyses of existing data to ensure that the increased flexibility is not leading to adverse treatment of high-acuity beneficiaries.

Finally, PhRMA urges CMS to consider how this additional plan affects Part D benefits. The Part D program has uniformity of benefit requirements that are very similar to those that apply to MA plans, and very similar non-discrimination requirements. The basic requirement is set forth in 42 CFR section 423.104(b), providing that a Part D sponsor must offer the plan to all Part D eligible beneficiaries residing in the plan's service area; and "[a]t a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area."[32] Likewise Part D and MA have substantially identical non-discrimination requirements, which prohibit plan benefit designs that discourage enrollment by certain beneficiaries.[33]

Given these similarities in the uniformity of benefit and non-discrimination rules that apply to Part D and Medicare Advantage, we think the same flexibility that CMS identified for MA plans—allowing tailored offerings for individuals with certain serious medical conditions, provided that the offering is available to all enrollees with that condition and these tailored offerings are not aimed at attracting enrollment by individuals with lower-cost health conditions—would generally apply in the same manner to Part D benefits, and thus permit somewhat greater flexibility in Part D benefit designs. We recognize the programmatic

[32] CMS guidance also elaborates on these principles and provides, for example, that Part D plans must provide the same negotiated prices to enrollees in all phases of the Part D benefit, and must not apply preferential utilization management criteria, DUR rules, or transition policies to a subset of their enrollees for non-medical reasons. Medicare Prescription Drug Benefit Manual, Chapter 5, sections 20.6, 50.5.3. To preclude discriminatory cost-sharing on individual items and services, CMS caps the cost-sharing on certain items and services in the annual Call Letter process. For 2018 and in previous years, CMS has limited the cost-sharing for most Part B drugs to 20% or $50 (both for MA plans that use the mandatory MOOP and for those that use the lower, voluntary MOOP). See, e.g., CMS, Announcement of Calendar year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information, at 126 (Apr. 3, 2017), https://www.cms.gov/Medicare/healthPlans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf. We strongly encourage CMS to maintain this 20%/$50 cap on Medicare Advantage cost-sharing for Part B drugs.

[33] See SSA 1860D-11(d)(2)(D)(Part D); SSA 1852(b)(1)(A)(MA).

complexity of making such changes, but also note the irony of plans offering diabetic enrollees zero cost-sharing for endocrinologist visits, but charging 33% coinsurance for a biopharmaceutical anti-diabetic agent that could avoid the need for some physician or hospital visits all together.

For these reasons, we request that in the preamble to the final Call Letter CMS specifically address the underlying similarities in the MA and Part D uniformity of benefit and non-discrimination rules. This includes identifying any differences in these rules that it sees as calling for less flexibility to offer tailored cost-sharing or supplemental benefits on the Part D side and the specific ways in which CMS thinks that flexibilities might differ in Part D. We hope that CMS ultimately will include a proposal extending its new approach permitting somewhat more flexible benefit designs to Part D in its next rulemaking cycle.

Attachment VI, Section III, Formulary Submissions

Description:

CMS recommends changes to the formulary review and submission requirements for CY 2019, including removing drugs with low Part D utilization from the formulary reference file (FRF). As in previous years, new drugs appearing in the May release of the FRF will not be included in the out-of-pocket cost (OOPC) model. CMS intends to release the draft FRF in February and to offer a summary formulary update window. However, CMS proposes to move the summer update window to later in the summer to allow drugs released in July and August to be included in formulary submissions during the update window. New for CY 2019, CMS proposes to add an enhancement only window to update the Medicare Plan Finder in the late fall and a formulary update window in January 2019. Finally, CMS is considering allowing further flexibility for Part D plan sponsors to offer access to over-the-counter drugs (OTCs), including dietary supplements and cough medicines. CMS suggests that it could allow sponsors to include additional OTC products without the requirement that the OTC product offset the use of a Part D drug.

Comments:

PhRMA appreciates that the draft Call Letter reiterates that the absence of a drug from the FRF does not imply that the drug is ineligible for Part D coverage. However, it is our understanding that some plan sponsors may still decline to provide coverage for Part D-eligible drugs simply because they are not listed on the FRF. We are therefore concerned that removing drugs with low Part D utilization from the FRF may result in plan sponsors erroneously excluding certain medicines from formularies—especially those used to treat rare diseases, as the low utilization is indicative of the rarity of the condition—potentially resulting in access barriers for beneficiaries. While we appreciate that CMS has made the draft CY 2019 FRF and the list of drugs targeted for deletion available for review, we urge CMS not to move forward with this proposal until it provides more detailed information on the criteria and/or thresholds used to identify drugs with low Part D utilization and to provide stakeholders with an opportunity to comment on the proposed methodology.

PhRMA understands that CMS faces time constraints in updating the OOPC model each year. However, we continue to have concerns that not incorporating the changes in the May 2018 release of the 2019 FRF in an updated version of the 2019 OOPC model could jeopardize access to newly-approved medications. Plan sponsors rely on the OOPC model in constructing their bids. Failing to account for newly released drugs in those bids could result in plan sponsors designing their formularies and coverage to limit access to

these newly released drugs, especially where the use of these drugs could impact the accuracy of those bids and impact the financial viability of the plan. To the extent possible, we again urge CMS to reconsider including the May 2018 release of the CY 2019 FRF in the 2019 OOPC model.

In addition, PhRMA supports CMS intention to delay the summer formulary update window and to add a Medicare Plan Finder update window in the fall and a formulary update window in January of the coverage year. These important update opportunities will allow for improved beneficiary transparency, which will help ensure beneficiaries can make informed enrollment decisions based on the most up-to-date information and that their chosen plan best meets their coverage and affordability needs. These new, more frequent formulary update windows will also help ensure that beneficiaries will have timely knowledge of and access to innovative new therapy options.

While we recognize CMS' interest in increased flexibility for plans to cover OTC products, we are concerned that these changes could lead to increased program costs, and run counter to the congressional intent of the program and statutory definition of a Part D drug, which intends to provide access to a *prescription drug* benefit program.[34] CMS does not provide any evidence in the draft Call Letter to suggest that beneficiaries lack current access to OTC therapies outside of the Part D benefit. Further, we would be very concerned if an expansion of the OTC policy resulted in additional utilization management controls, potentially creating barriers to access the actual Part D benefit—prescription drugs. If CMS were to move forward and adopt additional OTC flexibility, at a minimum, we urge CMS to structure the flexibility such that Medicare program costs would not increase and to restrict inappropriate use of UM edits that could create barriers to access clinically appropriate prescription medicines.

Further, we are particularly concerned by CMS' suggestion that it may consider the expansion of these flexibilities to include not only OTC drugs, but also dietary supplements. Not only are dietary supplements not prescription drugs, and thus not a "covered Part D drug" under the statute,[35] they are not subject to the drug pre-market review and approval process. Dietary supplements may not be marketed with any claim that they are intended to diagnose, cure, mitigate, or treat disease.[36] Instead, the Food and Drug Administration regulates dietary supplements as a food within its Center for Food Safety and Applied Nutrition.[37] For these reasons, PhRMA urges CMS to not expand the Part D OTC program to include dietary supplements.

Finally, as CMS recognizes, OTC drugs are not "covered Part D drugs" that qualify as Part D benefits (and the same is true of dietary supplements, which are not drugs at all). However, CMS has permitted plans to use OTC drugs as part of their utilization management programs (which are included as administrative costs in plan bids and a statutory requirement under Social Security Act § 1860D-4(c)(1)(A)).[38] While we have concerns about this theory, CMS at least articulated a statutory rationale for spending Medicare funds on OTC products (and allowing their costs to be built into enrollee premiums) in these circumstances. The

[34] Social Security Act § 1860D-2(e).
[35] *Id.*
[36] 21 U.S. Code § 201(g)(1)B).
[37] See 21 U.S.C. § 321(f), (ff).
[38] See Medicare Prescription Drug Benefit Manual, chapter 6 § 10.10, chapter 7. § 60.2; CMS FAQ on OTC drugs, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QACY2007OTCsandUM_051206.pdf

new call letter proposal, however, suggested expanding plans' ability to provide OTC drugs (and now dietary supplements as well) without identifying any purpose these products would serve that is required or permitted by the Part D statute. Accordingly, we are concerned that spending Medicare funds on these items and building them into enrollees' premiums is not authorized by the Part D statute and allowing this would thus exceed CMS' authority. PhRMA strongly supports CMS' efforts to increase flexibility in Part D and Medicare Advantage, but this must always be done within the law.

Attachment VI, Section III, Benefit Review and Tier Composition

Description:

CMS reminds sponsors that drug tier labels should be representative of the drugs that largely make up that tier. Sponsors will continue to have the option of selecting a non-preferred *drug* tier or a non-preferred *brand* tier, but not both. New for CY 2019, CMS proposes a maximum threshold of 25% generic composition should a plan sponsor use a "brand tier" designation.

Sponsors will continue to have flexibility to determine what cost-sharing structure is most appropriate for their benefit design. However, CMS will continue to scrutinize the expected cost-sharing amounts to protect against outliers and to ensure that the resulting coinsurance amount for a drug is not discriminatory. CMS again clarifies that if a non-specialty tier coinsurance is greater than 25%, CMS will compare the expected cost-sharing amounts to the established copay threshold ($100).

Comments:

PhRMA continues to be concerned that CMS allows plan sponsors to use blended tiers that can include both brand and generic medicines, as well as allowing sponsors to use coinsurance on these blended tiers. CMS has previously expressed concern for the increased cost-sharing burden that beneficiaries may face for generic drugs on a non-preferred tier, but we note that CMS has generally not expressed the same concern for how the use of coinsurance could significantly impact beneficiary cost-sharing for and access to brand medicines placed on a non-preferred drug tier. While we appreciate CMS' clarification on the discriminatory outlier reviews and applaud CMS' intention to compare expected costs with the respective copay thresholds for that tier, we remain concerned that that many patients' actual out-of-pocket costs will be higher than the non-discriminatory $100 threshold—creating an access barrier for them to get treatment. In fact, across all 2017 PDPs with coinsurance on the non-preferred tier (representing 98% of all enrollment in PDPs), an average of 46% of medications placed on these tiers have cost-sharing that results in at least $100 in out-of-pocket costs for a beneficiary. Similarly, these same plans have an average of 7% of medications placed on these tiers resulting in at least $500 in out-of-pocket costs.[39]

PhRMA strongly urges CMS to rigorously evaluate cost-sharing levels and beneficiary out-of-pocket exposure for both brand and generic medicines to identify and address potential access barriers that may be created by disproportionately high cost-sharing. We remind CMS of its responsibility to continue enforcing statutory non-discrimination requirements[40] in evaluating plan benefit design for all medicines,

[39] Analysis by Avalere Health for PhRMA, February 2018. This analysis used the CMS Public Use Files and Part D enrollment files from September 2017 to analyze the distribution of drug cost-sharing and out-of-pocket costs for all PDPs using coinsurance for drugs on non-preferred tiers in 2017.
[40] Social Security Act § 1860D-11(e)(2)(D).

both brand and generic. Even with outlier reviews, we remain concerned that plan sponsors are structuring their non-preferred tiers by including large proportions of generics on both non-preferred brand and drug tiers and that this step allows plans to continue to shift coinsurance on these tiers higher. CMS' reliance on outlier reviews to test for non-discrimination does not protect from harmful benefit design trends that are not particularly out-of-the-ordinary.

Attachment VI, Section III, Improving Access to Part D Vaccines

Description:

CMS highlights that the Centers for Disease Control and Prevention has reported that vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap), and that approximately 70% of adults for whom the herpes zoster vaccine is recommended remain unprotected. CMS encourages Part D sponsors to either offer a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing in an effort to improve access to these and other Part D vaccines. In the "Benefits and Parameters for CY 2019 Threshold Values" table, CMS illustrates the Vaccine Tier and highlights in a footnote the ability to utilize a lower cost-sharing tier for vaccines.

Comments:

PhRMA continues to support efforts to strengthen beneficiary access to immunizations through Part D and commends CMS for encouraging plan sponsors to utilize available benefit parameters to offer a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing.

Vaccination is one of the most important public health achievements of the past century, saving countless lives and improving the quality of life by preventing many serious infectious diseases. Prevention not only saves lives, but also helps to lower health care costs. Research has shown that for adults 65 years and older, herpes zoster and pertussis comprised over $3 billion in total annual costs related to these vaccine-preventable diseases.[41]

While there are many factors contributing to low adult immunization rates, financial barriers stand out as one of the most impactful and avoidable barriers to prevention. In particular, Medicare beneficiaries often face some of the highest vaccine out-of-pocket costs. Vaccine coverage under Medicare is a patchwork. Medicare Part B provides first-dollar coverage for influenza and pneumococcal vaccines, as well as for Hepatitis B vaccine for diabetics and other high-risk groups. All other vaccines, including Tdap and shingles vaccines, are covered under the Part D program, and since there are no vaccine cost-sharing requirements for Part D plans, beneficiary out-of-pocket costs are often high.

Manatt Health Strategies recently analyzed vaccine cost-sharing for non-LIS beneficiaries in Part D and found that in 2017, only 4% had access to vaccines without cost-sharing. Overall, no stand-alone PDP enrollees and fewer than 9% of MAPD enrollees had access to zero-cost vaccines. For MAPD enrollees, more than 30% had a coinsurance rate greater than 35%, with median estimated out-of-pocket costs between $39 and $47. Among MAPDs that required copayments in 2017, fewer than 3% beneficiaries had copayments less than $26 for the vaccines in the analysis. No stand-alone PDP offered $0 cost-sharing for

[41] McLaughlin et al., "Estimated Human and Economic Burden of Four Major Adult Vaccine-Preventable Diseases in the United States, 2013," *Journal of Primary Prevention*, June 2015, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4486398/

vaccines. Among PDPs that required coinsurance in 2017, rates were rarely less than 11% and were 35% or greater for most vaccines in the analysis. Fewer than 9% of beneficiaries enrolled in PDPs that required vaccine copayments had cost-sharing under $26 in 2017. The overall cost-sharing for PDP enrollees ranged from $27 to $75, depending on the vaccine. The analysis also noted that for some vaccines, estimated out-of-pocket costs could exceed $100 for both MAPD or PDP beneficiaries.[42] These findings echo those from 2016 report by Avalere Health that examined Medicare Part D plan coverage between 2011 and 2016 for 10 adult vaccines from the list of ACIP-recommended vaccines that either had age specific recommendations for seniors or conditions where seniors were the target population.[43]

PhRMA supports policy options that strengthen access to immunization services within the Part D program, including eliminating financial barriers, and we believe it is important for CMS to continue encouraging sponsors to cover vaccines at $0 or low cost-sharing tiers. We also continue to encourage CMS to evaluate additional benefit or coverage options to help increase adult immunization rates in the Part D program.

Attachment VI, Section III, Specialty Tiers

Description:

Based on analysis using CY 2017 PDE data, CMS determined that around 1% of 30-day equivalent prescription fills exceed the current specialty tier threshold of $670 and, therefore, plans to maintain the $670 threshold for the specialty tier in CY 2019. This cost threshold may or may not be increased moving forward based on CMS' ongoing investigation of specialty tier trends.

Comments:

PhRMA continues to have significant concerns with the current Part D specialty tier policy. In the final 2017 Call Letter[44], CMS stated that it would analyze whether the inclusion of drugs on the specialty tier and tiering exceptions for specialty tier drugs had an adverse impact on the utilization or enrollment decisions of certain types of beneficiaries. We are disappointed that CMS has not yet provided an update on the status of these analyses, especially since a growing body of academic research shows that high cost-sharing can adversely impact beneficiary access and adherence to needed therapies:

- One study examined the impact of high cost-sharing on specialty drug initiation under Part D, focusing on access to tyrosine kinase inhibitors (TKIs) that have revolutionized the treatment of chronic myeloid leukemia (CML). The analysis found that Part D enrollees who did not receive the low-income subsidy (LIS) and were diagnosed with CML were less likely than enrollees who did receive subsidies (and paid only nominal out-of-pocket costs) to have a claim for a TKI within six

[42] Manatt Health Strategies, Issue Brief with Chart Pack; "Trends in Medicare Part D Benefit Design and Cost Sharing for Adult Vaccines, 2015-2017; February 2018, available at https://www.manatt.com/Insights/White-Papers/2018/Medicare-Part-D-Cost-Sharing-Trends-for-Adult-Vacc.

[43] Avalere Health, "Adult Vaccine Coverage in Medicare Part D Plans", February 2016. http://avalere.com/expertise/managed-care/insights/medicare-has-the-potential-to-avoid-preventable-illnesses-by-encouraging-br (accessed February 25, 2016).

[44] Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 4, 2016, p. 203.

months of diagnosis (45.3% vs. 66.9%). Additionally, non-LIS beneficiaries took twice as long to fill one claim for a TKI (an average 50.9 days vs. 23.7)[45]

- Another study found that among Part D enrollees with psoriasis, less than 40% were adherent and almost half discontinued biologic treatment within 12 months of initiation. Further, Part D enrollees with psoriasis who did not receive the LIS were twice as likely to discontinue treatment relative to enrollees receiving subsidies.[46]
- A third study found that for Part D enrollees with rheumatoid arthritis (RA), high cost-sharing was associated with treatment interruptions. Among enrollees who used a Part D biologic in the prior year, those facing high cost-sharing were less likely to continue using a Part D biologic relative to those beneficiaries receiving cost-sharing subsidies. When Part D enrollees with RA did fill a Part D biologic, those facing high cost-sharing were twice as likely to experience an interruption in treatment (defined as a gap of more than 30 days) compared to beneficiaries receiving subsidies.[47]

Delayed initiation of treatment or failure to initiate treatment altogether can have a significant impact on clinical outcomes, especially for patients who need specialty tier treatments due to chronic and other serious conditions.[48] We strongly encourage CMS to provide an update on the status of these analyses and an opportunity for stakeholders to review and provide input on next steps. We believe the findings of these analyses will be critical to informing future policy directions for the specialty tier to ensure beneficiaries have appropriate access to medically necessary medicines. We also note that CMS did not provide an updated version of the Part D specialty tier methodology in the final 2017 or 2018 Call Letter. We urge CMS to release an updated version of this methodology with the final 2019 Call Letter this April.

As we have stated previously, we believe the current specialty tier policy may work against the principles of non-discrimination that CMS must strive to uphold. The defining features of the specialty tier are that it is limited to "very high cost and unique drugs" and CMS allows plans to exempt the drugs on the specialty tier from cost-sharing exceptions; CMS justifies this policy by establishing maximum thresholds for cost-sharing on the specialty tier, whether a copay or coinsurance. Even with these maximum cost-sharing thresholds, CMS still permits plans to impose very high cost-sharing on beneficiaries (as much as $100 copay or 33% coinsurance in the initial coverage period if the plan has a zero deductible), which can be cost-prohibitive and create significant access barriers for beneficiaries who need these medicines, as described in the literature above. In fact, nearly all PDPs are using coinsurance for the specialty tier in 2018.[49]

PhRMA is not aware of any other benefit design that so aggressively differentiates patient out-of-pocket costs based on a patient's non-elective need for more costly services. For instance, the costs of hospitalizations vary widely; many patients have lower cost hospitalizations and some patients have

[45] Doshi, JA., Li, P, Huo, H, et al. Medicare Part D Cost-sharing And Specialty Drug Initiation In Newly Diagnosed Chronic Myeloid Leukemia Patients. *Value in Health*,19(3):78-86. doi:10.1016/j.jval.2016.03.035

[46] Doshi, JA. et al. "Biologic Therapy Adherence, Discontinuation, Switching, And Restarting Among Patients With Psoriasis In The US Medicare Population". *Journal of the American Academy of Dermatology.* 2016;74(6):57-1065.e4.

[47] Doshi, JA, Hu, T, Li, P, et al. Specialty Tier-Level Cost-sharing and Biologic Use in the Medicare Part D Initial Coverage Period among Beneficiaries with Rheumatoid Arthritis. *Arthritis Care & Research*. 2016;doi:10.1002/acr.22880

[48] Mitchell L, "Who Pays for Specialty Medicines?" *Pharmaceutical Executive*, Nov. 1, 2012.

[49] Hoadley & Cubanski, "Medicare Part D: A First Look at Prescription Drug Plans in 2018," KFF Issue Brief, October 2017, http://files.kff.org/attachment/Issue-Brief-Medicare-Part-D-A-First-Look-at-Prescription-Drug-Plans-in-2018

comparatively high cost hospitalizations.[50] Yet we are not aware of plan benefit designs in which patients with the costly hospital stays are charged a dramatically higher "specialty tier" hospital coinsurance percentage as compared to patients needing less expensive hospital care. Indeed, such a practice would run counter to the very purpose of insurance.

Once again, PhRMA strongly urges a more patient-centered approach to the Part D specialty tier that would, at a minimum, remove the specialty tier's exemption from formulary exceptions and allow patients to appeal specialty tier cost-sharing by demonstrating a medical need for the specialty tier drug. We find this policy change particularly urgent given CMS' focus on making the tiering exceptions process more accessible to patients in an earlier section of the 2018 draft Call Letter and in one of the proposals in the recent proposed rule on MA and Part D.[51] Permitting tiering exceptions to the formulary—as the statute requires[52]—is meaningless if plans are permitted to include a drug on the specialty tier with high cost-sharing and no ability to appeal that cost-sharing.

It is neither fair nor reasonable to require patients to pay cost-sharing as high as 33% coinsurance when they can demonstrate that they must take a specific medicine and have no reasonable alternative. In fact, the regulation allowing plans to create a "specialty tier" that strips away beneficiaries' statutory right to seek cost-sharing exceptions for non-preferred drugs applies specifically to "very high cost and *unique*" drugs.[53] To impose a very high and un-appealable level of cost-sharing in such circumstances amounts to discrimination based on a particular patient's clinical needs or health status. Patients who have previously undergone step therapy and/or have otherwise demonstrated that drugs on lower tiers are not clinically appropriate should pay cost-sharing as if the drug were available on a more favorable tier. Requiring these types of patients to pay cost-sharing up to 33% coinsurance singles them out based on their specific prescription drug needs or specific conditions without any clinical or utilization management rationale. Based on the Part D benefit design, it also concentrates these individuals' spending early in the year, with little if any opportunity to spread that spending out. Eliminating the specialty tier exemption from the formulary exceptions process could help to mitigate financial hardship and also align CMS' specialty tier policy with the statute.[54]

In addition to significant concerns with the specialty tier in Part D, we also urge CMS to monitor trends related to non-preferred drug tiers (brand-specific or not). Cost-sharing on non-preferred tiers is not restrained to a maximum 33% coinsurance or $100 copay as it is on the specialty tier. According to the Kaiser Family Foundation, virtually all PDPs are using coinsurance for their non-preferred drug tiers in Part D in 2018. The typical coinsurance on this tier is 40% but also can be as high as 50%.[55] This high cost-sharing burden raises the same access concerns noted above. We also note that CMS' current policy

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[50] S.R. Machlin and K. Carper, "Statistical Brief #164: Expenses for Hospital Inpatient Stays, 2004" Agency for Healthcare Research and Quality.

[51] As noted in our comment letter on the proposed rule, there were also proposals on tiering exceptions that would make exceptions less accessible to patients.

[52] Social Security Act § 1860D-4(g)(2) (if a PDP "provides for tiered cost-sharing …and provides lower cost-sharing for preferred drugs …, a Part D eligible individual … enrolled in the plan may request an exception to the tiered cost-sharing structure," and "[u]nder such an exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects").

[53] 42 CFR § 423.578(a)(7)(emphasis added).

[54] Social Security Act § 1860D-4(g)(2).

[55] *Op. cit.* Hoadley & Cubanski

related to tier labeling and composition, which allows mixing brand and generic medicines on a non-preferred drug tier, may serve to exacerbate the OOP cost burden placed on beneficiaries, with lower average cost-sharing for generic products masking the disproportionate cost-sharing that beneficiaries would face for brand products placed on the same tier.

Finally, if CMS continues to permit plan sponsors to use a specialty tier in Part D, CMS should make clear that plan decisions to assign a medicine to the specialty tier cannot be based solely on reaching a specified cost threshold. Decisions should also be based on clinical criteria, such as widely accepted guidelines indicative of clinical best practice, and demonstrating that there are non-specialty tier alternatives suitable for most patients with the condition. It is inappropriate for the cost of a drug to be the only criterion for assigning specialty tier status. Failing to consider clinical factors may place beneficiaries in a situation where they do not have a non-specialty tier therapeutic alternative, and they are also unable to request a cost-sharing exception for their needed product on the specialty tier. This current policy is harmful to patients and we strongly believe that a broader framework would establish a more balanced approach to identifying specialty medicines in Part D.

Attachment VI, Section III, Improving Drug Utilization Review Controls in Part D

Description: CMS proposes several updates to its overutilization policy for CY 2019. In addition to existing Drug Utilization Review (DUR) controls, CMS is proposing new strategies to manage chronic overuse among beneficiaries who are taking what CMS deems to be high levels of prescription opioids as well as to manage initiation of opioid use in opioid naïve patients. Specific drug utilization controls proposed by CMS addressed in our comments include:

- Adding additional flags in the Overutilization Monitoring System (OMS) for high risk beneficiaries who use "potentiator" drugs (such as gabapentin and pregabalin) in combination with prescription opioids.
- Expecting sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) (which can only be overridden by the sponsor) at a dosage level of 90 Morphine Milligram Equivalent (MME) or more (regardless of the number prescribing physicians or dispensing pharmacies), with a no more than 7-day supply allowance.
- Implementing a days' supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum.
- Expecting sponsors to implement soft POS safety edits (which can be overridden by a pharmacist) based on duplicative therapy of multiple long-acting opioids and potentially implementing concurrent prescription opioid and benzodiazepine soft edits.

Also addressed in these comments are efforts to improve access to Medication-Assisted Treatment (MAT). CMS is seeking to align policies with recent FDA efforts to strengthen labeling requirements for buprenorphine MAT products. In aligning with this position, CMS will not approve sponsor prior authorization criteria that requires a beneficiary to obtain an authorization any more frequently than once during a plan year. Further, once a sponsor has authorized MAT for a beneficiary in the prior plan year, CMS expects that the sponsor will carry that authorization through to the subsequent plan year.

Comments:

PhRMA supports the use of appropriate means to address misuse, abuse and potentially problematic utilization of prescription drugs, which can endanger patients' safety and health, and also increase costs to the health care system through increased utilization of other health care services such as avoidable emergency room visits and hospitalizations. We urge CMS to implement measures to assure that efforts aimed at curbing overutilization of controlled substances do not become unduly restrictive or impede access for patients with legitimate medical need for these medications, particularly for patients with chronic pain, patients in hospice or patients with terminal illness. Inappropriately restricting access, particularly for vulnerable populations would work against the goals of the Part D program and we caution CMS to be cognizant of the need to guard against these risks.

Over the years, PhRMA has expressed support for the thoughtful and stepwise approach CMS has taken to help ensure Part D plans monitor and seek to prevent inappropriate prescribing and use through DUR and quality assurance programs. We've also expressed appreciation for the additional analyses that CMS has conducted to assess the impact and validity of the OMS opioid overutilization criteria for identifying beneficiaries whose opioid use may require focused case management. This approach has enabled the continued refinement of criteria for identifying potentially inappropriate levels of opioid utilization while also working to eliminate the identification of false positives. However, we are concerned that the current proposed shift in focus from retrospective DUR to concurrent DUR, particularly through the use of hard formulary-level safety edits, may inappropriately stigmatize chronic pain patients and create barriers to accessing needed care.

As expressed in previous comments, we are supportive of the *Center for Disease Control's (CDC) Guideline for Prescribing Opioid for Chronic Pain* in that it can serve as a tool for primary care prescribers to help inform appropriate decision-making and foster increased communication between providers and patients. However, we are concerned that aligning coverage policies with the guideline and effectively creating a maximum daily threshold for all beneficiaries, regardless of prescriber specialty, prior to dispensing runs counter to the intended goal of the guideline and may harm some chronic pain patients as a result. It is important to note that the guideline was developed for the purposes of providing primary care clinicians with guidance on managing chronic pain with opioid analgesics and may not be appropriately applied to other specialties. It was not intended to inform broad coverage decisions. The CDC acknowledges that individual patient needs may vary, particularly the needs of complex patients with long-term and persistent pain management challenges. Moreover, they acknowledge that not all elements of the guidelines have a strong evidence-base. It is critical moving forward, that CMS' efforts to appropriately manage pain are updated and informed by the output of HHS Pain Management Task Force charged with developing and disseminating best practices, when that effort is completed.

We are appreciative of CMS' commitment to addressing the opioid crisis; however, we urge the agency to take a holistic view in considering policy changes aimed to limit inappropriate levels of opioid utilization and the environment within which the proposed coverage limitations will be implemented. These efforts are a critical component of our nation's efforts to address this complex public health challenge currently devastating families and communities across the country, but they cannot be considered in a vacuum. We urge CMS to take into account the significant challenges patients face in accessing non-opioid alternatives for long-term pain management, including non-pharmacological modalities of care. Likewise, we urge consideration of the potential consequences of poor coverage and access policies for beneficiaries

struggling with addiction. To have a meaningful impact on this crisis we need a comprehensive and dynamic approach which addresses contributing factors in a coordinated and thoughtful manner while also minimizing unintended consequences for patients with chronic pain and those struggling with addiction.

The comments we've provided below aim to strike this balance.

1. Retrospective DUR

"Opioid Potentiator Drugs"

We appreciate CMS' efforts to develop additional flags in OMS to alert Part D sponsors of potentially problematic concurrent use of drugs that may potentiate the central nervous system effects of prescription opioids which may be addressed during case management. We support a focused case management approach and efforts to ensure sponsors make appropriate clinical contact with prescribers to assure patient safety within the program. We appreciate the additional analysis performed to assess whether high dose gabapentin use may be increasing among beneficiaries taking opioids. However, additional analysis may be warranted to better understand prescribing patterns related to these drugs. As CMS notes, clinicians are currently looking for alternatives to opioids for the treatment of pain. To the extent that increased use of gabapentinoids may be reflective of this trend rather than an indicator of abuse we express caution. Likewise, we encourage CMS to work closely with clinicians to develop appropriate specifications for this flag and to ensure that the case management approach employed by sponsors is based on sound clinical evidence.

2. Concurrent DUR

Cumulative MME Daily Dose Safety Edits for high, Chronic Prescription Opioid Users

We appreciate CMS' efforts to ensure sponsors implement safety edits to prevent unsafe dosing of drugs at the time of dispensing as part of their concurrent DUR requirements for Part D drugs. However, we are concerned that the implementation of a cumulative MME daily dose safety edit at the pharmacy for high chronic opioid users set at 90 MME may prove inappropriate for some patients with certain medical conditions and may be used as a dosing ceiling rather than a safety precaution in some cases.

As noted above and in previous comments, we believe the CDC guideline for prescribing opioids for chronic pain is an important tool to inform appropriate clinical decision-making among primary care prescribers. However, we are concerned to the extent it may be used to dictate coverage decisions broadly and for prescribers beyond those in primary care roles. The CDC acknowledges that the guideline was not intended to limit access to pain management options but rather to foster communication between prescribers and patients. Moreover, available evidence suggests there are technical challenges in making MME conversions based on the CDC's opioid calculator due to the unique pharmacological characteristics and properties of different opioids (e.g. methadone, tapentadol). The mathematical formula embedded in the calculator does not account for these differences and may result in inappropriate and dangerous conversions.[56] These challenges underscore the dangers in relying upon a one-size-fits-all approach in determining potentially inappropriate levels of opioid utilization to inform coverage decisions.

[56] Fudin J, et al. Safety Concerns with the Centers for Disease Control Opioid Calculator. Journal of Pain Research. 2018; 11:1-4: https://www.dovepress.com/safety-concerns-with-the-centers-for-disease-control-opioid-calculator-peer-reviewed-article-JPR

We are additionally concerned that implementing a hard edit set at 90 MME will further allow sponsors to use the edit as a dose ceiling rather than as a measure to ensure safety. CMS acknowledges that this occurred last year when sponsors implemented hard and soft safety edits at or above 200 Morphine Equivalent Dose (MED) and 90 MED, respectively. Subsequent complaints submitted via the CMS Complaint Tracking Module during the first months of 2017 necessitated that CMS issue additional guidance to sponsors to ensure the safety edits were not implemented as a prescribing limit or to apply additional clinical criteria for the use of opioids.[57] Given the expected increase in volume due to the significant reduction in the hard edit threshold to 90 MME, we are concerned with plan sponsor ability to appropriately meet these expectations.

Furthermore, CMS is effectively requiring patients with chronic pain and/or serious medical conditions to become quickly knowledgeable in seeking coverage determinations. While we appreciate CMS' efforts to ensure sponsors provide a 7-day supply allowance to beneficiaries and to expedite review of coverage determinations based on MME alone, these efforts presume that beneficiaries with legitimate medical needs will be successful in navigating this process. It is important to recognize that many of the patients CMS expects to successfully obtain a coverage determination, suffer from serious and painful medical conditions and face a range of physical, cognitive, and mental health challenges. We appreciate CMS' efforts to ensure the safety of those taking high levels of opioid medications; however, we feel that a case management approach is more appropriate in achieving this goal. Rather than placing additional burdens on patients, such an approach will ensure the process of determining medical necessity will occur between the sponsor and the patient's prescriber(s), prior to implementing a limitation on patient coverage of needed medicines. To the extent that the hard edit is implemented as proposed, we suggest that rather than permitting a 7-day supply allowance CMS consider permitting sponsors to allow for the dispensing of a 30-day prescription. This will provide greater flexibility in seeking a coverage determination allow for adequate time to handle any challenges that may arise as a result.

Lastly, as efforts to address potentially inappropriate utilization among chronic opioid users move forward, we urge CMS to consider potentially unintended consequences for patients struggling with addiction and for those patients who have developed physical dependence on the opioid analgesic but do not have opioid use disorder. Without plans in place to taper these patients under closely monitored medical supervision, or transition them to a more appropriate treatment plan, or intervene as needed to ensure patients obtain addiction treatment or recovery services, many of these beneficiaries may be harmed by a sudden and abrupt limitation on coverage. As mentioned previously, patients face challenges in accessing addiction and recovery services due to significant coverage and access barriers. Likewise, drug utilization controls aimed to improve patient safety must also consider the safety of these beneficiaries and ensure they can access the care that they need to break the cycle of addiction.

Days Supply Limits for Opioid Naïve Patients

PhRMA appreciates CMS efforts to ensure the appropriate use of opioids in opioid naïve patients. Too often patients are prescribed a 30-day supply of opioid medications for the treatment of acute pain (i.e. pain resulting from acute illness, trauma, surgery, or another cause, that is reasonably expected to last only a short period of time), when a lesser amount would suffice. We support policies to ensure that no more than

[57] HPMS memo, Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose (MED) Opioid Point-of-Sale (POS) Edit. July 7, 2017.

a 7-day supply of opioids is prescribed for the treatment of acute pain and believe such policies can help reduce the risk associated with inadvertent overprescribing of opioids.

However, we believe CMS should ensure there are appropriate exceptions—including pain associated with a cancer diagnosis or other terminal illness, palliative care, hospice care, and individuals receiving treatment for substance use disorder. We also believe there should be an exemption to limits when the prescriber determines that the condition causing the acute pain requires more than the initial limited supply due to projected longer duration of pain. In such circumstances, the prescriber should affirmatively note the rational for deviating from the limit in the patient's health record and document screening for substance use disorder. A recent article in JAMA Surgery reinforces the importance of such an exemption, finding that there are insufficient data to accurately assess the appropriate number of days of initial prescribing and noting the uncertainty surrounding optimal prescribing practices.[58] This finding reinforces the importance of CMS continuing to engage with various medical subspecialties to expand the development of evidence-based clinical guidelines to provide additional insights and direction to inform appropriate prescribing across pain indications.

Acknowledging that CMS is proposing a limitation on coverage rather than a limitation on prescribing, CMS should require sponsors and/or pharmacists on behalf of prescribers to make timely contact with prescribers to verify the medical necessity of a prescription beyond the 7-day supply limit. We also encourage CMS to explore efforts to ensure pharmacists check the relevant Prescription Drug Monitoring Program (PDMP) prior to dispensing.

Opioid Duplicative Therapy and Concurrent Use of Opioids and Benzodiazepine Soft Safety Edits

We appreciate CMS' efforts to implement safety measures to ensure the appropriate use of medicines, particularly as it relates to duplicative opioid therapy and concurrent use of opioids and benzodiazepines. We are concerned however, with the potential for "flag fatigue" at the pharmacy as it may be overly burdensome for pharmacists and may discourage appropriate due diligence with prescribers. We appreciate CMS' current efforts to flag concurrent opioid and benzodiazepine use for sponsors in the OMS as this approach ensures plans conduct appropriate case management to verify prescriber awareness of concurrent prescribing. We urge CMS to consider whether a similar approach to curbing potentially inappropriate concurrent use of more than one long-acting opioid and separately, concurrent use of more than one short-acting opioid, may be more appropriately addressed as a flag through the OMS.

3. Access to MAT

PhRMA applauds CMS for aligning policies with recent FDA efforts to strengthen labeling requirements for buprenorphine MAT products by reducing sponsor use of prior authorization requirements. While MAT combined with behavioral health counseling has been found to be effective in reducing the risk of relapse and improving chances of recovery, few of those who need treatment receive it due to access barriers. The President's Commission on Combatting Drug Addiction and the Opioid Crisis found that patients in need of addiction treatment are often subjected to dangerous fail-first protocols, life-time limits, frequent prior authorization requirements and claims denials, and called on both state and federal agencies to enforce mental health parity to address some of these disparities. We support a comprehensive

[58] Scully RE et al. Defining Optimal Length of Opioid Pain Medication Prescription After Common Surgical Procedures. *JAMA Surgery.* 2017;153(1):37-43.

approach to treating those with opioid use disorder and we urge CMS to continue to explore ways to improve enforcement of mental health and substance abuse treatment parity and coverage and access to the full range of treatment and recovery services, including all forms of MAT. Likewise, as CMS implements additional limits on opioid access for the treatment of pain moving forward, we urge CMS to address coverage and access barriers to alternative treatments for pain including non-opioid analgesics and non-pharmacological alternative treatment options.

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We thank you in advance for your time in reviewing our comments and suggested enhancements to the 2019 draft Call Letter and look forward to continuing to work with CMS regarding these important issues impacting the Part D program.

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