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950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

April 6, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

VIA ELECTRONIC FILING TO:
http://www.regulations.gov

Re: [CMS-4190-P] Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Dear Ms. Verma:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on proposed Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (the proposed rule).

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. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone. Consistent with that mission, PhRMA companies are committed to the continued success of the Medicare Prescription Drug Benefit Program (Part D).

Nearly 17 years following the enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), Part D has succeeded beyond expectations, delivering affordable prescription drug coverage for nearly 46 million seniors and people with disabilities at a lower cost to taxpayers than was originally anticipated. However, some Part D beneficiaries today struggle to access their prescribed medicines due to out-of-pocket costs. When beneficiaries do not adhere to the treatment regimen prescribed by their health care provider, they are more likely to need medical care, increasing costs under Medicare Parts A and B. For example, recent research has found that Medicare beneficiaries with heart failure who were not

eligible for the low-income subsidy (LIS) had higher average out-of-pocket costs per prescription which was associated with a 40 percent increase in inpatient days.[1]

For the past decade, PhRMA has expressed concern with the specialty tier and the impacts this policy has on beneficiaries' ability to access and afford needed medicines that happen to meet the specialty tier criteria. We are concerned that CMS's proposal to allow Part D plan sponsors to include a second specialty tier on their formularies is a step in the wrong direction. As we discuss in detail below, the proposal to add an additional specialty tier is likely to result in confusion for beneficiaries and unlikely to improve access or meaningfully reduce program costs.

In addition to the concerns regarding CMS's proposal to allow for a second specialty tier in Part D, we have the following comments on the proposed rule:

- **Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services:** A Medicare Advantage (MA) enrollee's annual cost sharing for all Part A and B services may not exceed the maximum out-of-pocket (MOOP) limit set by CMS. The Part A/B MOOP has important benefits for the MA program and its enrollees, including helping to protect enrollees from excessive annual cost sharing. Given its benefits, the MOOP should be extended to Part D for MA prescription drug plans (MA-PDs). This could improve adherence to Part D prescribed drug regimens, curb spending on many Part A and B services (including hospitalizations, which increase with poor adherence to drug regimens), and help MA-PDs to better coordinate Part A/B and D-covered care for their enrollees.
- **Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing:** PhRMA supports the CMS proposal to maintain the current upper limits for Part B prescription cost sharing.
- **Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act:** CMS is implementing key provisions of the SUPPORT Act related to Part D Drug Management Programs, suspension of pharmacy payments pending investigations of credible allegations of fraud, and beneficiary education on opioid risks as well as coverage of non-opioid treatment options. We continue to express support for CMS's efforts to curb overutilization of controlled substances and ensure program integrity while also ensuring not to impede patients' access to medically necessary drugs. Likewise, we appreciate the additional steps taken to ensure drug utilization control measures are targeted towards appropriate patient populations and are used to help improve the care of patients with complex and chronic health conditions.

[1] McGee, BT, Higgins MK, Phillips V, Butler J. Prescription drug spending and hospital use among Medicare beneficiaries with heart failure, Res Social Adm Pharm. 2019.

Lastly, we are supportive of CMS's efforts to move forward with plan disclosures of appropriate evidence-based information regarding the risks of prolonged opioid use as well as information regarding plan coverage of non-opioid treatment options. As always, our comments aim to ensure there aren't unintended consequences, which may impede access to medically necessary and appropriate treatment for vulnerable patient populations.

- **Real time benefit tool for beneficiaries:** CMS is proposing to implement a beneficiary real-time benefit tool that would provide timely and relevant cost sharing information to patients. While PhRMA believes such tools could facilitate more meaningful conversations around shared clinical decision making, technical and operational details will need to be resolved for such tools to reach their full potential.
- **Medicare Advantage and Part D Prescription Drug Program Quality Rating System:** PhRMA commends CMS for the Agency's continued commitment to improving the MA and Part D quality performance measurement program. We support the increased weighting of patient experience/complaints and access measures, and strongly encourage CMS to retain the statin use in persons with diabetes (SUPD) measure as an intermediate outcome measure.

Our detailed comments follow below.

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Permitting a Second, "Preferred" Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

In the proposed rule, CMS seeks to allow Part D plan sponsors to establish formularies with up to two specialty tiers and design an exceptions process that exempts drugs on those tiers from tiering exceptions to non-specialty tiers. If there are two specialty tiers, one must be a "preferred" tier that offers lower cost sharing than the proposed maximum allowable specialty tier cost sharing. Plan sponsors would have the flexibility to determine the Part D drugs that are placed on either specialty tier, subject to the ingredient cost threshold and the requirements of the CMS formulary review and approval process. Additionally, CMS proposes to codify current methodologies for cost sharing and calculations relative to the specialty tier, with some modifications. The specialty tier cost threshold would be set to reflect drugs with the top one percent of monthly ingredient costs; it would be evaluated annually and changed to reflect increases greater than 10 percent, rounded to the nearest $10 increment.

For the past decade, PhRMA has expressed concern with the specialty tier and the impacts this policy has on beneficiaries' ability to access and afford needed medicines that happen to meet the specialty tier criteria, and the lack of appeal rights those beneficiaries have. Research clearly demonstrates that high cost sharing adversely impacts beneficiary access and adherence to

needed therapies, particularly for medicines placed on the Part D specialty tier. Additionally, by imposing higher cost sharing based on beneficiaries' need for certain medicines, the specialty tier contradicts rules around non-discrimination in the Part D program.

While we appreciate the Administration's efforts to put forward policies that aim to increase competition in the Part D program and reduce out-of-pocket costs for patients, we do not believe a second preferred specialty tier in Part D is the best way to achieve these goals. We believe that the proposal would make formularies even more complicated and less patient-centered. We are particularly concerned that the second specialty tier would not meaningfully reduce patient costs, while increasing the complexity of the Part D benefit design structure. If CMS is going to proceed with the second specialty tier approach, the proposal must be implemented with appropriate protections for beneficiaries to ensure that none are worse off than under today's policy.

<u>The Part D specialty tier creates a large cost-sharing burden for certain beneficiaries, who are prevented from appealing for access to necessary medicines at preferred tier rates</u>

The defining features of the specialty tier are that it is limited to high cost drugs and biologicals[2] and that CMS allows plans to exempt the drugs on the specialty tier from cost-sharing exceptions. Plans may impose very high cost sharing on beneficiaries (33 percent coinsurance in the initial coverage period if the plan has no deductible), which can be cost-prohibitive and creates significant access barriers for beneficiaries who need these medicines.

When faced with high out-of-pocket costs, many beneficiaries walk away from the pharmacy counter without their prescribed medicine. One study found that when beneficiary cost sharing exceeded $250, 67 percent of new prescriptions for brand medicines were abandoned.[3] 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.[4]

A substantial body of academic research also shows that high cost sharing for specialty tier medicines can adversely impact beneficiary access and adherence to needed therapies.[5] For example, among patients with chronic myeloid leukemia (CML), high cost sharing is associated with reduced and/or delayed initiation of treatment. One study found that non-LIS Part D

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[2] 42 CFR § 423.560.
[3] Amundsen Consulting. Medicare Part D abandonment: deep dive into branded product abandonment. November 2017.
[4] Pharmaceutical Executive. Who pays for specialty medicines? November 1, 2012.
[5] See, e.g., 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.; 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 Nov;68(11):1624-1630; P Li, Y Wong, J Jahnke, A Pettit, J Doshi, Association of high cost sharing and targeted therapy initiation among elderly Medicare patients with metastatic renal cell carcinoma. Cancer Medicine 2018;7(1):75-86.

enrollees newly diagnosed with CML faced mean out-of-pocket costs of $2,600 or more for their first prescription for a tyrosine kinase inhibitor (TKI). Non-LIS Part D enrollees facing high cost sharing had substantially lower TKI initiation rates within 6 months of CML diagnosis and took nearly twice as long to initiate TKI treatment in comparison to Part D enrollees receiving LIS and facing nominal out-of-pocket costs.[6]

Additionally, current CMS regulation that allows plans to create a "specialty tier" effectively strips away beneficiaries' statutory[7] right to seek cost-sharing exceptions for "very high cost" drugs.[8] The statute gives beneficiaries a right to request tiering exceptions for any non-preferred drug if there is a preferred drug with lower cost sharing to treat the same condition and the beneficiary's physician determines that the preferred drug would be less effective or have adverse effects for the beneficiary; in these circumstances, the plan must at least consider the request.[9]

The Part D specialty tier runs counter to Part D's non-discrimination requirements

As we have stated previously, we believe the current specialty tier policy may not be consistent with the non-discrimination requirement that CMS must uphold.[10] The non-discrimination provision requires that a plan's design does not "substantially discourage enrollment by certain Part D eligible individuals."[11] Allowing plans to have a specialty tier that imposes very high and unappealable cost sharing on certain beneficiaries is inconsistent with this provision. It is also unique to the pharmacy benefit. For medical care, patients typically do not face benefit designs that so aggressively differentiate out-of-pocket costs based on the non-elective need for more costly services. Although patients may pay more for a visit to a specialist as compared to a primary care physician, this differential is usually minimal.[12] While high cost services, such as

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[6] Doshi JA., Li P, Huo H, et al., Medicare Part D cost-sharing and specialty drug initiation in newly diagnosed chronic myeloid leukemia patients, Am J Manag Care. 2016 Mar;22(4 Suppl):s78-86.

[7] Social Security Act § 1860D-4(g)(2) (if a Part D plan "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").

[8] 42 CFR §§ 423.578(a)(6)(iii) and 423.560.

[9] SSA § 1860D-4(g)(2). The MMA conference report similarly states that "[a] beneficiary in a plan that provides for tiered cost-sharing can request coverage of a non-preferred drug on the same conditions applicable to preferred drugs, if the prescribing physician determines that the preferred drug for the treatment of the same condition is not as effective for the enrollee or has adverse effects for the enrollee." H.R. Conf. Rep. 108-391 (2003), reprinted in 2004 U.S.C.C.A.N. 1808, 1834.

[10] Please see our comment letter on the 2020 Draft Call Letter.

[11] Social Security Act § 1860D-11(e)(2)(D).

[12] For example, CY 2021 in-network service category cost sharing requirements for Medicare Advantage plans limit primary care physician cost sharing to $35 and physician specialist cost sharing to $50 for plans subject to the voluntary and mandatory MOOP. Centers for Medicare and Medicaid Services, Contract year 2021 Part C benefits review and evaluation. February 6, 2020.

hospitalizations, can result in a wide range of incurred costs,[13] we are not aware of plan benefit designs in which patients with more 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.

By imposing a very high and unappealable level of cost sharing, the specialty tier effectively discriminates against certain patients based on their clinical needs or health status. At a minimum, 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 patients to pay higher cost sharing singles them out based on their specific prescription drug needs or specific conditions without any clinical or utilization management rationale.

The implementation of a second specialty tier is a step in the wrong direction and is unlikely to lower drug costs or reduce out-of-pocket costs

While we support the Administration's efforts to lower drug prices and reduce out-of-pocket costs for patients, we do not believe a second preferred specialty tier in Part D is the best way to achieve these goals. Our concerns with the proposed policy are multifold. Most significantly, the proposal is unlikely to substantially lower out-of-pocket costs for beneficiaries. The proposed rule states the coinsurance amount for the preferred specialty tier needs to be lower than the 25 percent to 33 percent floor of the current specialty tier, depending on the deductible for that plan. However, there is no proposed minimum cost-sharing differential between the two tiers, and Part D sponsors will not have incentives to reduce coinsurance significantly for the preferred specialty tier. Therefore, in a best-case scenario, beneficiaries will likely remain responsible for close to 25 percent coinsurance for preferred specialty tier medications and remain unable to request tiering exceptions.

Additionally, the proposal increases the complexity of the Part D benefit-design structure, which could challenge the consumer experience and result in patients selecting plans that do not meet their health needs. The proliferation of tiers on Part D formularies has made it confusing and difficult for beneficiaries to understand their plan design and predict their cost sharing. Today, the vast majority (93 percent) of Part D plans use formularies with five coverage tiers, and 7 percent are now using a sixth tier.[14] Adding a second specialty tier could exacerbate the current trend and increase patient confusion when selecting a Part D plan.

We are also concerned that implementation of a second specialty tier may result in greater use of utilization management, such as step therapy, which may impede patient access to needed

[13] Agency for Healthcare Research and Quality, Statistical brief #164: expenses for hospital inpatient stays, 2004. March 2007. https://meps.ahrq.gov/data_files/publications/st164/stat164.shtml.
[14] Avalere. 2020 Medicare Part D formularies: an initial analysis. December 2019.

medicines. Part D plans already employ utilization management at consistent or higher rates than the commercial market, especially for "high cost" medicines.[15] These utilization management tools can increase administrative burden for providers and delay access to treatment.

PhRMA disagrees with CMS's claim that without the specialty tier, plan costs could increase. Without a specialty tier, plans would continue to negotiate with manufacturers to minimize plan costs, just as they do in other markets that do not have specialty tiers. In Part D, plans have considerable flexibility to structure formularies and apply utilization management to balance access and cost containment. CMS should be moving away from policies like the specialty tier, which increase costs and barriers to access for beneficiaries, in favor of patient-centered changes that improve access and affordability of medicines. Continued development of innovative treatments and cures increases the likelihood that more beneficiaries will be prescribed drugs that fall within the specialty tier(s), leading to higher out-of-pocket expenses for a greater percentage of the Medicare population. We urge CMS to prioritize policies that reduce patient out-of-pocket costs while ensuring patients' access to medicines remains strong and to reconsider finalizing this proposal to establish a preferred specialty tier.

Finally, we are unclear about CMS's intent for introducing a preferred specialty tier, as the agency admits in the proposed rule that it "remains concerned about whether this proposal will actually achieve the potential benefits to the Part D program and Part D enrollees asserted by stakeholders in support of 2 specialty tiers."[16] In its own regulatory impact analysis, the CMS Office of the Actuary does not project any savings from the second specialty tier proposal, noting: "Our conclusion is that the provisions of the proposed rule to allow Part D sponsors to structure their benefits with a second, 'preferred' specialty tier are unlikely to have a material impact on Part D costs."[17] Although CMS also notes that it is unlikely that there would be patient harms under the proposed approach, given the beneficiary experience with the existing specialty tier, we strongly believe that there should be clear evidence of the potential benefits before such a drastic change to the Part D program is undertaken.

<u>If CMS moves forward with the proposal, the second specialty tier should be implemented with strong protections to prevent beneficiary harm</u>

As stated above, PhRMA has deep concerns with the direction CMS is pursuing with the second specialty tier proposal. However, if CMS proceeds with finalizing the proposal, the second specialty tier should be implemented in a way such that Part D sponsors cannot increase beneficiary costs or reduce patient access to medicines on the specialty tier. We provide feedback on the specific areas where CMS sought comment on the specialty tier proposal below.

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[15] Analysis of MMIT and PlanScape databases of 2018 commercial and Part D formularies by Avalere for PhRMA. June 2018.
[16] 85 FR 9054.
[17] 85 FR 9186-9187.

1. *CMS should lower, not increase, cost sharing on the specialty tier*. As described above, there is a wealth of evidence that the specialty tier policy in place today creates a large cost-sharing burden for patients that is affecting adherence to treatment regimens. PhRMA is extremely concerned that CMS is soliciting comment on whether to increase cost sharing for the specialty tier above the 25 percent/33 percent thresholds in place today for plans with and without a deductible, respectively. Such a change would clearly conflict with non-discrimination rules in Part D, as CMS suggests in the proposed rule.[18] Instead, CMS should finalize the alternative suggested approach where the maximum allowable cost sharing is 25 percent for any non-preferred specialty tier, regardless of whether the plan has a deductible.

2. *CMS should implement the preferred specialty tier with lower cost sharing than the current specialty tier*. CMS sought comment on determining the cost sharing percentage for the preferred specialty tier. PhRMA strongly believes that Part D sponsors offering the second specialty tier must offer lower cost sharing for medicines on that tier. Such an approach will ensure no patient is worse-off today than under the proposed policy. Similarly, PhRMA recommends that CMS implement a meaningful difference policy to define the cost sharing between the two tiers. This will ensure that patients, not plans, will benefit from the second specialty tier.

3. *Part D sponsors should not be permitted to exempt drugs on either specialty tier from the tiering exceptions process altogether*. CMS proposes to require plan sponsors offering two specialty tiers to allow tiering exceptions from the non-preferred specialty tier to the preferred specialty tier when a clinically appropriate therapeutic alternative is available on the preferred specialty tier. However, consistent with current policy, sponsors would not be required to allow tiering exceptions from any specialty tier to a lower, non-specialty tier. Though CMS's proposed expansion of tiering exceptions offers some patient protections, the policy does not go far enough and is likely to be limited in practice. PhRMA recommends that CMS broaden the tiering exception process to avoid punishing patients who need specialty tier drugs and should prohibit Part D sponsors from exempting any specialty drug from the tiering exceptions process altogether. Formulary tiering exceptions—as the statute requires[19]—are rendered meaningless if plans are permitted to hide high-cost drugs from the tiering exceptions process by simply placing them on a specialty tier.

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[18] 85 FR 9055.

[19] Social Security Act § 1860D-4(g)(2) (if a Part D plan "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").

4. *The preferred specialty tier should not be restricted to certain types of medicines*. If CMS finalizes a second specialty tier, PhRMA agrees with CMS's proposed approach and does not recommend the preferred specialty tier be limited to only certain types of drugs, such as generic drugs or biosimilar biologics.

Specialty tier threshold updates are warranted on an annual basis to improve accuracy

If CMS finalizes its proposal to codify the specialty tier, PhRMA welcomes the improved transparency of the tier calculation methodology and its annual evaluation. But PhRMA has concerns with CMS's proposed approach of only updating the specialty tier threshold if CMS determines that the threshold would increase by more than 10 percent prior to rounding.

CMS argues that the 10 percent threshold for increasing the specialty tier is needed for stability. We recognize that the value that captures the top one percent of 30-day equivalent ingredient costs could both increase and decrease significantly on a year-to-year basis under the methodology CMS employs. PhRMA agrees with CMS that stability in the specialty tier threshold is important for beneficiaries and Part D plan sponsors.

However, PhRMA also believes that annual updates in the specialty threshold are crucial for accurately determining which medicines are eligible for specialty tier placement. Updating the specialty tier threshold only for changes greater than 10 percent could, at the margin, result in medications remaining eligible for the specialty tier when their ingredient cost has in fact fallen below the threshold. Given the higher cost sharing burden that can be imposed on patients for medicines on the specialty tier, as well as beneficiaries' inability to seek a tiering exception, accurately determining on an annual basis which drugs should be eligible for the specialty tier should be a priority.

To help balance a desire for stability in the threshold with the need for an accurate assessment of which medicines are eligible, PhRMA recommends that the specialty tier threshold be grown at the Part D annual percentage increase (API), rounded to the nearest $10, starting in contract year (CY) 2022. This change would bring more stable, estimable growth in the value of the specialty tier threshold year-to-year by bringing it in line with the annual growth in the Part D deductible, initial coverage limit, and out-of-pocket threshold.

Given that growth in API is projected to be higher in future years than the historical growth in the specialty tier threshold,[20] indexing the specialty tier threshold to API could result in a threshold that eventually represents the ingredient cost of fewer than the top one percent. To

[20] PhRMA analysis of the 2019 Medicare Trustees Report.

address this issue, PhRMA proposes that CMS periodically recalibrate the specialty tier threshold using the top one percent methodology described in section V.F.6 of the proposed rule.

We believe the approach we have outlined strikes the right balance between stability and accuracy in determining the specialty tier threshold. However, PhRMA is open to other approaches that also achieve these desired goals.

CMS should codify existing guidance for determining if previously approved drugs are eligible for the specialty tier

PhRMA is concerned that the regulatory text proposed in item number 67 for § 423.104 of the Code of Federal Regulations (CFR) does not include the level of specificity to ensure that the specialty tier only captures the appropriate drugs and thus could be read as deviating from current CMS guidance on how eligibility for the specialty tier is determined for previously approved Part D medicines.[21]

As stated in the Medicare Prescription Drug Benefit Manual,[22] Part D plans currently must evaluate the price of drugs at the product strength, package size, and formulation level in order to determine appropriate inclusion of a previously approved medicine on the specialty tier. If the price of the majority of claims for a particular package size, product strength, and formulation level do not exceed the specialty threshold, then that package size, product strength, and formulation is not permitted to be placed on the specialty tier.[23] But the current language included in the proposed rule for § 423.104 does not include this language.[24]

PhRMA urges CMS to codify the existing guidance and explicitly include the requirement for plans to still evaluate each previously approved medicine at the product strength, package size, and formulation level. Because the specialty tier can impose significant cost sharing requirements on beneficiaries, it is important to appropriately determine which medicines are eligible for inclusion on that tier. If there is variation in the 30-day equivalent ingredient cost for an individual drug product across formulations, package sizes, or product strengths such that some National Drug Codes (NDCs) fall below the specialty threshold while others are above it, Part D beneficiaries should not be subject to potentially higher out-of-pocket costs based on claims history across all NDCs combined.

[21] 85 Fed. Reg. 32. Feb. 18, 2020, at 9240.
[22] Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.4. Rev. 18 01-15-16.
[23] *Id.*
[24] 85 Fed. Reg. 32. Feb. 18, 2020, at 9240.

The maximum dose should not be used to evaluate newly-approved drugs for specialty tier eligibility

For newly approved Part D medicines, CMS proposes to allow plans to estimate the 30-day equivalent ingredient cost based on the maximum dose specified in the FDA-approved labeling when evaluating whether new medicines would be eligible for the specialty tier. While plans will understandably lack prescribing history for newly approved drugs, PhRMA is concerned that relying on the maximum dose will not yield an accurate assessment of specialty tier eligibility.

Instead, PhRMA recommends that CMS require Part D plans to estimate for newly approved medicines the 30-day equivalent ingredient cost for each drug product strength, package size, and formulation level. Similar to existing guidance, only those product strengths, package size, and formulation levels whose ingredient cost exceeded the specialty threshold would be considered eligible for the specialty tier.[25]

CMS should contemplate future changes to the non-preferred tier to address high beneficiary cost sharing

Additionally, PhRMA continues to be concerned with the high cost-sharing burden beneficiaries face when accessing medicines on the non-preferred tier. In 2017, CMS began allowing Part D plan sponsors to offer a "blended" non-preferred drug tier, which consists of both brand and generic drugs, and, in 2019, 99 percent of Part D plans and 89 percent of MA-PDs took up this option.[26] Allowing plans to include a large number of lower-cost generic drugs on the blended tier results in significantly lower average cost sharing across the tier, while in fact many patients' actual out-of-pocket costs are considerably higher than the non-discriminatory $100 threshold—creating an access barrier for them to get treatment. In fact, across all 2020 Part D plans with coinsurance on the blended non-preferred tier, brand medicines on this blended tier had cost sharing that resulted in beneficiary out-of-pocket costs greater than $100 dollars 75 percent of the time. Similarly, brand medicines placed on these tiers had cost sharing exceeding $500 dollars 16 percent of the time and cost sharing exceeding $1,000 dollars more than 5 percent of the time.[27] CMS should consider an alternative to the tier composition policy that would discourage or prohibit blended tiers and monitor whether cost-sharing amounts paid by beneficiaries taking brand medicines on this tier exceed the discriminatory threshold. Such a change would protect beneficiaries from harmful benefit design trends that are resulting in unreasonably high cost sharing for beneficiaries who rely on these medicines.

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[25] Medicare Prescription Drug Benefit Manual, Ch. 6, Sec. 30.2.4. Rev. 18 01-15-16.
[26] Avalere. Effect of potential policy change to Part D generic tiering on patient cost sharing and Part D plan costs. February 28 2019. https://avalere.com/insights/effect-of-potential-policy-change-to-part-d-generic-tiering-on-patient-cost-sharing-and-part-d-plan-costs.
[27] Analysis by Avalere for PhRMA. February 2020.

Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

In the proposed rule, CMS is seeking comment on proposals, beginning with coverage for the 2022 contract year, to (1) establish explicit authority for up to three MOOP limits, including the current mandatory and voluntary MOOP limits and a third, intermediate MOOP limit; (2) codify the methodology for setting MOOP limits; and (3) adjust the methodology to take into account how Medicare Advantage (MA) eligibility for Medicare beneficiaries is changing to remove the current limits on MA enrollment for Medicare eligible beneficiaries with diagnoses of end-stage renal disease (ESRD).

PhRMA believes the Part A/B MOOP has important benefits for the MA program and its enrollees. By helping to protect enrollees from excessive annual cost sharing, the MOOP ensures that sicker Medicare patients are not discouraged from enrolling in an MA plan – which is why CMS established the MOOP – and also improves enrollees' adherence to treatment regimens and their health, as studies repeatedly show that higher cost sharing leads to reduced or delayed initiation of treatment[28] and lower adherence rates,[29] which in turn worsen patient outcomes and increase overall Medicare spending.[30]

Stakeholders have increasingly expressed concern about high cost sharing due to the lack of a similar out-of-pocket cap in Part D, as well as the misaligned incentives that may lead plans to prefer coverage of medicines with high list prices and large rebates.[31] While we are pleased that

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[28] 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, Am J Manag Care. 2016;22(4 Suppl):s78-86.

[29] 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. J Am Acad Dermatol. 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 Res. 2016 Nov;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. (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").

[30] 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. (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 percent 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, Am J Manag Care. 2017; 23(4):248-252. Stuart B, Davidoff A, Lopert R, Shaffer T, Shoemaker SJ, Lloyd J. Does medication adherence lower Medicare spending among beneficiaries with diabetes? Health Services Research. 2011;46(4):1180-1199.

[31] See HHS OIG proposed rule, Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. at 2341.

there is ongoing bipartisan congressional interest in implementing a Part D out-of-pocket limit and redesigning the benefit to address plans' misaligned incentives, PhRMA continues to 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 while we wait for Congress to act. Non-LIS Part D enrollees who reach catastrophic coverage may face substantial and continuing cost-sharing charges—provided that the individual keeps taking his or her medication. Without a cap on Part D cost sharing, the risk of nonadherence and worsened health outcomes for individuals in catastrophic coverage is apparent. For instance, a Kaiser Family Foundation report found that catastrophic coverage cost sharing amounted to 40 percent of total annual Part D cost sharing, on average, for non-LIS enrollees who reached catastrophic coverage.[32] Unless enrollees qualified for low-income subsidies, the report noted, "the absence of an annual out-of-pocket spending limit under Part D exposes enrollees to significant costs."[33]

Thus, 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 health care policy perspective, a MOOP for Part D services would be an appropriate and sound strategy offering substantial benefits to the MA program and its enrollees and prospective enrollees.[34] 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 spending in its next MA rulemaking and would welcome the opportunity to work with CMS on further developing this approach in the interim.

Lastly, CMS proposes changes to the MOOP methodology to implement provisions of the Cures Act that allow for Medicare eligible beneficiaries with ESRD to enroll in MA.[35] MA plans have the potential to bring greater care coordination and improved health outcomes for Medicare beneficiaries with ESRD. CMS should ensure that plans are adequately compensated for the costs of providing services for these beneficiaries and should carefully evaluate and monitor for

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[32] Kaiser Family Foundation. No limit: Medicare Part D enrollees exposed to high out-of-pocket drug costs without a hard cap on spending. November 2017. http://files.kff.org/attachment/Issue-Brief-No-Limit-Medicare-Part-D-Enrollees-Exposed-to-High-Out-of-Pocket-Drug-Costs-Without-a-Hard-Cap-on-Spending.
[33] Ibid.
[34] Please see our comment letter on the proposed Medicare Advantage and Part D rule for 2019 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.
[35] 85 FR 9073.

any unintended consequences that might result in access or quality of care issues for this vulnerable population.

Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

CMS is also proposing to codify existing policy regarding the specific benefit categories for which MA plans must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis, including drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs and other drugs covered under Part B).

PhRMA supports the CMS proposal to maintain the current upper limits for Part B prescription cost sharing to help 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 that could increase cost-sharing limits for prescription medicines covered under Part B.

Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

Mandatory Drug Management Programs (DMPs) § 423.153

The proposed rule would implement, as required by section 2004 of the SUPPORT Act, mandatory implementation of Drug Management Programs—otherwise known as "lock-in"—by Part D sponsors beginning on or after January 1, 2022. Additionally, as required by the Act, CMS is proposing to modify the definition of potentially at-risk beneficiaries for the purposes of Part D lock-in programs to include Part D eligible individuals who have been identified as having a history of opioid-related overdose. CMS is also proposing that, starting in plan year 2021, beneficiaries with sickle cell disease are classified as exempt individuals for the purposes of lock-in programs. Additionally, CMS is proposing to automatically escalate to external review by an independent outside entity review of lock-in appeals that have been affirmed by Part D sponsors upon reconsideration. And finally, CMS is proposing to amend the Part D Medication Therapy Management (MTM) program requirements to conform with SUPPORT Act provisions beginning in January 1, 2021 by expanding the population targeted for MTM program enrollment to include at-risk beneficiaries and requiring Part D plans to provide enrollees with information about the safe disposal of prescription drugs that are controlled substances.

PhRMA supports the use of appropriate means to address misuse, abuse, and potentially problematic utilization of prescription drugs, which can endanger patients' safety, 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 also appreciate CMS's work to assure that efforts aimed at curbing overutilization of controlled substances do not become unduly restrictive or impede patient access to medically necessary drugs, particularly for patients with chronic pain, patients in hospice, or patients with cancer diagnoses. Inappropriately restricting access, particularly for vulnerable populations, would work against the goals of the Part D program and we trust that CMS is cognizant of the need to guard against these risks.

Over the years, PhRMA has expressed support for the incremental steps taken by the agency to help ensure Part D plans monitor and seek to prevent inappropriate prescribing and use through drug utilization review (DUR) and quality assurance programs. We've also expressed appreciation for the additional analyses that CMS has conducted over the years to assess the impact and validity of the Overutilization Monitoring System (OMS) opioid overutilization criteria for identifying beneficiaries whose opioid use may require focused case management. Likewise, we continue to support efforts to refine criteria for identifying potentially inappropriate levels of opioid overutilization while also minimizing the identification of false positives. Continued refinement of measures to identify at-risk beneficiaries will remain of particular importance as lock-in programs become a mandatory requirement in Part D. As CMS moves forward with this SUPPORT Act provision, a thoughtful and clinical evidence-based approach will be critical to preventing misuse and abuse in the program while also ensuring that chronic pain patients are not stigmatized or unnecessarily limited in their ability to access needed care.

With these principles in mind, we appreciate that CMS is proposing to include beneficiaries with a history of opioid-related overdose and recent opioid-related claims in the definition of potentially at-risk beneficiaries as well as the analysis that was conducted to identify these individuals. History of overdose is identified as a risk factor in the CDC's Guidelines for Prescribing Opioids for Chronic Pain and to the extent this risk is not identified at the point of prescribing it is important that plans ensure appropriate case management is conducted with prescribers to ensure patient safety and to mitigate potential adverse events.[36]

Likewise, we appreciate CMS's continued efforts to consider the needs of patients with persistent and complicated pain management issues—such as those with sickle cell disease—in determining appropriate exemptions from Part D lock-in programs. In addition to exempting beneficiaries with active cancer-related pain, those residing in long-term care facilities, and those

[36] Dowell D, Haegerich TM, Chou R, CDC guideline for prescribing opioids for chronic pain--United States, 2016. JAMA. 2016 Apr 19;315(15):1624-45.

receiving hospice, palliative, or end-of-life care, we suggest continued assessment of relevant clinical guidelines, including those of medical sub-specialties, to determine the appropriateness of exempting additional beneficiaries with chronic and complex pain conditions for whom stringent utilization controls such as a Part D lock-in may impede access to legitimate medical care.

We also appreciate steps taken to improve the appeals process by automatically escalating lock-in appeals that have been affirmed by Part D sponsors upon reconsideration to external review by an independent outside entity review. We have expressed concerns with the existing Part D appeals process for beneficiaries in the past and are pleased to see this improvement as it will limit disruptions in needed care for patients who may be inappropriately identified as at-risk beneficiaries for the purposes of a lock-in.

Meaningful policies should also ensure individuals determined to be at-risk beneficiaries get the care they need and address the complexity of care of these patients. Automatic enrollment of at-risk beneficiaries in MTM programs is an important step towards appropriately coordinating the care and needs of beneficiaries who may be treated by several providers for multiple chronic conditions while also struggling with complex pain management and/or mental or substance use disorder issues. Sixteen percent of Americans who have mental health disorders receive over half of the opioids prescribed in the U.S.[37] And an estimated 8.2 million adults in the US have both a substance use disorder and a mental illness.[38] Among those with co-occurring disorders more than half received neither mental health care or substance use treatment in the previous year, highlighting the serious gaps in treating this complex and vulnerable population.[39] We applaud CMS's efforts to move forward with the proposed MTM policy as it will help further improve the care for at-risk beneficiaries by providing a critical intervention point for screening and referral to treatment for patients struggling with these issues.

The SUPPORT Act provided a critical improvement for patients struggling with both mental health and substance use issues, particularly for Medicare and dually-eligible beneficiaries. Though the MTM policy proposed here is an important step forward, we continue to urge consideration of the widespread and systemic barriers patients continue to face in accessing appropriate treatment for mental health and substance use disorders. Moving forward, continued efforts to ensure beneficiaries determined to be at-risk are referred to, and can access the care they need, will remain critical to removing barriers faced by these patients.

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[37] Davis MA, Prescription opioid use among adults with mental health disorders in the United States, J Am Board Fam Med. 2017 Jul-Aug;30(4):407-417.
[38] Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: Results from the 2016 national health survey on drug use and health. September 2017. https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf.
[39] Han B, Compton WM, Blanco C, Colpe LJ, Prevalence, treatment, and unmet treatment needs of US adults with mental health and substance use disorders, Health Affairs. 2017 Oct 1;36(10):1739-1747.

And lastly, we would like to express appreciation for efforts to ensure at-risk beneficiaries are provided with education on the safe disposal of prescription drugs that are controlled substances—including information on drug takeback programs, in-home disposal, and cost-effective means for safe disposal of such drugs. It is vital to dispose of medications properly in order to keep medications away from potential abusers or to prevent accidental poisonings in the home. The National Survey on Drug Use and Health finds that those in the household population who report non-medical use of prescription medicines are mostly likely to obtain them from a family member or a friend.[40] Likewise, we support efforts to increase and enhance educational efforts aimed at patients and others around the importance of secure storage of medicines to prevent access by individuals other than the patient or caregiver and to ensure safe methods to dispose of any unused medicines.

Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

CMS is proposing to undertake rulemaking to implement provisions outlined in sections 2008 and 6063 of the SUPPORT Act. Section 2008 requires that plan sponsors' payment suspensions based on credible allegations of fraud and abuse be implemented in the same manner as CMS implements payment suspensions. Under the provision, plan sponsors are required to notify the Secretary of the imposition of a payment suspension that is based on a credible allegation of fraud. Section 6063 requires the Secretary to establish a secure internet website portal to enable the sharing of data among MA plans, prescription drug plans, and the Secretary, and referrals of "substantiated or suspicious activities" as well as the dissemination of quarterly reports to MA plans and Part D plans on fraud, waste, and abuse schemes and suspicious activity trends reported through the portal. Beginning with plan year 2021, section 6063 also requires Part D plans to submit to the Secretary information on investigations, credible evidence of suspicious activities of providers or suppliers related to fraud, and other actions taken by the plans related to inappropriate opioid prescribing. The Secretary is required to issue regulations that define the term inappropriate prescribing with respect to opioids, identify a method to determine if providers are inappropriately prescribing, and identify the information plan sponsors are required to submit.

PhRMA applauds CMS's efforts to implement SUPPORT Act provisions aimed to ensure MA plans' and Part D plans' payment suspensions are implemented in the same manner as CMS payment implements suspensions, and that information is made available to both plans and CMS to ensure alignment on program integrity efforts. Preventing fraud and abuse in the program and

[40] Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: results from the 2018 national survey on drug use and health. August 2019. https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf.

ensuring unscrupulous prescribers are not able to evade program integrity efforts are critical to protecting patient safety and preventing fraudulent and illegal activity. We encourage a thoughtful and evidence-based approach to these efforts so as not to erroneously capture otherwise appropriate levels of opioid prescribing which may impact providers and thus the care of patients with complex pain management issues. To this end, with respect to the proposed definition of "inappropriate opioid prescribing," we applaud that CMS is seeking input from clinical experts regarding evidence-based guidelines for opioid prescribing across clinical specialties and care settings and we strongly urge consideration of potential outlier specialties in finalizing this definition.

Beneficiaries' Education on Opioid Risks and Alternative Treatments (§423.128)

Section 6102 of the SUPPORT Act amended section 1860D-4(a)(1)(B) of the Social Security Act to require that, for plan year 2021 and each subsequent plan year, Part D sponsors also must disclose to each enrollee, with respect to the treatment of pain, information about the risks of prolonged opioid use. In addition to this information, with respect to the treatment of pain, MA-PD sponsors must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans. Sponsors of standalone Part D plans must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B. Section 6102 of the SUPPORT Act also amended section 1860D-4(a)(1)(C) of the Social Security Act to permit Part D sponsors to disclose this opioid risk and alternative treatment coverage information to only a subset of plan enrollees. CMS is proposing to amend regulations at § 423.128 to reflect that Part D sponsors may provide such information to a subset of such enrollees, in accordance with section 1860D-4(a)(1)(C), in lieu of providing it to all enrollees. CMS provides several suggested options for disclosure of information to a subset of enrollees.

PhRMA appreciates CMS's efforts to implement SUPPORT Act provisions aimed towards expanding educational efforts to ensure patients are disclosed information about the risks of prolonged opioid use and believe it is critical that patients are educated regarding the risks of addiction and understand relevant signs of substance use disorder. We also would like to encourage that these disclosures include information on available points of access for screening of substance use disorder treatment (e.g. SAMHSA's Behavioral Health Treatment Services Locator). We also believe it is critical that this information be based on sound clinical expertise and evidence-based guidelines to ensure plans do not provide patients with potentially harmful information.

It is equally important that beneficiaries are provided with information about non-opioid treatment options to ensure patients are made aware of these options and encourage a discussion with providers regarding appropriate alternatives or complements to existing strategies for the management of pain. Likewise, we applaud CMS's efforts to ensure that sponsors disclose plan

coverage of non-opioid treatments—including both pharmacologic and non-pharmacologic options. However, while these are critical steps to ensure patients are provided with appropriate information regarding non-opioid options, we urge CMS to further consider the impact of continued coverage challenges patients face in accessing non-opioid alternatives for long-term pain management, including other non-pharmacological modalities of care.

Real Time Benefit Tool for Beneficiaries (§ 423.128)

In addition to a prescriber real time benefit tool (RTBT) requirement, effective January 2021, CMS is proposing a requirement that Part D sponsors implement a beneficiary RTBT that would allow enrollees to access timely and clinically-appropriate beneficiary-specific formulary and benefit information in real time, no later than January 1, 2022.

PhRMA commends CMS for its efforts to make plan benefit and cost-sharing information more accessible in Medicare Part D. Price transparency initiatives such as RTBT empower patients and providers and hold the potential to improve the quality of health care and reduce other health care costs. There is growing evidence that informed patients who are engaged in collaborative dialogue and meaningful decision making with their clinicians have the potential to drive better health outcomes, improve care quality and make our health care system more efficient.[41] Patients deserve accurate, timely, and easily understood data that are relevant to their health care needs to better inform decisions about their care. When appropriately structured to support beneficiary decision making, supplementing useful information about the costs and benefits of health care is essential to driving more efficient and higher quality care.

CMS notes that Part D enrollees can currently utilize tools to access prescription drug information for a particular plan, though the data are not provided in real-time. Applications such as Blue Button 2.0 or the eMedicare Initiative have been developed to provide a more user-friendly, streamlined online health care experience for beneficiaries that provides greater health care coverage information at their fingertips, including a mobile optimized out-of-pocket cost calculator that provides information on both overall costs and prescription drug costs.[42] Additionally, Medicare Plan Finder (MPF) provides beneficiaries with an estimate of their cost sharing for the upcoming plan year based on their medication list.

While the information provided to beneficiaries in MPF can be helpful in informing plan selection and estimated cost sharing, complex drug formularies and the lack of standardization of such formulary and benefit information in real time from health plans can make it difficult for

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[41] Avalere. The promise of shared decision making in improving value in the US healthcare system. December 11, 2017. https://avalere.com/insights/issue-brief-the-promise-of-shared-decision-making-in-improving-value-in-the-us-healthcare-system.
[42] Centers for Medicare and Medicaid Services. CMS announces new streamlined user experience for Medicare beneficiaries. October 1, 2018. https://www.cms.gov/newsroom/press-releases/cms-announces-new-streamlined-user-experience-medicare-beneficiaries-0.

patients to understand their expected prescription costs as they progress through the plan year. We continue to have concerns that technical and operational details must be worked through for RTBTs to reach their full potential. These include the absence of an industry-adopted transaction standard for RTBTs in their current form. We strongly recommend that CMS continue to work with affected stakeholders and standards development and accrediting organizations (SDOs) in expediting a real-time benefit standard that is patient-centric and has undergone rigorous testing to ensure data accuracy.

We also note with concern that CMS suggests including negotiated price—along with a patient's out-of-pocket costs—as part of the information the RTBT provides.[43] In most instances, this additional information is not directly relevant to the patient and such extraneous information could cause confusion or distract from the information the patient and provider need to make the best decision for the patient's care. We do not believe this data point would be useful to include in a beneficiary-focused RTBT.

PhRMA also believes there should be communication between CMS and the Office of the National Coordinator (ONC) for a more coordinated approach and implementation of RTBT in an interoperable manner that does not add to provider burden and protects patient data. A thoughtfully-developed RTBT that has gained industry adoption and standardization would be a complementary addition to the cost-sharing tools available to beneficiaries today. PhRMA looks forward to continued efforts and collaboration with CMS to implement a RTBT that provides meaningful and timely information to beneficiaries that can improve their care decisions.

Medicare Advantage and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

CMS is proposing several substantive changes to measures in the Star Ratings system, including measure weights and classification of existing measures.

Statin Use in Persons with Diabetes

CMS finalized the addition of the Statin Use in Person with Diabetes (SUPD) measure beginning with the 2019 Part C and Part D Star Ratings, with the first-year measure weight of 1, and then considered an intermediate outcome measure for the subsequent 2020 Star Ratings with an increase to a weight of 3. Following clarification from the measure developer that this measure is classified as a process measure, and in an effort to align with a similar Part C measure (Statin Therapy for Patients with Cardiovascular Disease), which is considered a process measure, CMS is proposing to modify the SUPD measure category from an intermediate outcome to process measure, and downgrading the weight from 3 to 1, starting with the 2023 Star Ratings.

[43] 83 Fed. Reg. 231 at 62166.

In the absence of outcomes-focused measure additions to the Star Ratings program that address appropriate diabetes and cardiovascular care, we are concerned about the proposed reclassification and weighting of the SUPD measure, given the strong correlation between the two conditions.[44] As an example, there is currently no measure for use in any of CMS's quality reporting programs, including the Star Ratings, that addresses appropriate management of patients with concurrent chronic diseases, including diabetes and cardiovascular disease. We encourage CMS to continue to explore ways to close these measure gaps, as 80 percent of U.S. adults age 65 and over have multiple chronic conditions.[45]

PhRMA supports the inclusion of statin therapy measures that align with the 2019 ACC/AHA blood cholesterol guidelines, which address use of statins in patients with diabetes.[46] The complications associated with diabetes are serious, disabling, and often life-threatening. The risks of developing these complications increase both over time and when blood glucose levels are poorly controlled. Nearly 70 percent of persons with diabetes aged 65 and older die from some form of heart disease and adults with diabetes are two-to-four times more likely to die from heart disease than adults without diabetes.[47] We have previously supported the inclusion of the SUPD measure to the Star Ratings as a complement to the existing statin adherence measure and believe it should remain as an intermediate outcome measure, with a weight of 3, to reflect the measure's role in improving patient care and overall health status.

While we support the inclusion of both statin-related measures as outcomes measures in the Star Ratings as an important start, we remain concerned that these measures are not sufficient to address critical measure gaps created by retirement of the previous cholesterol screening and control measures for persons with diabetes, and that they do not 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 its measurement of cardiovascular care for patients with diabetes to include screening, monitoring, and the outcomes of treatment. PhRMA also strongly encourages CMS to reconsider its proposal to reclassify the SUPD measure as a process measure and maintain its status as an intermediate outcome measure.

For future consideration, PhRMA encourages the development of clinically relevant measures in therapeutic areas that are representative of the Medicare population to appropriately assess the

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[44] National Institute of Diabetes and Digestive and Kidney Diseases. Diabetes, heart disease, and stroke. February 2017. https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-problems/heart-disease-stroke
[45] RAND Corporation. Multiple chronic conditions in the United States. 2017. https://www.rand.org/pubs/tools/TL221.html.
[46] Arnett DK, et al., 2019 ACC/AHA guideline on the primary prevention of cardiovascular disease: executive summary: a report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines, J Am Coll Cardiol. 2019 Sep 10;74(10):1376-1414.
[47] American Heart Association. Cardiovascular disease and diabetes. August 30, 2015. https://www.heart.org/en/health-topics/diabetes/why-diabetes-matters/cardiovascular-disease--diabetes.

quality of care provided, including measures that address multiple chronic conditions. Adherence measures serve as important proxies of clinical progression of a disease. We encourage CMS to consider enhancing current adherence measures by capturing additional guideline-recommended therapies to provide a more comprehensive reflection of care quality.

Measure Weights: Patient Experience/Complaints and Access Measures

CMS is proposing to incorporate more of the patient voice when evaluating care quality within the Star Ratings program by increasing the weight of patient experience/complaints and access measures from 2 to 4. These measures include the patient experience of care measures collected through the CAHPS survey, Members Choosing to Leave the Plan, Appeals, Call Center and Complaints measures.

PhRMA commends CMS for recognizing the importance of the beneficiary experience as a key component of care quality. Our members have a long-standing interest in ensuring that Medicare beneficiaries have access to needed therapies. Robust, accurate, and transparent information regarding access problems, appeals, and complaints is critical to determining whether plans are providing timely and appropriate access to needed care. Patient interactions with health plans and providers should be captured and reflected in quality measures to inform future health care decisions. Ensuring that beneficiaries receive high quality customer service while minimizing barriers to care should be a top priority of the program, and we support the proposal to increase the weight of patient experience and access measures.

While we are encouraged by these developments to place greater emphasis on experience and access, we also stress the importance of data accuracy informing these measures, now that greater weight will potentially be assigned to them. Historically, we have strongly urged that CMS 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. An example is strengthening quality measures on timely decisions made by plans about appeals, to include cases dismissed by the independent review entity (IRE). We have also supported expanded data collection for Part D appeals that would facilitate more accurate and detailed examination of beneficiaries' access to therapy. Data integrity and completeness of appeals information is essential to ensuring that beneficiary access to high quality care is not hindered.

Future Measure Concepts

PhRMA supports CMS's continued commitment to improving the MA and Part D quality performance measurement program. As the Star Rating program evolves, inclusion of additional outcome measures addressing a broader range of conditions as well as appropriate medication management would strengthen the program and help assure that it achieves its goals. In particular, gaps in currently available measures related to cancer treatment, pain management,

mental illness, dementia/cognitive impairment, infectious diseases (e.g., human immunodeficiency virus (HIV), hepatitis C), vaccine-preventable illness, and other common chronic conditions such as cardiovascular disease, diabetes, heart failure, and chronic obstructive pulmonary disease (COPD), each hamper the ability of the program to appropriately measure quality of care for these conditions.

Additionally, there is strong alignment and clinical evidence that supports the need for quality measures that address adult immunization status. It is important for adults and seniors to receive certain vaccinations as they age to avoid a variety of serious conditions. The immune system naturally weakens over a patient's lifespan and vaccines can be critical to prevent illness among the elderly, who may be particularly vulnerable to infection. Despite the strong evidence behind vaccine effectiveness, rates of the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP)-recommended adult immunizations consistently remain below national targets. In fact, the prevalence of illnesses attributable to vaccine-preventable disease remains higher in adults than children.[48] As there are greater opportunities to improve use of ACIP[49]-recommended vaccines, we reiterate our support of including adult immunization status measures to the display page and Star Ratings in the near future.

PhRMA also encourages 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 outcome (PRO) data sources—to ensure that measure sets or composite measures provide a complete picture of the quality of care. CMS should encourage measure developers to focus resources in these disease areas and measure types, and work to include new measures as they are endorsed by a multi-stakeholder consensus-based organization and available for implementation. Other measure types such as quality of life, functional status, and PROs, which provide an important patient perspective on care, should also be included as additional outcome measures. As an interim step, CMS could consider placing greater weight on current outcomes measures, while scaling back on process measures. Measuring the outcomes of care delivered by health plans is particularly essential to ensure that plans deliver high quality care to patients and do not restrict patient access to essential treatments as plans seek to manage the cost of care.

[48] Williams WW, Lu P, O'Halloran A, et al., Surveillance of vaccination coverage among adult populations — United States, 2015. MMWR Surveill Summ 2017;66(No. SS-11):1–28.
[49] Weinberger B, Grubeck-Loebenstein B, Vaccines for the elderly. Clin Microbiol Infect. 2012 Oct;18 Suppl 5:100-8.

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PhRMA appreciates CMS's consideration of our concerns. We stand ready to assist with any of the issues raised in our letter. Please contact Ashley Czin at 202-572-7784 or ACzin@phrma.org with any questions.

Sincerely,

Ashley Czin
Senior Director
Policy and Research

Amanda Pezalla
Assistant General Counsel
for Federal Programs