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VIA ELECTRONIC FILING TO: www.regulations.gov

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: 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 Draft Call Letter

Dear Administrator Verma:

Lilly USA, LLC (Lilly) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) CY 2019 Advance Notice and Draft Call Letter (the Draft Call Letter).[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through the discovery and development of breakthrough medicines and technologies, as well as through the analysis and distribution of health information. Ultimately, our goal is to develop products that save and improve peoples' lives.

Lilly supports CMS's commitment to improving the quality of the Medicare Advantage and Part D programs. Lilly has been a strong supporter of Medicare Advantage and Medicare Part D since the programs' inception and remains committed to ensuring that Medicare Part D beneficiaries have affordable access to all critical therapies. We support many of the proposals in the Draft Call Letter that strengthen beneficiary protections and foster timely access to needed treatments. However, we would also like to highlight important opportunities to improve affordability for beneficiaries and promote high quality care at the same time. Below, we offer our rationale for positions on several important topics and request that CMS consider these recommendations for inclusion in the CY 2019 Final Call Letter:

- CMS should modernize its specialty tier policy to address the growth in patient out-of-pocket costs and to ensure uniform enforcement of Medicare's nondiscrimination protections
- CMS's benefit review process should include new measures to protect beneficiaries from excessive cost-sharing amounts and potentially discriminatory practices
- CMS should enact policies to promote formulary access and prioritize new quality measures for innovative, non-opioid treatments as part of the broader effort to combat opioid abuse
- CMS should include Part D drugs in the uniformity flexibility proposed for Medicare Advantage (MA) plans

[1] Centers for Medicare and Medicaid Services (CMS), 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, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf

- CMS should extend Part D to the MA maximum out-of-pocket (MOOP) cap as part of the agency's guidance on Part C cost-sharing flexibility
- CMS should eliminate the Meaningful Difference (MD) threshold for both Medicare Advantage and Prescription Drug Plans (PDPs), and pursue alternatives to the Out-of-Pocket Cost (OOPC) Tool that can offer beneficiaries more useful decision support during open enrollment
- CMS should continue to use the annual Call Letter process to make enhancements to the Star Ratings and also focus on new measures to address quality gaps in the treatment of pain, diabetes, and Alzheimer's/dementia

We discuss our recommended changes in more detail below.

I. CMS should modernize its specialty tier policy to address the growth in patient out-of-pocket costs and to ensure uniform enforcement of Medicare's nondiscrimination protections

In the 2019 Draft Call Letter, CMS reaffirms the decision to maintain the specialty tier threshold at $670 for CY 2019 based on an analysis of CY 2017 prescription drug event (PDE) data showing that just around 1 percent of 30 day-equivalent fills exceeded $670.[2] CMS reiterates its position that it will continue to monitor these trends and make updates to the specialty tier in future years as necessary. As in prior years, we restate our concerns with how specialty tiers are being defined by the agency and the absence of a more reliable means of indexing the threshold on an annual basis. These drugs often represent novel advances in the treatment of chronic conditions such as cancer, multiple sclerosis, and inflammatory disease that typically require unique handling, storage, and/or distribution. However, because this threshold has been updated only one time since 2008, a growing share of drugs that do not exhibit any of the characteristics of a "specialty drug" are now eligible for specialty tier placement. Estimates suggest that specialty drugs represent approximately 1 percent of total prescriptions written per year[3][4], yet according to CMS's own analysis, 14 percent of all drugs on the formulary reference file met the criteria for specialty tier eligibility in CY 2016 – and the overwhelming majority of these drugs (79 percent) were in fact added to the specialty tier by plan sponsors.[5] This imbalance suggests that patients may be abandoning prescribed therapies due to specialty tier placement – and the agency's focus on the total number of scripts filled above $670 (~1 percent) may not be a useful criterion when determining whether to raise the specialty tier threshold each year.

Due to breakthroughs in innovation and advances made in personalized medicine, specialty and biologic agents will represent a growing share of the treatment options available for Medicare beneficiaries in the years ahead.[6] While we appreciate the concerns associated with

[2] Id at 201.
[3] America's Health Insurance Plans. Issue Brief - Specialty Drugs: Issues and Challenges https://www.ahip.org/wp-content/uploads/2015/07/IssueBrief_SpecialtyDrugs_7.9.15.pdf. July 2015.
[4] Pew Charitable Trusts. Specialty Drugs and Health Care Costs. http://www.pewtrusts.org/~/media/assets/2015/11/specialty-drugs-and-health-care-costs_artfinal.pdf. November 2015.
[5] Centers for Medicare and Medicaid Services (CMS). Medicare Part D Specialty Tier Methodology. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/CY-2016-Specialty-Tier-Methodology.pdf. April 2015.
[6] Diplomat Pharmacy Inc. Specialty Drug Approvals: 2015 Highlights and 2016 Projections. https://issuu.com/diplomatrx/docs/specialty_drug_approvals_2015_highl_7a4d31141f4d2f?e=15248128/32508071

these trends, it is also clear that CMS's current policy has enabled a disproportionately large number of non-specialty drugs to be treated as specialty drugs in the Part D program. The result has been a shift in the burden of Part D costs onto the most vulnerable patient populations. Aside from the affordability problems created for patients, poor access to specialty therapies can also lead to higher rates of noncompliance and poor outcomes[7], while also raising the serious concern that Medicare's nondiscrimination protections are not being fairly applied. To remedy these concerns, Lilly suggests that CMS implement the following changes to its specialty tier policy:

Define specialty tiers on factors other than price alone.

By defining "specialty drugs" solely based on price, a growing share of conventional drugs are nonetheless eligible for specialty tier placement, effectively rendering the designation irrelevant and exposing sicker beneficiaries to higher out-of-pocket costs. We ask that the agency begin defining specialty tiers based on additional factors beyond price – such as how the drug is manufactured, stored, and delivered, along with other clinical criteria related to dosing and administration that would more aptly reflect the nature of a "specialty" product. Lilly recommends working with numerous stakeholder groups to gain alignment on such criteria. We also ask that CMS condition specialty tier eligibility on the presence of these various clinical and/or biological properties.

Substantially raise the specialty tier cost threshold or begin indexing it to a reasonable benchmark.

Lilly supports CMS's position to continue monitoring ongoing trends in prescription drug event (PDE) data to better inform future changes to the specialty tier. However, if the agency chooses to continue defining the specialty tier placement strictly in financial terms, we ask that increases to the specialty tier threshold be made annually, using an appropriate indexing methodology to support more consistent increases and limit the impact of high out-of-pocket costs for the most vulnerable beneficiaries.

Allow patients the right to appeal specialty tier cost-sharing.

One of the fundamental protections related to the Part D appeals process is the right of beneficiaries to request an exception to cost-sharing associated with "conventional" formulary tiers that are believed to be discriminatory or excessive. However, CMS prohibits beneficiaries from requesting a tiering exception for specialty tier products. Without a more reliable means to differentiate a conventional drug from a specialty drug (as stated above), the line between "non-preferred brands" and "specialty products" can be too easily blurred. With a price-based threshold of $670, plan sponsors can simply add brands to the specialty tier that do not exhibit any of the characteristics that are germane to "specialty drugs" in the first place – notably, unique manufacturing, storage, route of administration, or conditions treated. In these situations, false distinctions may be created among similar drugs. As an example, a beneficiary enrolled in one plan may be granted the opportunity to submit a tiering exception request for a particular treatment, yet a second beneficiary with a nearly identical clinical profile – but enrolled in another plan – may be denied this right for the exact same drug based solely on the plan

[7] Health Affairs. "Medication Affordability Gains Following Medicare Part D Are Eroding Among Elderly With Multiple Chronic Conditions". http://content.healthaffairs.org/content/33/8/1435.abstract

sponsor's placement of the drug. This can create unequal outcomes in matters of affordability and access for beneficiaries, given that one plan sponsor may cover a product that meets or exceeds the specialty tier threshold in a non-preferred brand tier, while another may place the same product in the specialty tier. Thus, CMS's prohibition on tiering exceptions for specialty tier drugs seems to run counter to the agency's well-established nondiscrimination principles. Lilly urges CMS to lift this restriction through regulatory guidance and permit beneficiaries to submit tiering exceptions for specialty tier drugs as a matter of fairness and to mitigate the risk of discrimination based on health status. Should CMS permit these exceptions, we also urge the agency to require plan sponsors to notify enrollees of these new rights in a simple and transparent way.

II. CMS's benefit review process should include new measures to protect beneficiaries from excessive cost-sharing amounts and potentially discriminatory practices

In the Draft Call Letter, CMS states that it will continue to scrutinize coinsurance tiers for cost-sharing impacts, and will compare any coinsurance value for a non-specialty tier greater than 25 percent to the established copay thresholds ($100) to determine whether such coinsurance values are discriminatory.[8] CMS also reminds sponsors that Drug Tier Labels should be representative of the drugs that make up that tier. We appreciate CMS's interest in identifying outliers that may result in onerous out-of-pocket burden for patients; however, we hasten to point out that patient out-of-pocket liability easily surpasses $100 for many branded drugs due to precipitous growth in the use of coinsurance on non-preferred drug tiers. The use of coinsurance tiers has increased dramatically, with 63 percent of all drugs residing on PDP coinsurance tiers in 2017, versus only 38 percent of drugs in 2013.[9] In 2017, approximately 97 percent of PDP enrollees were in a plan with either two or three coinsurance tiers, and the average coinsurance for the non-preferred brand tier was 43 percent.[10] Clearly, the current process of assessing outliers is not shielding beneficiaries from coinsurance levels that are well in excess of the established copay threshold. We also believe that the agency's guidance in the Draft Call Letter that "a coinsurance structure is the preferable cost-sharing structure for the non-preferred drug tier" could send a mixed signal that inadvertently undermines the spirit of the outlier reviews in limiting onerous cost-sharing.[11] We respectfully ask the agency to consider issuing additional guidance on coinsurance for non-preferred drug tiers that more effectively protects beneficiaries from a pattern of unsustainable cost-sharing.

III. CMS should enact policies to promote formulary access and prioritize new quality measures for innovative, non-opioid treatments as part of the broader effort to combat opioid abuse

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[8] Centers for Medicare and Medicaid Services (CMS), 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, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf. Pg 198.

[9] Avalere Health. Key Trends in the Part D Landscape: Considerations for 2017. Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. August 2017.

[10] Avalere Health. Key Trends in the Part D Landscape: Considerations for 2017. Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. August 2017.

[11] Centers for Medicare and Medicaid Services (CMS), 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, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf. Pg 198-199.

In the Draft Call Letter, CMS proposes new drug utilization review controls to improve efforts to manage chronic overuse among beneficiaries who are taking high levels of prescription opioids as well as opioid naïve patients.[12] Lilly supports these efforts and encourages CMS to support policies that position the reimbursement system towards an emphasis on non-addictive treatment alternatives. As part of the agency's utilization management review, we also ask that CMS apply greater scrutiny to formulary edits that may restrict access to novel therapies. These techniques could have the effect of making it easier to rely on opioid therapies for access, which in turn could make it harder for patients to break out of the cycle of opioid dependence and misuse. Lilly strongly encourages the agency to assess plan sponsor coverage policies and cost-sharing structures to ensure that access to safer, innovative pain treatments is not impeded.

Lilly applauds Health and Human Services' (HHS) ongoing efforts to address the epidemic of opioid abuse.[13] While opioids may have a clinical role in an acute setting, the risk of abuse and diversion is heightened when they are used chronically, with uncertain clinical benefit. According to the Center for Disease Control, "…evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent."[14] One of the primary objectives of the CDC's Guideline for Prescribing Opioids for Chronic Pain is "…to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose."[15]

In order to more fully integrate the CDC guidelines into the Medicare Part D program, Lilly requests that CMS examine new plan-based quality measures for the Star Ratings Program that encourage providers and patients to focus on appropriate use and visibility into alternative treatment options. Over the next several years, new, non-opioid pharmacologic therapies may become available, and additional measures that raise patient awareness of these therapies for chronic pain will be needed. Quality measures that support the use of new non-opioid pharmacologic therapies could contribute to better patient health outcomes while also meaningfully addressing the epidemic of opioid-related addiction in the U.S. CMS should promote measures that encourage providers to engage patients in conversations that address the range of treatment options available and how to effectively manage their pain. These measures should also include regular assessments of functional status improvements over time to address the high rates of inadequate relief and functional restoration with existing therapies.

IV. CMS should include Part D drugs in the uniformity flexibility proposed for Medicare Advantage (MA) plans

As noted in the CY 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit

[12] Id at 203-204.
[13] Health and Human Services (HHS). Understanding the Opioid Epidemic. http://www.hhs.gov/opioids/about-the-epidemic/
[14] Center for Disease Control. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
[15] GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN, https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf

Programs and the PACE Program Proposed Rule[16], CMS restates that the agency has the authority to permit MA organizations to reduce cost-sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided all similarly situated enrollees are treated the same.[17] This flexibility would permit MA plan sponsors to prioritize higher quality care for patients with chronic conditions by experimenting on a broader scale with value-based insurance design (VBID) techniques. Lilly supports this interpretation and is encouraged by the agency's willingness to promote evidence-based approaches to foster improved outcomes and better value in the Medicare program. We would also like to take this opportunity to reiterate our request that CMS include Part D drugs in this uniformity flexibility.

A large body of evidence has demonstrated that adherence to prescription drugs can have a significant and positive impact on patient care, while also reducing costs over the long term. The Congressional Budget Office (CBO) has found that every 1 percent increase in the utilization of prescription medicines decreases Medicare spending in Parts A and B by 0.20 percent. CBO further validated the benefits of prescription drugs by announcing in 2012 that this methodology would be incorporated into the budgetary impact assessments of future legislative proposals affecting the Medicare program.[18] Additionally, a study by IQVIA found that better use of medicines could eliminate up to $213 billion in US health care costs annually (representing 8 percent of the nation's health care spending), and nearly half of this savings came from improved outcomes related to medication adherence.[19]

Incorporating Part D into MA flexibility can also positively influence the trajectory of value-based agreements in the Medicare program – a key priority for CMS, as articulated in the Innovation Center (CMMI) New Direction Request for Information (RFI) released on September 20, 2017.[20] VBID can complement plan sponsors' interest in exploring value-based arrangements because both VBID and value-based arrangements encourage consideration of how the value of a medicine varies between different patients. Plans may rely on the real-world evidence generated from VBID to broaden participation in value-based agreements and leverage investments in high-value treatments to lower medical spending. We agree with comments submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) that there are strong similarities in the uniformity of benefit and non-discrimination rules that apply to Part D and Medicare Advantage, which should give CMS the ability to extend the same plan design flexibility to Part D drugs. We also ask that CMS address these similarities in the Final Call Letter and consider making this change during future rule-making.

V. CMS should extend Part D to the MA maximum out-of-pocket (MOOP) cap as part of the agency's guidance on Part C cost-sharing flexibility

[16] 82 Fed. Reg. 56336, 56527 (November 28, 2017).
[17] Centers for Medicare and Medicaid Services (CMS), 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, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf at 184.
[18] Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012. Available at: https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf
[19] IQVIA. Avoidable Costs in US Healthcare: the $200 Billion Opportunity from using medicines responsibly. http://www.imshealth.com/files/web/IMSH%20Institute/Reports/Avoidable_Costs_in%20_US_Healthcare/IHII_AvoidableCosts_2013.pdf. June 2013.
[20] Centers for Medicare & Medicaid Services. Available at: https://innovation.cms.gov/Files/x/newdirection-rfi.pdf

In the Draft Call Letter, CMS announces the continuation of the current policy of giving MA plans greater flexibility in establishing Parts A and B cost-sharing by adopting a lower, voluntary MOOP limit than the higher, mandatory limit.[21] CMS also solicits comment on whether the current interpretation of cost sharing limits across a number of Part A and B service categories is impacting plans' ability to offer more flexible benefit designs. Lilly supports giving MA plan sponsors the flexibility to voluntarily offer a lower MOOP limit, particularly as beneficiaries have been exposed to significant growth in total out-of-pocket costs in recent years. The MOOP provides a critical affordability protection for MA beneficiaries, and is likely one of many plan features that has contributed to the rapid growth in Medicare Advantage enrollment over the past several years.[22]

For these reasons, we ask the agency to consider its authority to apply Part D costs to the MA MOOP. Although CMS does not address Part D costs in the context of the MOOP directly, the evidence to support such a change is compelling. Among all Medicare Advantage-Prescription Drug Plans (MA-PDs) in 2017, one quarter of all drugs were placed in a coinsurance tier, with 37 percent of all brand drugs placed in the non-preferred tier and 40 percent of brand drugs placed in the specialty tier.[23] This type of cost-sharing may not be sustainable given the high degree of script abandonment seen at far lower levels of cost-sharing. According to recent data by IQVIA, when beneficiary cost-sharing exceeded $250 – a threshold that is not at all uncommon within MA-PDs –71 percent of new specialty prescriptions were abandoned.[24] Poor medication adherence also forecloses an opportunity for plan sponsors to reap the benefits of lower Part A and B spending brought about by the use of prescription drugs – a positive outcome that would be consistent with the agency's goal of using benefit design flexibility to promote high-value care. Applying Part D costs to the MOOP would provide a critical financial safeguard for patients and enable better integration across interrelated service categories. Finally, we echo the comments submitted by the Biotechnology Innovation Organization (BIO) that CMS should carefully monitor efforts to allow additional flexibility to MA-PDs to prevent discriminatory practices against patients with complex and/or chronic conditions.

VI. CMS should eliminate the Meaningful Difference threshold for both Medicare Advantage and Prescription Drug Plans, and pursue alternatives to the Out-of-Pocket Cost (OOPC) Tool that can offer beneficiaries more useful decision support during open enrollment

CMS restates its intent to eliminate the meaningful difference (MD) requirement entirely for Medicare Advantage plans, and between the first and second enhanced plans for PDPs (but not between a PDP's basic and first enhanced plan) in CY2019.[25] CMS also intends to revisit the

[21] Centers for Medicare and Medicaid Services (CMS), 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, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf at 176-180.
[22] Kaiser Family Foundation. Medicare Advantage Spotlight 2017. https://www.kff.org/medicare/issue-brief/medicare-advantage-2017-spotlight-enrollment-market-update/. June 2017.
[23] Avalere Health. Key Trends in the Part D Landscape: Considerations for 2017. Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. August 2017.
[24] Amundsen Consulting, division of IQVIA. Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment. November 2017.
[25] Centers for Medicare and Medicaid Services (CMS), 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, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf at 197-198.

use of the OOPC tool used to establish meaningful difference between basic and enhanced PDPs. We applaud CMS's decision, but ask the agency to eliminate the meaningful difference test in all instances for PDPs and pursue a suitable replacement that will provide more meaningful decision support for beneficiaries during open enrollment.

Lilly has repeatedly advocated for the elimination of the OOPC test due to glaring technical flaws with the calculator that inadvertently promote formulary "gaming" behavior and access barriers for certain beneficiaries enrolled in basic plans, while offering little clarity to beneficiaries about the true differences between plans. Because the OOPC tool's methodology assigns higher "values" for older products with higher market share, sponsors may engage in artificial decision-making that encourages removal of these "high value" drugs from basic plan formularies in order to make enhanced plan formularies appear richer and more "meaningfully different". This dynamic disproportionately hurts low-income beneficiaries more inclined to enroll in basic plan coverage, and we believe this runs counter to the central tenet of fairness in the Part D program. At a minimum, we believe that CMS should change the OOPC tool's current assumption that non-formulary drugs will be paid 100 percent by members, and instead value these drugs at the sponsor's exception tier co-insurance level, as the agency originally proposed (but never finalized) in the CY 2014 Draft Call Letter.[26] A potentially better approach would be to eliminate the OOPC tool altogether in favor of decision support tools on Medicare PlanFinder that would go further in clarifying true differences in plan options for beneficiaries.

We urge CMS to explore additional prompts on PlanFinder with personalized information about a patient's specific drug profile that could encourage more tailored comparison-shopping. This information could provide clearer information about how a plan's out-of-pocket costs impact overall affordability beyond just premium cost. As an example, flags could be added to PlanFinder to denote the type of enhancement used (reduced cost-sharing on tiers, coverage of additional drugs, improved benefit design, additional gap coverage) as a way to help beneficiaries distinguish plans and make better plan choices. CMS should also explore opportunities to improve the financial literacy of consumers by creating educational forums or tools outlining the structure and implications of different plan designs prior to and after open enrollment. CMS could provide additional versions of these resources to State Health Insurance Assistance Program (SHIP) counselors to enable more continuous, "hands-on" education throughout the year. Modifications such as these would address the agency's concerns with the proliferation of plan designs and the potential risk of beneficiary confusion. At the same time, they would yield information that is far more useful to beneficiaries about the differences across plan designs without the unintended consequences that result from a reliance on the OOPC tool.

VII. CMS should continue to use the annual Call Letter process to make enhancements to the Star Ratings and also focus on new measures to address quality gaps in the treatment of pain, diabetes, and Alzheimer's/dementia

[26] Centers for Medicare and Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter, page 144. http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Advance2014.pdf

Consistent with our comments submitted on January 16, 2018, we disagree with CMS's proposal to codify aspects of the 5-Star Ratings methodology, including the process for adding, updating and removing measures through formal rulemaking, rather than the annual Call Letter process. While it may be reasonable and appropriate to subject certain minor program changes to formal rulemaking, such as the measure weighting system, this proposal will limit opportunities for CMS to make timely changes to measures based on evolving standards of care. We appreciate CMS's desire to increase program transparency and more clearly explain the principles surrounding methodological changes the 5-Star Program. However, the process of endorsing, proposing, reviewing, and adopting new quality measures into the program is already lengthy and laborious. There is currently a two-year lag in the data collection periods to any corresponding performance year, and CMS has already acknowledged that the proposal will create a longer lead time for both new measure additions and substantive changes to existing measures.[27]

We remain concerned that adding more lead-time to an already arduous process would stifle the adoption of new quality measures aligned with the latest innovative advances in medicine and technology. As we have indicated in previous comments to CMS, Lilly is concerned that federal quality reporting programs contain an insufficient number of measures tied directly to improvements in patient outcomes. Robust outcome measures enable plans and providers to assess the value of certain drug therapies in clear and quantifiable ways. We support the important role that quality measures play in value-based care, and to be maximally effective, measures must be consistent with evolving standards of care. The current sub-regulatory process through the annual Part D Call Letter provides ample lead-time for stakeholder involvement and transparency. Additionally, measures under consideration are placed on the Display Page for testing before being formally added to the Star Ratings Program. This process already strikes an appropriate balance between stakeholder input and testing of new measures, while also ensuring that Star measures reflect the latest treatment guidelines and current standards of care.

Lilly appreciates the opportunity to make suggestions about the future development of quality measures for the Star Ratings program. We support CMS's effort to promote high quality care and believe that the program is creating benefits for millions of Part D enrollees. At the same time, unmet needs for more robust quality measures exist across several important therapeutic areas, such as pain management, diabetes, and Alzheimer's/dementia.

2019 Display Measures

Opioid Use

CMS proposes to add a Pharmacy Quality Alliance (PQA) measure examining high dosage opioid use from multiple providers among individuals 18 or older without cancer to the 2019 Part D display page.[28] As mentioned previously, Lilly supports CMS's efforts to combat the opioid crisis. Adding a measure to the display page that tracks the extent to which patients are receiving high-dose opioids from four or more prescribers and four or more pharmacies is a

[27] 82 Fed Reg. 56384
[28] Centers for Medicare and Medicaid Services (CMS), 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, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf. Pg 142.

responsible approach to better identify cases of abuse and diversion. We recommend that CMS also consider the addition of measures to the display page that evaluate opioid utilization patterns when used for chronic pain, for example, by assessing the percentage of patients without cancer who have been on high doses of opioid therapy longer than three months. The National Committee for Quality Alliance (NCQA), for example, is engaged in a comprehensive effort to identify new measures to combat opioid abuse, which includes a draft measure focused on the "Risk of Chronic Opioid Use".[29] We encourage CMS to work closely with NCQA and other measure developers to identify a suitable measure for the Medicare Advantage Program that monitors opioid abuse with a particular emphasis on the harm associated with chronic use.

Forecasting to 2020 and Beyond – Potential Changes to Existing Measures

Telehealth and Remote Access Technologies (Part C)

CMS solicits feedback on the appropriateness of including telehealth and/or remote access technology encounters, as allowed under the current statutory definition of Medicare-covered telehealth services and/or as an MA supplemental benefit, as eligible encounters in various Part C quality measures.[30] Lilly supports the inclusion of these encounters in various Part C quality measures, particularly as it relates to diabetes care and pain management. With this proposal, CMS would take a positive step towards more fully realizing the promise of remote access technology in both lowering costs and improving care. Medicare's current reimbursement system lacks appropriate incentives for providers to experiment with new technology, and these gaps underscore an area where the Medicare program has failed to keep pace with major advances in health informatics and technology. As a recent example, diabetes stakeholders are currently investing in new technologies – including connected devices, mobile health apps and data sharing – to satisfy unmet needs for people with diabetes and to improve outcomes. This form of mobile health technology can integrate diabetes devices and drugs together into "connected systems" that give diabetes patients and providers new insight into dosing patterns and blood glucose levels to support successful self-management, which may reduce the risk of, and costs associated with, long-term hyperglycemia and severe hypoglycemic events among patients requiring insulin.

In addition, telemedicine encounters can also improve the quality of care for patients suffering from various pain conditions by improving access to providers and facilitating more timely diagnosis. For example, data has shown that the number of certified headache sub-specialists is disproportionately small when compared to the total population of patients suffering from migraine, and six states have no certified headache specialists at all.[31] The use of telehealth could greatly improve care in underserved markets, and failing to track these encounters within Part C measures could obscure legitimate quality improvements undertaken by providers. By aligning quality measures to these new technologies – and, crucially, by modernizing

[29] The National Committee for Quality Alliance (NCQA). Proposed New Measure for HEDIS 2019: Risk of Chronic Opioid Use (COU). http://www.ncqa.org/Portals/0/PublicComment/HEDIS-2018/02.%20Risk%20of%20Chronic%20Opioid%20Use.pdf?ver=2018-02-12-095720-590. February 2018.
[30] Centers for Medicare and Medicaid Services (CMS), 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, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf. Pg 146.
[31] Mauser, Emily D., and Noah L. Rosen. "So Many Migraines, So Few Subspecialists: Analysis of the Geographic Location of United Council for Neurologic Subspecialties (UCNS) Certified Headache Subspecialists Compared to United States Headache Demographics." Headache: The Journal of Head and Face Pain, vol. 54, no. 8, 2014, at1347–1357.

reimbursement policies for mobile health technologies and telehealth services at the same time – CMS could enable an ecosystem that supports the experimentation and adoption of new treatment approaches that may significantly improve quality and health outcomes.

Potential New Measures for 2020 and Beyond

Chronic Pain

As stated above, Lilly supports federal and state efforts to combat the opioid crisis using various utilization management and quality metrics to better identify patterns of abuse and diversion. To complement these efforts, however, we urge the agency to create additional opportunities to promote access to novel, non-opioid therapies that can also play a significant role in transitioning patients to safer treatment options for their pain. Beyond the addiction risks, a substantial unmet need also exists relative to inadequate response to existing therapies. Chronic pain conditions, such as osteoarthritis (OA), chronic lower back Pain (CLBP), and cancer pain have a significant economic burden with regard to healthcare utilization, work absenteeism, and loss of productivity – in large part because of the shortcomings of current pain medications in managing chronic pain. In 2010, the economic costs of pain in the US ranged from $560–$635 billion, with $261–$300 billion in additional health care costs and $299–$355 billion in lost productivity.[32] A large majority of patients with moderate to severe OA, CLBP, and moderate to severe cancer pain experience inadequate relief – in addition to a high incidence of opioid usage among these patients.[33] While opioids can be effective in managing acute pain, use of opioids to manage chronic conditions (3 months or greater) such as OA and CLBP does not have a strong body of evidence to support the long-term risk-benefit. Efficacy diminishes while the risk of addiction and the burden of side effects are high. NSAIDs are another mainstay of moderate to severe OA treatment. While effective as rescue medications, NSAIDs carry significant CV risk if used on a chronic basis. Many patients may also lack understanding of appropriate pain management, which can create barriers to informed engagement. In short, measures that raise patient awareness of new, non-opioid therapies for chronic pain are needed.

Migraine-Related Pain

There are currently thirty-six million Americans (12 percent of the population) that suffer from migraines.[34] Migraines can be extremely disabling and costly, accounting for more than $20 billion in direct (e.g. doctor visits, medications) and indirect (e.g. missed work, lost productivity) costs each year in the United States.[35] Potential treatments for both acute and chronic migraine hold the promise of addressing unmet needs in the management of chronic pain that can all too often lead to a dependence on drugs with highly addictive properties, such as opioids. Novel treatments that are focused on prevention of migraine, for example, may also be effective in reducing downstream over-utilization of therapies – particularly those with addictive properties. We urge the agency to work through the Measure Applications Partnership (MAP) and the National Quality Forum (NQF) to expedite the formal endorsement and adoption of the

[32] Gaskin, DJ, Richard P. The economic costs of pain in the United States. Available at: http://www.ncbi.nlm.nih.gov/pubmed/22607834
[33] Bill McCarberg. Tramadol extended-release in the management of chronic pain. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2386353/
[34] American Migraine Foundation. https://americanmigrainefoundation.org/living-with-migraines/types-of-headachemigraine/
[35] American Migraine Foundation. https://americanmigrainefoundation.org/living-with-migraines/types-of-headachemigraine/

following measures from the Headache Work Group Quality Measure Set, which has been convened by the American Academy of Neurology"[36]

- Percentage of Patients with Migraine Headache with Treatment Plans who report adherence to their treatment plan
- Percentage of Patients with Migraine Headache Seen for Migraine in the Emergency Department / Urgent Care / Inpatient Setting
- Preventive Migraine Medication Prescribed

Additionally, we request that CMS, along with the MAP, NQF, and other stakeholders, consider the development of new measures that address both poor response to and overuse of acute treatments for migraine. Recent survey data suggest that patients who report poor acute medication efficacy are 2.5-fold more likely to progress to chronic migraine than patients reporting maximal efficacy.[37] At the same time, overuse of medications intended for acute or symptomatic treatment of migraines may also lead to chronic migraines and/or medication overuse headaches.[38] Quality measures that address non-response and acute medication overuse in migraine patients could improve overall quality of care and positively impact clinical and economic outcomes.

Given the strong interest among measure developers to establish new quality targets across various pain subtypes, CMS could play a critical role with groups such as NCQA, PQA, and relevant professional societies in driving consensus on measures that address unmet needs for pain and minimize the risk of opioid overuse. We ask the agency to convene these groups in a more coordinated effort to create broad alignment on a plan-based measure set that opens up opportunities for providers and patients to move towards safe and effective new treatment options in the management of pain.

Diabetes Care

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 is limited and does not include the use of insulin, which is recommended, either alone or in combination with oral antidiabetics to achieve improved glycemic control. This presents a measure gap, given the vital role that insulin plays for patients in managing the disease and preventing 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, PQA has convened clinicians, researchers, and other stakeholders to closely examine the issue and identify evidence-based, methodologically sound solutions to overcome measurement challenges. PQA is presently examining novel methodologies to measure insulin treatment persistence, identify its predictors, and evaluate the associated clinical and economic

[36] American Academy of Neurology, Headache Workgroup Quality Measure Set. https://www.aan.com/uploadedFiles/Website_Library_Assets/Documents/3.Practice_Management/2.Quality_Improvement/1.Quality_Measures/1.All_Measures/2014%209%20%208%20REVISED%20AAN%20Headache%20Measurement%20Set.pdf2014.

[37] May A, Schulte LH. Chronic migraine: risk factors, mechanisms and treatment. Nat Rev Neurol 2016;12:455–64.

[38] Headache Classification Committee of the International Headache Society (IHS). "The International Classification of Headache Disorders, 3rd edition (beta version)." Cephalalgia 33(9) 629-808. 2013. https://www.ichd-3.org/8-headache-attributed-to-a-substance-or-its-withdrawal/8-3-headache-attributed-to-substance-withdrawal/

outcomes using health plan claims data and records of patients' actual refill times.[39] [40] The development of an insulin adherence measure would lead to improved glycemic / long-term metabolic control, a reduction in additional comorbidities, and relief from the existing economic burden for the approximately 30 percent of patients with diabetes currently being treated with insulin.[41] We encourage the agency to work closely with PQA to identify a feasible way to measure insulin adherence and translate this methodology into a meaningful quality measure within the Medicare Advantage program.

In the context of diabetes care, another measure gap exists relative to the treatment of hypoglycemia, which can inflict a serious human and financial toll on the healthcare system. According to a recent study that quantified the costs associated with emergency department visits or inpatient hospitalization for hypoglycemia, average per person costs were $1,965 for emergency room visits and $11,632 for inpatient admissions.[42] Additionally, based on 8,100 National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance cases, an estimated 97,648 emergency department visits for Insulin-related hypoglycemia and errors (IHEs) occurs annually; almost one-third result in hospitalization.[43] The Endocrine Society, through its Hypoglycemia Quality Collaborative Strategic Blueprint, has called for the development of new measures to support individuals at risk for hypoglycemia across settings of care. The Endocrine Society recommends a focus on measures to improve hypoglycemia risk evaluation through metrics such as individualized HbA1c targets goals, as well as those that use multiple clinical endpoints to better understand glycemic control, such as HbA1c, time-in-range, and hypoglycemia.[44] Moreover, the Pharmacy Quality Alliance (PQA) is testing new measures such as Serious Hypoglycemic Events Requiring Hospital Admission or ED Visit Associated with Anti-Diabetic Medications. Lilly supports these efforts and encourages CMS to work closely with measure developers to support the inclusion of new measures that minimize the risk of dangerous complications and use of costly emergency management services resulting from untreated hypoglycemia in patients with diabetes.

Alzheimer's/Dementia

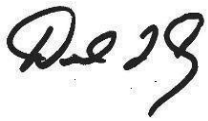
Dementia has been shown to have the most expensive healthcare-related cost of care during the last five years of life, with mean adjusted total health care spending per patient at $287,038 over this time[45]. These costs significantly exceed the total costs incurred for heart disease or cancer in the last five years of life ($175,136 and $173,383, respectively). In the near future, the Alzheimer's disease (AD) treatment paradigm has the potential to shift from a current focus on symptom relief to an actual slowing of disease progression. Therefore, quality

[39] Wei W, Pan C, Xie L, Baser O. Real-World Insulin Treatment Persistence among Patients with Type 2 Diabetes: Measures, Predictors and Outcomes. Endocr Pract. 2014;20:52-61.
[40] Slaubaugh SL, Bouchard JR, Li Y, Baltz JC, Meah YA, Moretz DC. Characteristics Relating to Adherence and Persistence to Basal Insulin Regimens among Elderly Insulin-Naïve Patients with Type 2 Diabetes: Pre-filled Pens versus Vials/Syringes. Adv Ther. 2015; 32:1206-21.
[41] Centers for Disease Control and Prevention. Age-Adjusted Percentage of Adults with Diabetes Using Diabetes Medication, by Type of Medication, United States, 1997–2011. Available at: http://www.cdc.gov/diabetes/statistics/meduse/fig2.htm
[42] Basu, Sanjay MD, PhD; Berkowitz, Seth A. MD, MPH; Seligman, Hilary MD, MAS. The Monthly Cycle of Hypoglycemia: An Observational Claims-based Study of Emergency Room Visits, Hospital Admissions, and Costs in a Commercially Insured Population. http://journals.lww.com/lww-medicalcare/Fulltext/2017/07000/The_Monthly_Cycle_of_Hypoglycemia__An.1.aspx. July 2017.
[43] Andrew I. Geller, MD, Nadine Shehab, PharmD, MPH, Maribeth C. Lovegrove, MPH, Scott R. Kegler, PhD, Kelly N. Weidenbach, DrPH, Gina J. Ryan, PharmD, BCPS, CDE, and Daniel S. Budnitz, MD, MPH. National Estimates of Insulin-related Hypoglycemia and Errors Leading to Emergency Department Visits and Hospitalizations. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4631022/pdf/nihms731980.pdf.
[44] Endocrine Society. Hypoglycemia Quality Collaborative Strategic Blueprint REPORT AND STRATEGIC RECOMMENDATIONS. Accessed August 2017.
[45] Source: The Annals of Internal Medicine. "The Burden of Health Care Costs for Patients With Dementia in the Last 5 Years of Life". November 2015. http://annals.org/article.aspx?articleid=2466364.

measures that prioritize better identification of disease staging, improved communication between physicians and patients, the importance of timely/early diagnosis, and tracking changes in cognitive function are integral to reducing AD-related health risks over time.

Lilly is grateful for the opportunity to comment on the revisions proposed in the CY2019 Draft Call Letter. We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you in the future to help ensure that patients have access to meaningful health care benefits and coverage under the Part D Program. Please do not hesitate to contact Ryan Urgo (urgo_ryan_v@lilly.com) or Derek Asay (Asay_Derek_L@Lilly.com) with any questions.

Sincerely,



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