

January 16, 2018

By Electronic Delivery

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Ms. Verma:

AstraZeneca Pharmaceuticals LP (AstraZeneca) is pleased to submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.¹

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular and Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit www.astrazeneca-us.com.

AstraZeneca appreciates the work done by CMS to solicit stakeholder feedback on potential changes to the Medicare Prescription Drug Benefit Program (Part D) and Medicare Advantage (MA) programs to promote innovation and empower MA and Part D sponsors with tools to improve quality of care and provide additional plan choices for enrollees. We, like CMS, are dedicated to improving the lives of Medicare beneficiaries and are committed to the success of the Part D program. As CMS creates new policies for the Part D and MA programs, we encourage CMS to retain the market-based, competitive foundation on which they were created. Part D and MA have been extremely successful in providing high-quality care to beneficiaries at lower-than-expected cost due to the use of a free-market based system in which plans compete to offer coverage to beneficiaries, and manufacturers and plans negotiate for discounts and rebates. We urge CMS to preserve this approach, which has demonstrated improvements in quality, cost savings, and high patient satisfaction.

AstraZeneca develops and manufactures multiple medicines that fall under the Part D benefit and we recognize our role in supporting the Part D program. Our detailed comments below outline our recommendations to CMS around the proposed changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program.

¹

CMS Proposes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-P) (November 16, 2017), *available at*: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-25068.pdf>

I. Extending the Proposed Medicare Advantage Changes to MA Prescription Drug Plans

CMS has proposed to re-evaluate the uniformity requirements that apply to MA plans to permit additional plan flexibility. Additionally, CMS has proposed to modify the maximum out-of-pocket (MOOP) limit on annual patient cost-sharing for Part A and B covered services. While we support these proposals, we also request that CMS consider whether these proposals also could be extended to Medicare Advantage Prescription Drug plans (MA-PD) to achieve the same objectives.

With respect to uniformity requirements, we appreciate that this additional flexibility may expand the use of value-based insurance design (VBID) models in MA as plans would have increased ability to align incentives under this program. AstraZeneca supports models and demonstrations that grant MA plans greater flexibility to tailor benefit designs, such as VBID. We also believe that CMS' proposed changes to the MA to increase plan flexibility could potentially be tendered to MA-PD plans under certain conditions:

- Commitment to Non-Discrimination Principles – We appreciate CMS' commitment to ensuring that proposals affording additional flexibility to MA plans do not conflict with existing MA non-discrimination principles and that enrollees with similar conditions are offered the same benefits. We recommend that CMS continue to reinforce patient protections and guard against discriminatory practices.
- Stability of Cost-Sharing and Benefit Offering – We recognize that any additional flexibility granted to MA plans will allow them to alter benefit design and care delivery. However, in the interest of patients, we urge CMS to ensure that MA-PD enrollees are not also subject to:
 - significant increases in cost-sharing for other covered items as an offset to supplemental benefits and/or reduced cost sharing in other areas and
 - reduced availability to medicines on a plan's formulary.
- Evidence-Based Value Determination – When determining value and evaluating high-value care under programs like VBID, we encourage CMS to support the use of the full spectrum of available evidence, including real world evidence and clinical and patient-centered measures of quality and value.

With respect to proposed flexibility in setting MOOP limits that pertain to MA Part A and Part B services, AstraZeneca also suggests that CMS consider extending a similar benefit to the MA-PD plans. Enrollees with significant out-of-pocket costs may consider skipping prescription refills or dosages to limit their costs. This issue of non-adherence could lead to avoidable complications for enrollees. We believe extending the MOOP to MA-PD plans could improve adherence to prescribed drug regimens, which could reduce hospitalizations and utilization of Part A and B services.

For example, adherence to treatment in Chronic Obstructive Pulmonary Disease (COPD) is an essential part of optimizing disease management.² Higher adherence levels have been associated with lower healthcare resource use and costs in patients initiating treatment for COPD.³ Despite the benefits of

² Bourbeau J, Bartlett SJ. "Patient adherence in COPD." *Thorax*, 2008;63:831-38.

³ Toy EL, Beaulieu NU, McHale JM, et al. "Treatment of COPD: Relationships between daily dosing frequency, adherence, resource use and costs." *Respir Med.*, 2011;105:435-44; Simoni-Wastila L, Wei YJ, Qian J, et al. "Association of chronic obstructive pulmonary disease maintenance medication adherence with all-cause hospitalization and spending in a Medicare population." *Am J Geriatr Pharmacother.*, 2012;10:201-210.

treatment, adherence to COPD medication remains low.⁴ A US retrospective database study showed that patients with COPD who were new to combined inhaled corticosteroid/long-acting beta-agonist (ICS/LABA) therapy filled their medication approximately four times during the 12-month follow-up period, with each fill only covering an estimated 30 days of treatment.⁵ AstraZeneca markets several products to treat patients with COPD who could benefit from policies that would improve adherence including SYMBICORT® 160/4.5 (budesonide 160 mcg and formoterol fumarate dihydrate 4.5 mcg) Inhalation Aerosol, TUDORZA® PRESSAIR® (aclidinium bromide inhalation powder), and DALIRESP® (roflumilast). Please see the full prescribing information for these products, including Boxed WARNING and Medication Guide, please visit: www.symbicorttouchpoints.com/; www.tudorzahcp.com/; www.daliresphcp.com/.

II. Tiering Exception Requests

We appreciate CMS' recognition that tiering exception requests are an important beneficiary protection. By ensuring that patients can access drugs in a higher-cost sharing tier at the cost-sharing level of a similar drug in a lower cost-sharing tier, tiering exceptions play an important role in ensuring that patients have meaningful access to the drug his or her prescriber believes is most appropriate. Within this proposed rule, CMS has suggested revisions to the Part D tiering exceptions policy, including allowing plan sponsors to impose further limits to tiering exception. CMS did not, however, make changes to its existing policy to exempt specialty tiers from tiering exceptions.

In agreement with PhRMA's recommendation included in their comment letter, we urge CMS to reconsider its position on tiering exceptions for specialty tier drugs and rescind the policy that allows plans the ability to deny tiering exception requests for specialty tier drugs. We concur with PhRMA that current statute gives beneficiaries a right to have tiering exceptions considered 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.

For example, for patients with ovarian and breast cancer, treatment options that are not on a preferred tier may be recommended by a physician and should be considered by plans for tiering exceptions. Among women in the United States, ovarian cancer is the ninth most common cancer and the fifth leading cause of cancer death. The risk of developing ovarian cancer is increased in women with specific inherited genetic abnormalities, including BRCA mutations. Additionally, approximately 155,000 women in the US are living with metastatic breast cancer – the most advanced stage of breast cancer. BRCA mutations account for about 20% to 25% of hereditary breast cancers and about 5 to 10% of all breast cancers.

AstraZeneca markets LYNPARZA® (olaparib) as a maintenance treatment of adult patients with recurrent, epithelial ovarian, fallopian tube or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy, regardless of BRCA status. LYNPARZA is also indicated for the use in adult patients with deleterious or suspected deleterious germline BRCA-mutated (*gBRCA*) advanced ovarian cancer, who have been treated with three or more prior lines of

⁴ Kern DM, Davis J, Williams SA, *et al.* "Comparative effectiveness of budesonide/formoterol combination and fluticasone/salmeterol combination among chronic obstructive pulmonary disease patients new to controller treatment: a US administrative claims database study." *Respiratory Research*, 2015;16:52.

⁵ *Id.*

chemotherapy; patients for this indication are selected for therapy based on an FDA-approved companion diagnostic. LYNPARZA most recently received FDA approval for use in the treatment of patients with germline BRCA-mutated (gBRCAm), HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Please see the full prescribing information online: www.lynparza.com.

LYNPARZA falls within MA-PD specialty tiers. However, for appropriate patients, the clinical profile of LYNPARZA could support its use. Physicians should be able to prescribe treatment options that do not fall on preferred specialty tiers assuming patients have the ability to receive tiering exceptions in those cases where a medicine is necessary for clinical reasons, to avoid adverse reactions, to improve outcomes, and to achieve high levels of adherence, for example.

Further, within CMS' proposed rule, the Agency is proposing additional barriers to tiering exceptions including limiting tiering exceptions for brand name drugs to cost-sharing for an alternative brand name drug for the patient's condition. We agree with PhRMA's comments around the potential negative impact these new regulations could have on beneficiary protections. We urge CMS to reconsider its proposal to impose new barriers to tiering exceptions.

III. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

We commend CMS for its commitment to quality measurement and improvement in MA and Part D. Moving forward, CMS has proposed multiple policies to stabilize the STAR Ratings System for the MA and Part D programs and clarify how measures will be added, removed, and updated.

In agreement with comments provided by PhRMA, we support CMS' proposal to codify aspects of the existing Star Ratings System for the MA and Part D programs for certain processes for which there are well-established measure specifications and methodologies. However, we have concerns with CMS' proposals that would subject new measures to rule-making. The existing process in place for the adoption of a measure is already lengthy and transparent and at times, there is an urgent need to implement quality measures to promote high-quality, safe, evidence-based care and to address public health issues. AstraZeneca believes that an additional regulatory hurdle to measure adoption will slow improvement in quality of care at a time when rapid development of quality measures is warranted.

Quality measures have real implications for care delivery and patient outcomes. Recently, AstraZeneca included comments in support of proposed transitions of care quality measures in response to CMS' *Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information*. Within those comments we suggested that CMS consider including medication-specific components in certain components of the indicators referenced within new HEDIS Transitions of Care measure for use in the Star Ratings Program.

We suggested to CMS that updates to transition of care measures include detailed information on all drug therapies prescribed, broader sharing of discharge information between specialist, patients and caregivers, as well as increased specificity around recommended post-discharge activities could further enhance a new HEDIS Transitions of Care measure. CMS noted that they shared relevant comments from external stakeholders with the National Committee for Quality Assurance (NCQA). We believe organizations like NCQA and the Pharmacy Quality Alliance (PQA) do extensive work to update measures as clinical guidelines change and develop new measures focused on health and drug plans. We therefore

do not believe additional rule-making is necessary, and believe it could slow the important work done to improve quality of care and ultimately patient outcomes.

AstraZeneca has observed the impact of breakdowns in transitions of care first hand in patients with Acute Coronary Syndrome (ACS). Discontinuation of prescribed dual oral antiplatelet (OAP) therapy early after hospital discharge (within 90 days) is associated with an increased risk of death or myocardial infarction (MI)⁶ and an increased risk of ACS-related rehospitalization and coronary revascularization (within 12 months after discharge).⁷ Further, in patients initiated on an OAP at hospital discharge, 30% did not fill their OAP prescription within 30 days of discharge.⁸ Robust transition of care measures could help to limit the number of patients who do not fill their prescriptions post-discharge and reduce harmful patient outcomes. To treat ACS, AstraZeneca manufactures BRILINTA® (ticagrelor) tablets, a P2Y12 platelet inhibitor. BRILINTA is indicated to reduce the rate of thrombotic cardiovascular events in patients with ACS, when administered with aspirin maintenance doses of <100mg. Please see the full prescribing information, including Boxed WARNING and medication guide, attached or online: www.brilintatouchpoints.com.

IV. Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point-of-Sale

CMS has requested feedback on potential future proposals to require Part D plan sponsors to pass through a minimum portion of manufacturer negotiated rebates and all pharmacy price concessions to beneficiaries at the point-of-sale. We appreciate CMS' work to ensure beneficiaries partake in any discounts achieved through pricing negotiations and rebates in the pharmaceutical supply chain, which are very often significant. In 2016, AstraZeneca paid in excess of \$5B⁹ in contractual obligations in the US under which entities such as Medicare and third-party managed-care organizations were entitled to rebates.

Within an analysis by HHS, CMS highlights the growth in reported Direct and Indirect Remuneration (DIR) by Part D sponsors. DIR refers to additional compensation provided to Part D plans or pharmacy benefit managers- including manufacturer rebates- that ultimately changes the final cost of the drug after the point-of-sale. DIR is not included when calculating beneficiary cost-sharing. We are aligned with PhRMA's position that CMS should consider requiring a portion of negotiated manufacturer rebates to be passed through to beneficiaries at the point-of-sale to, most importantly, improve patient affordability.

⁶ Ho PM, et al. "Adverse events after stopping Clopidogrel in post-acute coronary syndrome patients: Insights from a large integrated healthcare delivery system." *Circ Cardiovasc Qual Outcomes*, 2010; 3:303-308.

⁷ Ernst F, Johnston S, Curkendall S, Mozaffarian E, Stemkowski S. "Effect of early clopidogrel discontinuation on rehospitalization in acute coronary syndrome: Results from two distinct patient populations." *American Journal of Health-Systems Pharmacology*, 2011; 68,1015-1024.

⁸ Data on file, 3121101, AstraZeneca.

* Persistency rates are estimates based on retail prescription fills rates and may be higher or lower. Patients are considered to have discontinued therapy if they switch to another OAP molecule, a mail-order pharmacy, or a pharmacy outside of the database. Persistency can be overestimated by nonadherent patients. Data are from a retrospective cohort study of new-to-therapy ACS patients (excluding patients who underwent coronary artery bypass graft surgery) who received an OAP on the last day of hospital stay (n=5,115) from January 2011 to January 2013. The prescription activity of 3,583 patients who filled their first prescription within 30 days post discharge were tracked from hospital discharge to the retail setting. From that, 2,162 patients were included in the persistency analysis. The prescription activity for patients was tracked through 1 year of therapy. Data were obtained from linked IMS databases (insured and cash-paying patients).

⁹ AstraZeneca Annual Report and Form 20-F Information 2016. (pg. 77-78). Accessed at: https://www.astrazeneca.com/content/dam/az/Investor_Relations/Annual-report-2016/AZ_AR2016_Full_Report.pdf

Within PhRMA's comment letter, they detail the potential cost-savings to the government that could be incurred from this type of proposal, potential behavioral changes by plan sponsors and beneficiaries that could occur, as well as detail various scenarios under which CMS could implement such a policy while maintaining confidentiality of propriety, commercially sensitive data from pharmaceutical manufacturers as well as continue to incentivize the competitive nature of the Part D program. We urge CMS to refer to PhRMA comments on this matter and we encourage future, intensive discussions between manufacturers and the Agency as CMS considers a pathway for this policy.

Additionally, we recommend that CMS continue to explore how voluntary innovative payment arrangements may improve patient affordability, including at point-of-sale. AstraZeneca is committed to advancing innovative payment arrangements in both the private and public sectors. We are working with payers across our therapeutic areas to develop innovative, flexible ways to pay for medicines that focus on results, lower out-of-pocket costs, and enable patients to access the right treatments the first time. We now have many innovative arrangements in place that reflect the value of our medicines.

CMS should consider ways to appropriately include prescription drugs in new and existing delivery and payment models in a manner that promotes affordability, patient choice, and high-quality care. We also encourage CMS to ensure that all models create incentives for providers to improve medication adherence, transitions of care, and, particularly for patients with chronic conditions, long-term care management.

V. Extending e-Prescribing Standards to Electronic Prior Authorization (ePA) Transactions

As technology continues to advance in the healthcare environment, we are encouraged by CMS' efforts to promote technological advancements to create a safe, efficient, and interoperable healthcare system. CMS proposes to adopt NCPDP SCRIPT 2017071 as the new e-prescribing standard and AstraZeneca is supportive of this proposal. As a next step, we urge CMS to consider leveraging the e-prescribing platform to support electronic prior authorization. We believe this will bring efficiencies to Medicare's prior authorization system as well as improve access to prescribed medications and adherence to said medicines.

Electronic prior authorization (ePA) automates the prior authorization process by streamlining many of the communications among health care providers, payers and pharmacists. This process has traditionally been carried out through phone calls, paper forms, and faxes between payers and providers work to determine the clinical necessity of a medication. Adoption of ePA can ensure that this process occurs efficiently and reduce prescriptions abandoned at the pharmacy due to delays in prior authorization whereby improving adherence. Further, applying ePA to the Part D program could produce savings, reduce provider burdens and improve patient access. Over 80 % of physicians and clinical support staff say that having access to ePA is a priority and an expectation¹⁰.

VI. Medication Therapy Management (MTM) as "Quality-Improving Activities" under Medical Loss Ratio (MLR) Requirements

We agree with CMS' determination that medication therapy management (MTM) activities undertaken by plan sponsors always count as "quality-improving activities" for purposes of MLR calculations. MLR

¹⁰ Survey commissioned by Surescripts and conducted by Physicians Practice and HIMSS Media from Nov-Dec, 2015, with participation from more than 300 providers, clinical and administrative support staff and EHR vendors across the country. Accessed here: http://surescripts.com/docs/default-source/default-document-library/completepa-survey-campaign-providerinfographic-final_042116.pdf

provides financial incentives for plans to reduce administrative costs and spend more on health care quality-improving activities. Clarification of MTM as “quality-improving activities” serves to incentivize these activities with the goal of ensuring that covered Part D drugs are used to optimize therapeutic outcomes through improved medication use.

VII. Conclusion

AstraZeneca greatly appreciates the opportunity to provide these comments. We look forward to continued engagement with CMS to explore ways to improve the health of Medicare beneficiaries. If you have any questions or would like additional information on these or any other related topics, please contact Christie Bloomquist at 202-350-5542 or via e-mail at Christine.Bloomquist@astrazeneca.com.

Sincerely,

A handwritten signature in cursive script, appearing to read "CBloomquist".

Christie Bloomquist
Vice President Corporate Affairs, North America