



March 2, 2018

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

TRANSMITTED ELECTRONICALLY AT: www.regulations.gov

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

Dear Administrator Verma:

Bristol-Myers Squibb Company (BMS) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS's) "Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter" (Draft Call Letter).¹

BMS is a global biopharma company whose mission is firmly focused on discovering, developing, and delivering innovative, transformational medicines for patients with serious diseases. BMS is a leader in oncology care, developing breakthrough immuno-oncology therapies that improve long-term survival and quality of life for people living with cancer. BMS has been at the forefront of pioneering personalized medicine and patient-specific approaches to life-threatening diseases such as cancer. We are firmly committed to providing high-quality, cost-effective care for patients, including patients receiving services under the Medicare program.

BMS appreciates CMS's efforts to continue to clarify and update its Part D payment policies and monitor the evolving needs of program beneficiaries while ensuring beneficiary access to

¹ 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 2018 Call Letter, February 1, 2018, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf>.

medically necessary medications and services and putting the patient first. With those goals in mind, BMS is offering the comments below for CMS's consideration.

- BMS urges CMS to take steps to ensure that Part D plan formularies are updated as quickly as possible in Medicare Plan Finder when plans add a drug to their formulary so that beneficiaries have the information they need to make the right decision with respect to their prescription drug coverage.
- BMS acknowledges the Agency's efforts to help address the health care crisis in Puerto Rico through the adoption of the low-income subsidy (LIS) adjustment to Puerto Rican plan Star Ratings to account for the fact that Puerto Ricans are ineligible for LIS. Given the ongoing crisis in Puerto Rico, BMS urges CMS to take additional steps within its authority to help mitigate this crisis for Medicare beneficiaries and health care providers.
- BMS asks CMS to consider the Pharmacy Quality Alliance's (PQA's) "*Hospital Admission or Emergency Department Visits for Bleeding Events Associated with Anticoagulant Medications*" quality measure, currently in development, as a display or other measure as part of the Part D Star Ratings system for CY 2019.
- BMS supports including the *Adherence to Non-Warfarin Oral Anticoagulants* measure within the quarterly outlier reports to Part D contracts through the Patient Safety Analysis Website in the future, along with the beneficiary-level data so contracts can focus adherence improvement efforts for these members.

These comments are addressed in detail below.

1. BMS Asks CMS to Ensure That Formularies Are Updated As Quickly as Possible in Medicare Plan Finder, Particularly During the Annual Open Enrollment Period, So Beneficiaries Can Make Fully Informed Decisions When Choosing Part D Plans

Medicare Plan Finder is a CMS tool designed to assist beneficiaries in identifying the best Medicare Advantage or Prescription Drug Plan based a plan's prescription drug coverage and/or provider offerings. During Open Enrollment, beneficiaries use Plan Finder to determine whether prescribed medications are covered and to calculate their annual cost-sharing.

BMS is concerned that Medicare Plan Finder is not always updated in time for the Open Enrollment period. In many instances, Part D plan sponsors do not complete contract negotiations with manufacturers until after the deadline outlined by the Medicare Parts C and D Plan Calendar.² Delays in contracting decisions and the length of time it takes to update Plan Finder impacts a plan's ability to accurately reflect whether a particular drug is on a plan's formulary during the beneficiary annual Open Enrollment period³. When this occurs, Plan Finder is an

² Draft Call Letter, page 104.

³ *Id.*

inaccurate resource for beneficiaries who rely on the tool to evaluate whether their current prescription drug regimen would be covered by a plan and at what tier or cost-sharing amount. Beneficiaries, therefore, are unable to make informed decisions when choosing prescription drug coverage which in turn does not allow for a fully transparent process.

CMS already prohibits Part D plans from removing prescription drugs from their formularies during the Open Enrollment period and during the first sixty days of the plan year except where the Food and Drug Administration has determined that a drug is unsafe.⁴ We respectfully request that CMS accelerate the timeframe in which the information in Medicare Plan Finder is updated when a plan adds a drug to its formulary, particularly prior to and during the Open Enrollment window, so that beneficiaries have access to the information they need to make the best choice possible as to their prescription drug coverage. We would also suggest that CMS consider publishing an abridged update of additional medications that are added to plan formularies prior to Open Enrollment that could be posted to Medicare.gov website and would provide necessary transparency for beneficiaries – especially those with high drug costs.

2. BMS Acknowledges CMS Efforts to Address the Health Care Crisis in Puerto Rico but Urges CMS to Take Additional Steps to Address This Pressing Concern

BMS acknowledges the continued efforts CMS has taken to address the ongoing health care and financial crisis⁵ in Puerto Rico through the provision of an additional adjustment to address the lack of a Low Income Subsidy (LIS) indicator for enrollees in Puerto Rico.⁶ Congress attempted to address the lack of LIS for Medicare beneficiaries in Puerto Rico by providing for Medicaid coverage of prescription drugs, known as the enhanced allotment program (EAP).⁷ However, a Congressional task force⁸ concluded that the Medicaid prescription drug coverage available through EAP is inadequate to account for the lack of LIS for Puerto Rican Medicare beneficiaries. With approximately 46 percent of Puerto Ricans living below the poverty line, and a growing population of citizens eligible for Medicare,⁹ this lack of LIS in Puerto Rico has had and likely

⁴ MPDM, ch. 6, § 30.3.2.

⁵ See United States Congress, Congressional Task Force on Economic Growth in Puerto Rico: Report to the House and Senate, at 26 (Dec. 20, 2016) (recommending steps to make funding for Medicaid and Medicare in Puerto Rico more equitable to help address the health care crisis), available at <http://www.finance.senate.gov/imo/media/doc/Bipartisan%20Congressional%20Task%20Force%20on%20Economic%20Growth%20in%20Puerto%20Rico%20Releases%20Final%20Report.pdf>; Letter from the Financial Oversight and Management Board for Puerto Rico to The Honorable Alejandro García Padilla, Governor of Puerto Rico (Dec. 20, 2016) (outlining the financial concerns that Puerto Rico continues to face and steps it must take to address this situation).

⁶ 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 2018 Call Letter, February 1, 2018, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf>, page 133.

⁷ United States Congress, Congressional Task Force on Economic Growth in Puerto Rico, 26

⁸ *Id.*

⁹ *Id.* See also Kaiser Family Foundation, 8 Questions & Answers about Puerto Rico, <http://kff.org/disparities-policy/fact-sheet/8-questions-and-answers-about-puerto-rico/>, Updated Sept. 26, 2016. QWWWWWW

will continue to have a substantial impact on the Puerto Rican Medicare population. CMS's decision to provide for a Star Ratings adjustment to account for the fact that LIS is not available in Puerto Rico¹⁰ was an important step toward treating Puerto Rico equitably, especially in light of the ongoing crisis.

Hurricane Maria placed additional pressure on the territory's already strained health care system especially for citizens in need of immediate medical care. It has been widely reported that many physicians are leaving the island due to Puerto Rico's struggling financial crisis leaving many municipalities without enough clinicians and triggering a cascade of problems for patients and hospitals.¹¹ BMS urges CMS to take additional steps within its authority to mitigate the impact of the ongoing health care crisis.

Exacerbating the gap in spending on prescription drug coverage for Medicare beneficiaries in Puerto Rico, the territory received \$5,790 in Medicare Advantage (MA) spending per enrollee compared to \$8,700 in U.S. states based on 2014 data.¹² It experiences the highest national prevalence of certain types of disease compared to the rest of the United States, including diabetes and hypertension, and has a high incidence of certain cancers, a leading cause of death in the region.¹³ HHS has taken some steps to address this issue, but the gravity of the crisis merits additional action. CMS should continue to examine what immediate steps it can take within its existing authority to help mitigate the crisis for Puerto Rican Medicare beneficiaries, such as exempting Puerto Rico from the same calculations and adjustments as required for the contiguous US which had been standard practice prior to the Affordable Care Act. And, the agency should work with Congress to support longer-term statutory changes to ensure that Puerto Rico is treated equitably when it comes to health care resources and policy to redress the current funding and health outcomes gap.

The previous Administration indicated that the exclusion of the Part D LIS for territories should be eliminated – however no action was taken. Likewise, certain market reforms enacted as part of the Affordable Care Act for states were never extended to territories, which could have provided stability to health plans. While CMS has proposed several adjustments in the CY 2019 Advance Call Letter, we note that Administrator Verma indicated during her confirmation hearing that, "Every effort should be made to ensure that Medicare Advantage plans in Puerto Rico are being fairly and properly compensated for the services they provide."¹⁴ We believe additional assistance is needed to provide long-term viability for Puerto Rico's MA program which is the backbone for the island's healthcare system.

¹⁰ CMS, Supporting Medicare in Puerto Rico, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-04-2.html> (April 4, 2016).

¹¹ Puerto Rico's Exodus of Doctors Adds Health Care Strain to Dire Financial Crisis, NBC News reported by Mariela Patron, August 8, 2017.

¹² Maria Levis, The Price of Inequality for Puerto Rico, *Health Affairs* (Dec. 29, 2015), available at <http://healthaffairs.org/blog/2015/12/29/the-price-of-inequality-for-puerto-rico/#one>.

¹³ Center for Disease Control & Prevention, Invasive Cancer Incidence, 2007-2011, *Morbidity and Mortality Weekly* (August 17, 2015), available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a5.htm>.

¹⁴ Confirmation hearing transcript, February 16, 2017.

3. BMS Urges CMS to Adopt PQA's New Anticoagulation Measure, Currently in Development, for CY 2019 Star Ratings

At a minimum, BMS requests that CMS consider the Pharmacy Quality Alliance (PQA) *"Hospital Admission or Emergency Department Visits for Bleeding Events Associated with Anticoagulant Medications"* metric for inclusion as a Star Rating system display or other measure for CY 2019 and beyond. BMS is optimistic that the measure will be fully developed by the end of 2018. Because the measure is focused on reducing adverse drug events due to anticoagulation, it will have the desired effect of improving patient safety and outcomes. For this reason, BMS urges CMS to include the PQA measure in the Medicare Star Ratings at the earliest opportunity. As a first step, BMS requests that the measure appear as a display measure in 2019 for inclusion in the CY 2020 Star Ratings.

PQA's measure is being established to address two key objectives in the HHS *"National Action Plan for Adverse Drug Event Prevention"*:¹⁵ (1) the identification of "common, preventable, and measurable adverse drug events (ADEs) that may result in significant patient harm;" and (2) the alignment of "efforts of Federal health agencies to reduce patient harms from these specific ADEs nationally."¹⁶ The ADE Action Plan identifies three high priority targets:

- Anticoagulants (with bleeding as the primary ADE of concern);
- Diabetes agents (with hypoglycemia as a primary ADE concern); and
- Opioids (with accidental overdoses, over-sedation, and respiratory depression as primary ADEs of concern).¹⁷

While there are existing Star measures for diabetes agents and opioids, there is not a measure for reducing hospital admission or emergency department visits due to bleeding events. BMS believes that PQA's expected new measure will ably address this gap in existing measures and allow the Federal government to address its target to reduce bleeds due to anticoagulation therapy.

In addition, BMS believes that the National Quality Forum's (NQF's) Measure Evaluation criteria serve as a useful framework for CMS to evaluate this measure for purposes of determining whether it should be added to the Star Rating system.¹⁸ These criteria include the following components:

¹⁵ HHS, Office of Disease Prevention and Health Promotion, National Action Plan for Adverse Drug Event Prevention (2014).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ NQF, Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement, http://www.qualityforum.org/Show_Content.aspx?id=322 (effective Aug. 2016).

- a) **Importance to Measure and Report.** HHS's ADE Action Plan states that *"there remains a need for measure concepts that track centrally important markers of anticoagulant safety (e.g., bleeding)"* as opposed to measures that address the "appropriateness of anticoagulation use."¹⁹ The expected PQA measure, which is focused on hospital admissions for patients on anticoagulants, helps to address anticoagulants safety and therefore is "important to making significant gains in healthcare quality where there is variation in or overall less-than-optimal performance."²⁰
- b) **Scientific Acceptability of Measure and Feasibility.** PQA is currently testing this measure with a focus on feasibility with plans for a socio-demographic status adjustment.
- c) **Usability and Use.** Using PQA's expected anticoagulation measure, plans could perform analyses of the relative risk of different anticoagulation medicines when structuring their formularies, both as to what should be included on those formularies and as to how they should be covered in terms of cost-sharing.
- d) **Uniqueness.** As stated above, because this measure focuses on anticoagulant safety, it fills a current gap in the cardiovascular measure space.

Based on these criteria, PQA's expected anticoagulation measure would be a positive addition in the Star Ratings system. BMS appreciates CMS's consideration of this measure as part of the Star Ratings for plans participating in Part D.

4. Additional Adherence Measure: Adherence to Non-Warfarin Oral Anticoagulants

CMS evaluated and declined to move forward on a PQA endorsed medication adherence measure for Adherence to Non-Warfarin Oral Anticoagulants (ADH-NWOA). The measure assesses the percentage of patients 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80 percent during the measurement period for non-warfarin oral anticoagulants.

We understand the use of data within the Medicare Part D population using 2016 Prescription Drug Event (PDE) data and anticipate the 2017 data will yield significant improvement in the low denominator issue seen in the Agency's analysis²¹ (37 percent of Medicare Advantage prescription drug and Prescription Drug Plan contracts had thirty or fewer member-years in the denominator for the ADH-NWOA measure). We support including this measure within the quarterly outlier reports to Part D contracts through the Patient Safety Analysis Website in the future, along with the beneficiary-level data so contracts can focus adherence improvement

¹⁹ HHS, Office of Disease Prevention and Health Promotion, National Action Plan for Adverse Drug Event Prevention, 76 (2014) (emphasis added).

²⁰ National Quality Forum, Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement, 7, http://www.qualityforum.org/Show_Content.aspx?id=322 (effective August 2016).

²¹ Draft Call Letter, page 104.

efforts for these members. We support comments submitted on this issue the Pharmaceutical and Research Manufacturers of America and also request that CMS revisit this analysis later in 2018 as the uptake of these novel agents has been significant throughout 2017.

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BMS thanks CMS for the opportunity to comment on the Draft Call Letter and appreciates its time and consideration. We would be happy to discuss these comments with you. If you have any questions, please do not hesitate to contact Christopher Dezii at (609) 302-3670 about the PQA quality measures or Amy Demske at (202) 783-8665 about other issues discussed in this letter.

Sincerely,



Tamar Thompson

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