Bristol-Myers Squibb
State and Federal Payment Agency Team
3401 Princeton Pike, Lawrence Township, NJ 08648

January 16, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Transmitted Electronically at: AdvanceNotice2018@cms.hhs.gov

BY ELECTRONIC DELIVERY

Re: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program [CMS-4182-P; RIN 0938-AT08]

Dear Administrator Verma:

Bristol-Myers Squibb Company (BMS) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule, "**Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program [CMS-4182-P; RIN 0938-AT08]**" ("Proposed Rule").[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 have a legacy of transforming patient outcomes in major diseases such as cardiovascular disease, HIV, and HCV. 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 medically necessary medications and services through patient-centered policies. With those goals in mind, BMS is offering the comments below for CMS's consideration. BMS also is recommending a new

[1] 82 Fed. Reg. 56336, November 28, 2017.

anticoagulation quality measure for adoption as a display measure as part of the CY 2019 Star Ratings system for Part D plans.

BMS's comments are summarized as follows:

- BMS urges CMS to reconsider codification of the Parts C and D Star Ratings program because the current program is working to improve patient access to quality health care. The proposed changes to the program will be duplicative when there are already transparent processes in place throughout the measure development process to provide stakeholder input. These proposals also do not provide a pathway for expedited approval and implementation of measures into the Star Ratings program that address public health emergencies or preventable adverse drug events.
- Consistent with CMS's commitment to improve quality measures, 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 the late stages of development with endorsement potentially by mid- to late 2018, as a display or other measure as part of the Part D Star Ratings system for CY 2019.
- BMS supports the comments provided by the Pharmaceutical Research Manufacturers of America (PhRMA) and Biotechnology Industry Organization (BIO).

These comments are addressed in detail below.

1. **BMS Urges CMS to Reconsider Codification of the Parts C and D Star Ratings Program.**

BMS appreciates the opportunity to comment on the Proposed Rule regarding the CMS Star Rating Program which has served the nation well for the accountability of care via measures and represented a good start in advancing the quality of care. The proposed codification for measure addition, which appears redundant to the current processes, seems to "freeze" the uptake of new metrics until 2024. Continuous quality improvement needs to address the requirements of the population and the rule proposed does not provide any mechanism to mitigate emerging crises such as bleeding from anticoagulation noted in the HHS Action Plan for Adverse Drug Event Prevention.[2] Failure to improve care via expansion of the measure set, which all can agree, is not currently comprehensive, impacts mostly vulnerable groups and, frankly, renders better care as expendable.

We recommend the addition and/or augmentation of processes that would expedite the current rules in advancing measures that matter to patients, especially outcome metrics. Developing outcome measures should be given priority status in updating the program, and a mechanism is required to do such. We understand that accountability can be difficult and challenging. However, these challenges must be met with the resolve to deliver the highest quality care possible based upon gaps in care.

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

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

BMS requests that CMS consider the 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.

Anticoagulants are used to treat many thromboembolic disorders, including nonvalvular atrial fibrillation (AF). The prevalence of AF in the U.S. is estimated to be between 2.7-6.1 million people.[3] Complications due to AF result in over 750,000 hospitalizations each year and contribute to nearly 130,000 deaths per year.[4] The AF patient population may have serious or life-threatening comorbidities, on top of the complexities of translating clinical trial outcomes into clinical practice. The annual costs of AF in the U.S. are more than $6 billion.[5]

Anticoagulants are safe and effective for the management of AF, but major bleeds can occur as a result of anticoagulation therapy. These adverse events can be serious or life-threatening and carry significant costs to the healthcare system. For example, a Medicare claims study that assessed the costs of major bleeds in patients with AF found that the annual reimbursed healthcare costs were $39,943.[6] Having a Star Rating aimed at incentivizing plans to focus on reducing adverse drug events in the Medicare population receiving anticoagulation therapy advances the Administration's goal of reducing adverse drug events in the Medicare population and is also consistent with the HHS Action Plan for Adverse Drug Event Prevention. [7]

PQA's measure is being established to address two key objectives in the Action Plan:[8] (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."[9] 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).[10]

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[3] Centers for Disease Control, National Center for Chronic Disease prevention and Health Promotion, Division for Heart Disease and Stroke Prevention. Atrial Fibrillation Fact Sheet. https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm

[4] AF Fact Sheet.

[5] AF Fact Sheet.

[6] Mercaldi CJ, Ciarametaro M, et al. *Cost Efficiency of Anticoagulation with Warfarin to Prevent Stroke in Medicare Beneficiaries with Nonvalvular Atrial Fibrillation*. Stroke 2011 Jan 42(1):112-8.

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

[8] Id.

[9] Id., 1.

[10] Id.

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. Given the inclusion of anticoagulants in the ADE Action Plan, it would be a missed opportunity to improve patient outcomes and reduce the cost of adverse drug events in the Medicare population to allow this measure to remain in limbo until 2024, which the rule proposes as the new timeline for Star Rating implementation.

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.[11] These criteria include the following components:

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."[12] 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."[13]
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.

3. **BMS Supports PhRMA and BIO Comments.**

BMS is a member company of both the Pharmaceutical Research Manufacturers of America (PhRMA) and Biotechnology Industry Organization (BIO). As such, BMS supports their comments submitted in response to this proposed rule.

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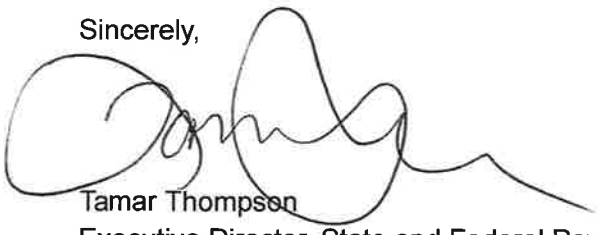
[11] NQF, Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement, http://www.qualityforum.org/Show_Content.aspx?id=322 (effective Aug. 2016).

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

[13] 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).

BMS thanks CMS for the opportunity to comment on the Proposed Rule 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 measure and Amy Demske at (202) 783-8665 for other questions.

Sincerely,



Tamar Thompson
Executive Director, State and Federal Payment Agencies
Value, Access and Payment
Bristol-Myers Squibb Company
Tamar.Thompson@bms.com
(202) 783-8617