Final Version: Submitted in Response to Online Format Required by CMS
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BIO Draft Comments in Response to the 2017 Star Ratings Update Request for Comments[1]

Note to Members: CMS requires that responses to individual proposed updates be submitted through an online form individually. Given these formatting requirements, BIO's draft comments will not follow our traditional comment letter format.

The Centers for Medicare & Medicaid Services (CMS) issued a "Request for Comments" (RFC), in which the Agency proposes methodology changes for the 2017 Star Ratings and display measures for Medicare Advantage (MA) and Prescription Drug Plans (PDPs). It also provides advanced notice of potential changes for the Star Ratings and display measures for 2018 and beyond. CMS asks for feedback on these proposals by 5 PM EST on December 10, 2015. There will be another opportunity to comment on these proposals as part of the annual MA/Part D Call Letter process next spring.

Section B(2): Removal of Measures from Star Ratings, High Risk Medication (Part D)

BIO supports the proposal to remove the High Risk Medication (HRM) measure from the Star Ratings and move it to the display measures for 2017. We agree that avoiding the utilization of potentially inappropriate medications for Medicare patients is an important quality of care metric, but that the HRM measure for Part D beneficiaries addresses this issue only tangentially. Moreover, this measure may be inadvertently applied in a punitive manner, disadvantaging plans that enroll certain types of patients who require therapies on the HRM list. As CMS notes in the RFC, therapies on the HRM list are not contraindicated for use in the Medicare population, but instead, placement on the list is meant to denote the need for clinicians to take particular care in weighing the benefits and risks of utilization in this population. The decision to prescribe the therapy should be made based on the clinical circumstances of an individual patient, circumstances not comprehensively described by prescription drug event (PDE) data, on which the HRM measure is based. Thus, even when an HRM-listed therapy is the most clinically appropriate treatment for an individual Medicare beneficiary, this measure may penalize the plan in which the beneficiary is enrolled by negatively impacting its Star Rating. When moved to the display measures, the HRM measure will still be reported to providers on a monthly basis, such that its potential to inform, but not unduly influence, clinical behavior will persist. For these reasons, BIO urges CMS to finalize the RFC proposal to remove the HRM measure from the Star Ratings and move it to the display measures for 2017.

Section H: Measurement and Methodological Enhancements

BIO asks CMS to explore the addition of Star Ratings measures specific to two therapeutic areas relevant to the Medicare population: psoriasis and rheumatoid arthritis (RA). First, BIO suggests the development of a plan-level measure to address treatment of psoriasis. In the 2016 Medicare Physician Fee Schedule Final Rule, CMS adopted the measure "Psoriasis: Clinical Response to Oral Systemic or Biologic Medications" within the Physician Quality Reporting System.[1] In doing so, CMS noted that the measure represents a National Quality Strategy domain gap in that it addresses person and caregiver centered experience and outcomes. Development of a plan-level measure for the Star Ratings will help to align

[1] CMS. 2015. Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond, available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf.

incentives across CMS' quality reporting programs and improve care for this common chronic condition.

Second, BIO recommends that CMS consider incorporating more granular and outcomes-based measures related to the treatment of RA in the Star Ratings program. Despite the availability of numerous treatment options for Rheumatoid Arthritis (RA), there continues to be a large number of patients who are inadequate responders. Some of the barriers to treatment escalation for patients and physicians result from concerns about injection experience, side effects, out-of-pocket cost requirements, and other patient access issues.[2][3] As a result, many patients are not achieving remission or necessary treatment escalation goals at an appropriate time.[4] Only about one-third of patients achieve clinical remission of RA and up to 40 percent of patients still experience moderate or high disease activity after one year of receiving biologics. Taken together, up to two-thirds of patients with RA are insufficiently controlled on their current therapy.[5][6] If patients fail to achieve treatment goals, it may contribute to irreversible disease progression.

Inadequate response to RA treatment can also lead to increased healthcare resource utilization and costs. RA is a chronic disease with a prevalence that increases with age, and as patients accrue dysfunction and damage over time, their level of disability also increases. The economic burden of inadequately treated RA can include increased healthcare spending on patient care as well as other indirect costs resulting from such disability. Higher costs arising from the complications of RA vary significantly depending on the patient's level of disease activity. Moderate or high disease activity can lead to structural damage, disability, increased risk of cardiovascular events, and increased healthcare resource utilization, including higher rates of hospitalizations, joint surgery, and durable medical equipment (DME) utilization.[7][8]

Given these risks, we remain concerned that existing quality measures for RA do not sufficiently reflect clinically meaningful characteristics of the disease. To achieve this goal, BIO asks CMS to incorporate Star Ratings measures that enable health plans and providers to classify RA patients according to their level of disease activity, and assess whether they have been initiated on an appropriate treatment as indicated by their disease activity. A 2011 study by Curtis et al. demonstrated a validated algorithm that relies on prescription claims data to identify an RA patient's level of disease activity (i.e, low or high).[9] Working with stakeholders to adapt this approach, future quality measures could be significantly more granular by taking patients' disease activity into consideration and setting up high-risk RA patients for the best possible outcomes. Additionally, to the extent possible, we encourage CMS to shift to more outcomes-focused Star Ratings measures for RA that are aligned with current clinical guidelines. A focus on outcomes-based measures can help advance the current standard of care in ways that can improve patient health and reduce costs associated with ongoing complications associated with uncontrolled RA.

Endnotes:
[1] 80 Fed. Reg. 70,886 (November 16, 2015).
[2] Wolfe F., and K. Michaud. 2007. Resistance of rheumatoid arthritis patients to changing therapy: discordance between disease activity and patients' treatment choices. *Arthritis & Rheumatology* 56(7):2135-2142.
[3] Solomon D.H., A. Bitton, J. N. Katz, H. Radner, E. Brown, and L. Frarnkel. 2014. Treat to target in rheumatoid arthritis: fact, fiction, or hypothesis? *Arthritis & Rheumatology* 66(4):775-782.
[4] Harrold L. R., J. T. Harrington, J. R. Curtis, *et. al*. 2012. Prescribing Practices in a US cohort of Rheumatoid Arthritis Patients Before and After Publication of the ACR Treatment Recommendations. *Arthritis & Rheumatology* 64(3):630-638.

[5] Harrold L., G. W. Reed, N. Boytsov, *et. al.* 2015. Combination therapy, switching and persistence patterns by longitudinal disease activity strata in patients with rheumatoid arthritis [abstract]. *Arthritis & Rheumatology* 67 (suppl 10).
[6]Shahouri S.H., K. Michaud, T. R. Mikulus, *et. al.* 2011. Remission of rheumatoid arthritis in clinical practice: application of the American College of Rheumatology/ European League Against Rheumatism 2011 remission criteria. *Arthritis & Rheumatology* 63(11):3204-3215.
[7] Stephens S., M. F. Botteman, M. A. Cifaldi, *et. al.* 2015. Modelling the cost-effectiveness of combination therapy for early, rapidly progressing rheumatoid arthritis by simulating the reversible and irreversible effects of the disease. *BMJ Open* 5(6):e006560.
[8] Solomon D.H., G. W. Reed, *et. al.* 2015. Disease activity in rheumatoid arthritis and the risk of cardiovascular events. *Arthritis & Rheumatology* 67(6):1449-1455.
[9] Curtis J.R., J. W. Baddley, *et. al.* 2011. Derivation and preliminary validation of an administrative claims-based algorithm for the effectiveness of medications for rheumatoid arthritis. *Arthritis Research & Therapy* 13(5):R155.