June 13, 2017

BY ELECTRONIC DELIVERY

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices (CMS-1677-P)

Dear Administrator Verma:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS's) Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Proposed Policy Changes and Fiscal Year 2018 Rates Proposed Rule (the "Proposed Rule"),[1] including with respect to CMS's Request for Information on policy proposals to better achieve transparency, flexibility, simplification, and innovation in the Medicare program.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

1 82 Fed. Reg. 19,796 (April 28, 2017).

BIO supports the development and use of appropriate, evidence-based quality measures throughout the healthcare system as a component of improving efficiency and clinical outcomes; additionally, we support policy proposals driven at increasing access to innovative care. Our comments, as you will see in the balance of this letter, are divided into two sections – the first focusing on the proposals contained in the FY 2018 Proposed Rule, and the second for providing feedback on the Request for Information.

FY 2018 Hospital Inpatient Prospective Payment System Proposed Rule

BIO's comments focus on several proposals including CMS's review of New Technology Add-on Payment Applications, the Hospital Value-Based Purchasing Program, the Hospital Inpatient Quality Reporting Program, the PPS-Exempt Cancer Hospital Quality Reporting Program, and the Long-Term Care Hospital Quality Reporting Program. Discussed in greater detail below:

- CMS should revisit the methodology used to calculate and recalibrate Medicare Severity-Diagnosis Related Groups (MS-DRGs) relative weights to seek out opportunities to adequately account for innovative treatment options and care for patients with rare diseases.
- Further, related to the MS-DRG system:
    - CMS should correct the issue of the inappropriate reassignment of autologous and allogenic transfusions within the MS-DRGs.
    - CMS should finalize the proposal for reclassification of certain cases of precereberal occlusion and transient ischemia when treated with tPA in the MS-DRGs.
- CMS should work to further improve the review of New Technology Add-on Payment (NTAP) applications. BIO has ongoing concerns about CMS's application of the criteria for determinations in the case of NTAP status, and potential impediments to new and innovative treatments as a result of this process.
- CMS should ensure that the consideration for extension of end-of-life measures from the PPS-Exempt Cancer Hospital Quality Reporting Program to the Hospital Inpatient Quality Reporting Program (IQRP) are appropriate for the populations served in the IQRP, patient-centric, and reflective of the care being provided in these settings.
- CMS should consider appropriate quality measures to ensure vaccination coverage and rates across programs by:
    - Reinstating the IMM-2 influenza immunization measure in the Hospital Value-Based Purchasing Program, which has been removed beginning with the FY 2018 performance year.
    - Retaining NQF #1659 "Influenza Immunization (IMM-2)" and NQF #0431 "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)" and revisiting the decision to remove IMM-1 (pneumococcal immunization measure) in the Hospital Inpatient Quality Reporting Program.
    - Retaining the previously finalized measure NQF#0431 "Influenza Vaccination Coverage among Healthcare Personnel (HCP)" for the PPS-Exempt Cancer Hospital Quality Reporting Program.
    - Revising, as proposed, the data collection period for NQF #0680 "Percent of Residents or Patients Who Were Assessed and Appropriately Given the

Seasonal Influenza Vaccine (Short Stay)" in the Long-Term Care Hospital Quality Reporting Program.
- Expanding the use of a herpes zoster vaccination measure, consistent with other programs, into the Hospital Inpatient Quality Reporting Program.

Hospital Inpatient Prospective Payment System Request for Information
In addition to our comments on the FY 2018 Proposed Rule detailed above, BIO would also like to provide the following feedback regarding the included Request for Information:

- CMS should further refine the MS-DRG system to appropriately account for and reflect patients with rare and orphan diseases, and to advance access to innovative treatment options.
- CMS should focus on opportunities to increase access to innovative treatment options for Medicare beneficiaries through NTAP by considering revisions to NTAP application determinations and appropriately accounting for the impact of NTAP in regulatory economic analyses.
- CMS should consider means to appropriately account for uninsured and underinsured care in Disproportionate Share Hospital (DSH) eligibility criteria calculations.

* * *

FY2018 Hospital Inpatient Prospective Payment System Proposed Rule Comments

I. CMS should revisit the methodology used to calculate and recalibrate Medicare Severity Diagnosis-Related Groups (MS-DRGs) relative weights to seek out opportunities to adequately account for innovative treatment options and care for patients with rare diseases.

As in previous years, CMS has proposed to calculate the MS-DRG relative weights for FY 2018 based on both claims data and hospital cost-report data from prior years, and proposes to continue the policy of removing statistical outliers from the data used for these calculations.[2] As a result, the MS-DRGs may in many cases be inadequate to account for patients with rare diseases. CMS also notes that the proposed rule "provides additional precision in our description of the methodology for 2018,"[3] but BIO finds that this additional description falls short in supplying further details of how to incorporate rare diseases and new, innovative into the MS-DRG calculus. CMS in the past has recognized the importance of ensuring patients with rare disorders have "adequate access to care and receive the necessary treatment,"[4] however this Proposed Rule and previous versions have not addressed adequate payments for necessary treatment through the MS-DRG system. Further, for novel therapies, the MS-DRG payments can present a barrier for appropriate valuation and thereby access to new treatments. BIO encourages CMS to work to identify ways to best incorporate the treatment of rare diseases and these new products into this calculation.

2 82 Fed. Reg. 19,816 (April 28, 2017).
3 Id. at 19,865.
4 77 Fed Reg. 52,258, 53,312 (August 31, 2012).

While we recognize that there are inherent challenges to making such determinations, since by definition these cases are not common enough to influence the relative weights of the MS-DRGs to which they are assigned, BIO urges CMS to explore opportunities to better account for these cases, particularly in light of continued innovative treatment advances. There are several avenues that CMS could explore to determine how to best account for orphan and rare disease treatments within the current system, including the creation of new MS-DRGs for specific patient subclasses with similar clinical needs, resource use, and length of stay. These cases may be identifiable by both diagnosis and targeted drug intervention. First, the increased granularity in the ICD-10 system should enable CMS to identify the frequency and magnitude of under-reimbursed disease states. Additionally, CMS could look to specific hospitals or centers of excellence in the management of certain subclasses of disease to seek out standards and protocols of care that would be best served by a new MS-DRG for a rare disease. BIO urges CMS to further investigate this issue and work closely with stakeholders in the rare disease space to seek out opportunities to improve the MS-DRG system for these patients in the hospital inpatient setting and to address the continued advancements in care and treatment.

II. Further, related to the MS-DRG system:

a. CMS should correct the issue of the inappropriate reassignment of autologous and allogenic transfusions within the MS-DRG system.

In the Proposed Rule, CMS shifted 20 autologous and allogeneic ICD-10 PCS transfusion codes from operating room (OR) status to non-OR status which has resulted in inappropriate reassignment of these codes to various MS-DRGs – moving from one of three MS-DRGs to over 70 different MS-DRGs with reduced payment rates.[5] BIO supports the appropriate reimbursement and coverage of these services, to ensure Medicare patients receive timely and appropriate treatment, by reassigning these transplant transfusion codes back into the appropriate MS-DRGs.

b. CMS should finalize the proposal for reclassification of certain cases of precereberal occlusion and transient ischemia when treated with tPA in the MS-DRG system.

In the Proposed Rule, CMS seeks to add clarity for cases of precereberal occlusion and transient ischemic attack for patients treated with tPA to reflect appropriate payment for the resources involved in evaluating and treating these patients by reclassifying certain cases in the MS-DRG.[6] CMS notes that a small number of cases would be captured in the new proposal, but believes this change will more accurately reflect proper payment for stroke care and use of tPA. BIO believes this change sets positive precedent for appropriate coding and payment practices and supports this change.

III. CMS should work to further improve the review of New Technology Add-on Payment (NTAP) applications.

5 See: National Marrow Donor Program. Medicare Policy Analysis: FY 2018 IPPS Proposed Rule. Available at: https://network.bethematchclinical.org/workarea/downloadasset.aspx?id=15547.
6 82 Fed Reg. 19,824 (April 28, 2017).

For FY 2018, CMS notes its received nine NTAP applications, addressing six in the proposed rule as three applications were withdrawn,[7] and details continuation of NTAP status for technologies approved for FY 2017 add-on payments into FY 2018. BIO is supportive of the continuation of NTAP status for products approved in FY 2017 into 2018, as proposed.[8] However, as in our previous comments to CMS around NTAP application determinations, BIO is concerned that CMS continues to be overly critical of the data provided in NTAP applications to support the existence of a "substantial clinical improvement," and often has failed to take into account clinical improvements of particular relevance to Medicare beneficiaries as a part of the assessment of applications. Of note, CMS states in the proposed rule that, "a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations of physician visits, or reduces recovery time comparable to the technologies previously available."[9]

As with the comment from the public input sessions on NTAP addressed in the Proposed Rule, BIO is supportive of making the NTAP process more patient-focused by including the suggested criteria listed by one commenter: (1) prohibiting local MACs from denying coverage and add-on payments for new medical services or technologies approved by the Secretary; and (2) broadening the criteria applied in making substantial clinical improvement determinations to require, in addition to existing criteria, that the Secretary consider whether the new technology or medical service meets one or more of the following criteria: (a) results in a reduction of the length of a hospital stay; (b) improves patient quality of life; (c) creates long-term clinical efficiencies in treatment; (d) addresses patient-centered objectives as defined by the Secretary; or (e) meets such other criteria as the Secretary may specify.[10] It is BIO's belief that recognizing patient-centric improvements and accounting for the continued push toward personalized medicine when assessing a new technology would greatly enhance the approach to review NTAP applications, align with the Food and Drug Administration's (FDA) incorporation of patient reported outcomes, achieve previously stated CMS objectives in covering a new technology or service, and best serve Medicare beneficiaries.

BIO maintains concerns with CMS's application of the criteria for NTAP status eligibility, where a new service or technology must: (1) be new; (2) be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) demonstrate a substantial clinical improvement over existing services or technologies.[11] We believe that in certain instances, CMS has inappropriately applied these criteria in consideration of NTAP applications. With regard to the "newness" criteria, the Agency employs three considerations: (1) whether a product uses the same or similar mechanism to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS-DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar type of patient population.[12] BIO is concerned that by taking an overly critical view in the case of the

7 Id. at 19,877.
8 Id. at 19,871.
9 Id. at 19,869.
10 Id. at 19,871.
11 42 CFR 412.87.
12 82 Fed. Reg. 19,869 (April 28, 2017).

application of each component of the "newness" criteria, CMS may be stunting the benefit of the NTAP for truly new products in the space and creating barriers to access.

For example, we believe that the criteria have been inappropriately applied, first, in the case of the FY 2018 application for KTE-C19 CAR-T therapy (axicabtagene ciloleucel).[13] CAR-T therapy is not substantially similar to any existing technologies that have been approved by the FDA and that have been on the market for more than two to three years, and therefore represents a new therapy for purposes of these considerations.[14] In regard to the considerations of the "newness" criteria, CAR-Ts do not use the same or a similar mechanism of action to achieve a therapeutic outcome as Blinatumomab (BLINCYTO®), a bi-specific T-cell engager (BiTE), or any other existing technology. The CAR-T cell mechanism of action is distinctly different as it combines the specificity of an antibody with the cytotoxic and memory functions of a T cell, performing direct cell lysis on target cells. Whereas BiTE technologies are designed to link a patient's available T cells to their tumor cells,[15] CAR-T therapies are designed to create lasting responses through the delivery of a cellular biologic made from a patient's own T cell. CAR-T cells multiply, differentiate into memory cells persisting in the body after infusion, and establish immune memory and a long-lived tumor response from a single treatment.[16,17]

Second, for the application for VYXEOS™,[18] BIO also believes that the criteria have been inappropriately applied. The CombiPlex technology employed in VYXEOS™ represents a unique mechanism of action, which is not similar to any existing technology and achieves substantial clinical outcomes through this new mode of delivery, and would be the first treatment approved with this unique mechanism of action. This technology allows for the maintenance of a 5:1 molar ratio of the two drugs, where in separate infusions this ratio cannot be maintained.[19] These are just two examples in which CMS could improve its review

13 Id. at 19,887.
14 Unlike Blincyto, chimeric antigen receptor modified T cells (CAR-T) are genetically modified autologous t-cells that are programmed to directly recognize and attack specific target cells. These genetically modified cellular immunotherapies are comprised of chimeric antigen receptor (CAR) T cells that recognize CD 19 expressing cancer cells and B cells (target cells). CARs are engineered receptors constructed from antigen recognition regions of antibodies fused to T cell signaling and costimulatory domains that can be used to program a patient's T cells to specifically target CD19 benign and malignant cells. Blincyto (blinatumomab) is vastly different as it belongs to a class of constructed monoclonal antibodies, bi specific T cell engagers.
15 BiTE technologies works by creating a link between CD19 on B-cells and CD3 on available T-cells. In contrast, CAR T cells interact with CD19 and use costimulatory signaling domains to enhance or amplify the activation of the T-cell. Evidence suggests that costimulatory signaling may increase CAR T cell cytokine production, facilitate T cell replication, potentially prevent CAR T cell exhaustion, increase T cell antitumor activity and enhance survival of CAR T cells in patients. CAR T cell use of costimulatory domain technologies further differentiates CAR T technologies from current treatment options. Additionally, unlike BiTEs, CAR T therapies are not bound to a half-life.
16 Note: given the two distinct indications for BiTE and CAR-T, there are also implications for appropriate coverage under the MS-DRGs.
17 If FDA approved, KTE-C19 would be the first and only engineered autologous cellular immunotherapy indicated for the treatment of adult patients with relapsed/refractory aggressive B cell non-Hodgkin lymphoma (NHL) who are ineligible for autologous stem cell transplant (ASCT), and therefore should meet the newness criteria.
18 82 Fed Reg. 19,890 (April 28, 2017).
19 In VYXEOS™, the CombiPlex technology maintains a 5:1 molar ratio of cytarabine and daunorubicin which is not substantially similar mechanistically to the separate infusion of the two drugs on different days where the ratio of cytarabine and daunorubicin cannot be maintained. VYXEOS™ is the first drug that will be approved with this unique mechanism of action and its clinical results demonstrates substantially improved clinical outcomes in the head-to-head pivotal study of VYXEOS™ compared to the conventional 7+3 regimen that has been in use for over 40 years where cytarabine and daunorubicin are administered in separate infusions on different days.

by considering products that represent a substantial clinical improvement as new for purposes of NTAP.

As stated above, it is BIO's belief that there are improvements that could be made to the consideration process for NTAP applications to ensure appropriate coverage for truly new and innovative technologies and treatments to advance patient care. First, CMS should reconsider its reviews of application criteria with a patient-centered focus, considerations around substantial clinical improvement, and application of the three-pronged approach application of the "newness" criteria. Further, CMS should consider the adoption of a more frequent NTAP review process, such as the quarterly process applied for Transitional Pass-Through Payment Status in the Hospital Outpatient Prospective Payment System, ensure receipt of the full three-year NTAP benefit for all therapies, and consider extension of the FDA approval timeframe to the start of the NTAP application year.[20]

IV. CMS should ensure that the consideration for extension of end-of-life measures from the PPS-Exempt Cancer Hospital Quality Reporting Program to the Hospital Inpatient Quality Reporting Program are appropriate for the populations served in the IQRP, patient-centric, and reflective of care being provided in these settings.

In the Proposed Rule, CMS is seeking feedback on the potential extension of four end-of-life cancer care quality measures beyond the PPS-Exempt Cancer Hospital Program and into the Inpatient Quality Reporting (IQR) Program. CMS notes that they believe these measures would be suitable for the Hospital IQR Program because they provide insight on the quality of end-of-life care for cancer patients provided in inpatient settings beyond PPS-exempt cancer hospitals.[21] BIO supports CMS efforts to ensure delivery of appropriate cancer care, including end-of-life care, however, we request that CMS provide evidence about the applicability of these quality measures in the non-cancer hospital setting. We think it is critically important that, first, measures be implemented appropriately, addressing discussions around innovative treatment options and patient and caregiver considerations around end-of-life care.

CMS raises the consideration of extending any of the following measures to the IQR program in future years: (1) proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life measure; (2) proportion of patients who died from cancer admitted to the ICU in the last 30 days of life measure; (3) proportion of patients who died from cancer not admitted to hospice measure; (4) proportion of patients who died from cancer admitted to hospice for less than 3 days measure.[22] The first measure notes that it was developed to compare like patients, which would prove impractical for use in IQR; and the second measure, as developed, was intended to be voluntary.[23] Each of these

---

20 Assuming all other NTAP criteria had been satisfied by July 1 of the NTAP application.
21 82 Fed. Reg. 20,056 (April 28, 2017).
22 Id.
23 American Society of Clinical Oncology developed measures for NQF include the note that "clinical indicators and quality measures are not intended to and should never supplant independent physician judgement with respect to a particular patient", and that measures are "strictly voluntary and discretionary". See: National Quality Forum. Cancer Endorsement Maintenance 2011, Final Report. December 2012. Available at: http://www.qualityforum.org/Publications/2012/12/Cancer_Endorsement_Maintenance_2011.aspx.

measures should be further explored with stakeholder groups, particularly patients, to discern important relevant patient-centric and culturally appropriate quality measures are employed for end-of-life care.

BIO believes that measures should focus on meaningful conversations around end-of-life care with patients and their caregivers. Further, CMS should ensure that measures do not supplant physician judgement with respect to a particular patient or clinical situation, in delivering innovative treatment, nor should they confound end-of-life care with palliative care.[24] For instance, CMS could shift focus toward measures around care plan preferences.[25,26] In developing such measure sets, BIO asks CMS to provide further detail and engage with the full range of stakeholders in the cancer community to assure the most appropriate care is being delivered across all settings. Additionally, BIO asks CMS to assess (or make performance data available for analysis) what the effect of the quality measures are to determine if there are any negative, unintended consequences or perverse incentives that arise from using the measures.

V. CMS should consider appropriate quality measures to ensure vaccination coverage and rates across programs.

a. BIO urges CMS to reinstate the IMM-2 influenza immunization measure in the Hospital Value-Based Purchasing Program, which has been removed beginning with the FY 2018 performance year.

Effective beginning in the FY 2018 performance year, CMS removed NQF #1659, "Influenza Immunization (IMM-2)", from the Hospital VBP Program based on an analysis that this measure had "topped out." BIO strongly urges CMS to reinstate this important measure in the Hospital VBP Program, as it helps ensure that providers continue to screen for and administer this vaccine in the inpatient setting where nosocomial influenza is a significant threat to patient health and safety. Further, BIO disagrees that the measure has "topped out," as influenza vaccination rates for all populations remain below Healthy People 2020 goals.[27]

---

24 See: National Quality Forum. Palliative and End-of-Life Care 2015-2016. Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=80678

25 See: National Quality Forum No. 0362 Available at: http://www.qualityforum.org/QPS/QPSTool.aspx?m=446&e=1#qpsPageState=%7B%22TabType%22%3A1,%22TabContentType%22%3A2,%22ItemsToCompare%22%3A%5B%5D,%22StandardID%22%3A446,%22EntityTypeID%22%3A1%7D; No. 1626 Available at: http://www.qualityforum.org/QPS/QPSTool.aspx?m=1626&e=1#qpsPageState=%7B%22TabType%22%3A1,%22TabContentType%22%3A2,%22ItemsToCompare%22%3A%5B%5D,%22StandardID%22%3A1626,%22EntityTypeID%22%3A1%7D

26 The quality measures mentioned above are discussed in further detail here: Corrigan J, Rising J, and Valuck T. "Building Additional Serious Illness Measures Into Medicare Programs." May 25, 2017. Available at: http://healthaffairs.org/blog/2017/05/25/building-additional-serious-illness-measures-into-medicare-programs/

27 According to the CDC, for the 2015- 2016 Influenza Season, the vaccination rate for individuals sixty-five years of age and older was 56.6 percent, and for individuals 18- 64 years of age with high-risk conditions the rate was only 43.5 percent. See: CDC. Flu Vaccination Coverage, United States, 2015-2016 Influenza Season. https://www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2016.htm#age-adults

Influenza causes approximately 200,000 hospitalizations and 36,000 deaths on an annual basis in the U.S.[28] and nosocomial influenza results in longer hospital stays and greater morbidity and mortality among patients, increasing healthcare costs.[29,30] Influenza vaccination is the primary method for preventing influenza infection, has been proven to be safe and effective, and is recommended by the Advisory Committee on Immunization Practices (ACIP) for all people ages 6 months and older.[31] Quality measures, such as IMM-2, are an important tool to improve immunization rates by ensuring healthcare providers offer recommended vaccines to their patients, and have demonstrated their health and economic benefits.[32] Further, as more healthcare providers and facilities adopt electronic health record (EHR) systems, the positive impact of immunization quality measures will become increasingly evident. For these reasons, BIO urges CMS to reinstate the IMM-2 influenza immunization measure in the Hospital VBP Program.

b. BIO supports CMS's retention of the NQF #1659 "Influenza Immunization (IMM-2)" and NQF #0431 "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)", and asks CMS to revisit the decision to remove IMM-1 (pneumococcal immunization measure) in the Hospital Inpatient Quality Reporting Program.

BIO commends CMS for retaining two important immunization measures in the IQR for the FY 2018 payment determination and subsequent years. First, is NQF #1659 "Influenza Vaccination (IMM-2)." BIO believes that the continued inclusion of this measure in the Hospital IQR Program is critical for driving influenza immunization rates among the Medicare population, which will have important benefits in terms of both improved public health and lower Medicare spending. Second, is NQF #0431 "Influenza Vaccination Coverage among Healthcare Personnel (HCP)." This measure encourages hospitals to ensure their healthcare personnel receive an annual influenza vaccine, and is an important step to protecting Medicare patients from nosocomial influenza, particularly since sick and elderly patients are at an increased risk of contracting infectious diseases. BIO commends CMS for retaining this important measure, which can help avoid preventable adverse patient outcomes, while also improving work productivity among healthcare providers.

---

28 Tilburt J, Mueller P, Ottenberg A, Poland G, Koenig B. Facing the challenges of influenza in healthcare settings: The ethical rationale for mandatory seasonal influenza vaccination and its implications for future pandemics. *Vaccine*. 2008;26(suppl4):D27-30.

29 Nosocomial influenza occurs when a patient develops symptoms after more than 72 hours of hospitalization. See: Lindley M, Yonek J, Ahmed F, Perz J, Torres G. Measurement of influenza vaccination coverage among healthcare personnel in US hospitals. *Infect Control Hosp Epidemiol*. 2009;30:1150-1157.

30 Salgado C, et al. reported a mean excess healthcare costs of $7,545 per case of nosocomial influenza. See: Salgado C, Giannetta E, Hayden F, Farr B. Preventing nosocomial influenza by improving the vaccine acceptance rate of clinicians. *Infect Control Hosp Epidemiol*. 2004;25(11):923-928.

31 U.S. Department of Health and Human Services. HHS Action Plan to Prevent Healthcare-Associated Infections: Influenza Vaccination of Healthcare Personnel. 2010. http://www.hhs.gov/ash/initiatives/hai/tier2_flu.html.

32 For example, following the introduction of performance measures for influenza and pneumococcal vaccinations in the Veterans Health Administration (VHA) in 1995, Among eligible adults, influenza vaccination rates increased from 27 percent to 70 percent, and pneumococcal vaccination rates rose from 28 percent to 85 percent, with limited variability in performance between networks; pneumonia hospitalization rates decreased by 50 percent, and it is estimated that the VHA saved $117 for each vaccine administered. See: Jha A, Wright S, Perlin J. Performance measures, vaccinations, and pneumonia rates among high-risk patients in Veterans Administration Health Care. *Am J Public Health*. 2007;97(12):2167-2172.

Finally, BIO again urges CMS to revisit their 2015 decision to remove NQF#1653, "Pneumococcal Immunization (IMM-1)," from the IQR program.[33] We remain concerned that the removal of this measure is resulting in missed opportunities to vaccinate patients, thereby leading to avoidable morbidity, mortality, and healthcare costs. Pneumonia has a significant public health and economic impact in the U.S.,[34] and beyond reducing morbidity and healthcare costs, adequate vaccination coverage can also help prevent the need for antibiotic treatments and the subsequent spread of antibiotic resistance. Despite these benefits, pneumococcal immunization rates are still suboptimal.[35,36] Further, the removal of this measure contradicts the stated objectives and priorities of HHS.[37] Immunization quality measures are an important mechanism for improving these rates, especially in hospitals where pneumococcal vaccines can be readily administered to vulnerable populations. Since the inclusion of quality measures evaluating the percentage of inpatients assessed for pneumococcal vaccination, large increases in vaccination rates have been observed. Between 2006 (when CMS first began reporting inpatient quality measure data assessing pneumococcal vaccination) and 2010, the percentage of pneumonia patients who were assessed and received the pneumococcal vaccine increased from 71 percent to 94 percent.[38]

BIO asks the Agency to either: (1) develop and validate a new measure for the hospital inpatient setting that reflects the August 2014 ACIP recommendations;[39] or (2) reinstate the IMM-1 measure after making minor modifications to the measure specifications that address the Agency's expressed concerns around accurate data collection and reporting.

---

33 80 Fed. Reg. 49,826 (August 17, 2015).

34 Pneumococcal disease is common in adults, with approximately 175,000 people hospitalized with pneumococcal pneumonia each year in the U.S. In 2012, the total cost for Medicare beneficiaries during, and one year following, a pneumonia hospitalization was approximately $15,682 higher than the cost for patients without pneumonia. In 2004, pneumococci caused an estimated 4 million illness episodes, resulting in direct medical costs (inpatient and outpatient) of $3.5 billion, and approximately half of these costs were for the care of patients 65 years and older. See: National Foundation for Infectious Diseases. Pneumococcal Disease Call to Action. April 2012. http://aahivm.org/Upload_Module/upload/Provider%20Resources/Pneumococcal%20CTA%20HCP%20Roles%20AAHIVM%20Partner.pdf.

35 In 2013, pneumococcal vaccination coverage among adults age 65 and older was only 59.7 percent, and among high-risk adults age 19-64 with conditions such as COPD, diabetes, and CVD, it was only 20 percent. See: Centers for Disease Control and Prevention. Noninfluenza Vaccination Coverage among Adults – United States, 2011. *MMWR Morb Mortal Wkly Rep*. 2013;63(04):66-72.

36 The Advisory Committee on Immunization Practices (ACIP) recommends that all adults aged 65 years or older—and adults aged 19-64 with certain health conditions, such as a weakened immune system, HIV, and kidney disease—receive PCV13 and PPSV23.

37 Specifically, *Healthy People 2020* established a goal of at least 90 percent of adults aged 65 or older ever receiving a pneumonia vaccine, which was reiterated as part of the 11th Scope of Work for the CMS Quality Improvement Organizations and the draft National Adult Immunization Plan. See: Office of Disease Prevention and Health Promotion. 2020 Topics & Objectives: Immunization and Infectious Disease. Available at: http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives; Shiree Southerland. Quality Innovation Network – Quality Improvement Organization Adult Immunization Task *National Adult and Influenza Immunization Summit.* May 14, 2015. Available at http://www.izsummitpartners.org/wp-content/uploads/2015/05/16b-1-Southerland-QIN-QIO-Adult-Imm-Task.pdf; National Vaccine Program Office. National Adult Immunization Plan. February 5, 2015.

38 Centers for Medicare & Medicaid Services. National Impact Assessment of Medicare Quality Measures. March 2012. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/NationalImpactAssessmentofQualityMeasuresFINAL.PDF. p. 40-42.

39 Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine among Adults aged ≥ 65 years. MMWR Morbidity and Mortality Weekly Report. 2014;64(37): 822-825.

Specifically, we encourage CMS—as acting measure steward—to consider the following modifications to the existing measure specifications manual. First, in order to reduce any provider confusion and provide guidance on implementation of the measure, BIO recommends CMS consider the addition of a decision-aid in the form of a flow chart for use with adults, similar to the existing flow chart used for high-risk children aged 5 to 18 years. This would provide hospitals with guidance as to how to evaluate if a patient needs to receive a pneumococcal vaccination (and which type) based on his or her vaccination history. We do, however, recognize that additional solutions are needed to guide hospitals in providing appropriate pneumococcal vaccination. We encourage CMS to work directly with hospitals and other stakeholders on developing solutions to ensure appropriate pneumococcal vaccination.

Second, BIO suggests CMS consider updating the measure specification to better align with the ACIP recommendations. The Health and Well-Being Standing Committee of the National Quality Forum (NQF) recently agreed to recommendations for updates to the NQF standard specifications for pneumococcal vaccinations aimed to align with the updated guidelines issued by the Centers for Disease Control and Prevention (CDC)/ACIP.[40] The Committee put forth these recommendations to NQF members and the public for comment, an effort reflective of support for continued use of the measure and in direct conflict with CMS's proposal to remove the measure. We urge CMS to consider these recommendations along with minor updates to the allowable values to account for minimum intervals between different types of pneumococcal vaccines, which will alleviate the feasibility challenges to implementing the measure.

Third, BIO suggests CMS include recommended measures for immunocompetent adults age 19-64 who are at increased risk for pneumococcal disease because they have several specific chronic diseases enumerated by ACIP. BIO urges the creation of a standard measure for this population group, given its size and significant need for improvement of pneumococcal vaccination coverage. [41] Such a measure might best be structured similarly to the way in which the other pneumococcal vaccination measures are designed, including measurement of whether or not the vaccination status of patients in this risk group was assessed, whether or not those for whom immunization was appropriate were offered an immunization, and whether or not they were actually immunized.

c. BIO supports retention of the previously finalized measure NQF#0431 "Influenza Vaccination Coverage among Healthcare Personnel (HCP)" for the PPS-Exempt Cancer Hospital Quality Reporting Program.

BIO commends CMS for retaining the previously finalized measure NQF #0431 "Influenza Vaccination Coverage among Healthcare Personnel (HCP)" in the PCHQR Program for the FY 2019 program year and subsequent years. This measure encourages

40 National Quality Forum, Health and Well-Being, Phase 2, Draft Report for Comment, released May 29, 2015
41 CDC has reported that in 2013 only 21.2% of adults in this group had received a pneumococcal vaccination, and this number has been essentially unchanged for at least a decade. See: (MMWR, Feb 6 2015, vol 64, pages 95-102).

hospitals to ensure their healthcare personnel receive an annual influenza vaccine. Increasing vaccination rates among healthcare personnel is an important step in protecting patients from nosocomial influenza, particularly patients with cancer who are at an increased risk of contracting influenza and suffering from associated complications. BIO appreciates CMS's preservation of this important measure, which can help avoid preventable adverse patient outcomes, while also improving work productivity among healthcare providers.

d. Revising, as proposed, the data collection period for NQF #0680 "Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)" in the Long-Term Care Hospital Quality Reporting Program.

CMS proposes revisions to the data collection period for NQF #0680, "Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)" measure within the Long-Term Care Hospital (LTCH) Quality Reporting Program. The objective of this revision is to help LTCHs better capture influenza vaccination data for patients in their hospital for one or more days during the influenza vaccination season (October 1 of a given year through March 31 of the subsequent year), regardless of the date(s) of their admission and/or discharge. This change thereby allows for the accurate calculation of data for the measure and ensures that LTCHs are receiving credit for recording the vaccination status of all patients in their care during the influenza vaccination season. BIO supports this revision and commends CMS for proposing modifications to the measure while retaining it in the LTCH Quality Reporting Program for FY 2019 payment determination and subsequent years and is pleased that the previously adopted measure NQF #0431 "Influenza Vaccination Coverage among Healthcare Personnel (HCP)" will remain in the LTCH Quality Reporting Program for the FY 2018 payment determination year and subsequent years.

e. Expanding the use of a herpes zoster vaccination measure, consistent with other programs, into the Inpatient Quality Reporting Program.

In line with stated objectives in other programs for improvement of immunization rates in line with the National Quality Strategy goals,[42] BIO urges CMS to expand inclusion of a herpes zoster vaccination measure into the IQR program. Herpes zoster, also known as shingles, can be painfully debilitating[43] and can lead to costly treatments among older adults. The Advisory Committee on Immunization Practices (ACIP) recommends the herpes zoster vaccine for adults 60 years and older, based on the vaccine's ability to reduce overall incidence, decrease pain associated with shingles, and the significant

42 Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Final Rule, 80 Fed. Reg. 68,678.
43 Vaccines. Shingles *Herpes Zoster – What is Shingles (Herpes Zoster)?* Accessed on 5/8/2017. https://www.vaccines.gov/diseases/shingles/index.html

impact in the 60 year and older population. [44,45] As the primary source of coverage for older Americans, Medicare provides important opportunities to improve herpes zoster immunization rates in the recommended population. We support CMS for taking the important step in the 2016 Home Health Payment System and Value-Based Purchasing Rule[46] to include a measure to improve herpes zoster vaccination rates and encourage CMS to take further steps to improve these rates across Medicare's most vulnerable populations.

* * *

Hospital Inpatient Prospective Payment System Request for Information
In addition to the comments provided above on the following issues, BIO asks CMS to further refine the following areas through future policy proposals and updates as a part of the Request for Information (RFI):

I. CMS should focus on opportunities to increase access to innovative treatment options for Medicare beneficiaries through NTAP by considering revisions to NTAP application determinations and appropriately accounting for the impact of NTAP in regulatory economic analyses.

As a part of the RFI, the Agency requests information on efforts to reduce regulatory burdens while increasing the quality of care for Medicare beneficiaries. Efforts in these areas appear related to the Administration's executive order requiring the repeal of two older regulations for every significant rule offered. Over the past several years, BIO has raised concerns about the manner in which the agency has administered the NTAP in the inpatient setting. This program was designed to improve patient access to breakthrough technologies representing a substantial clinical improvement for Medicare beneficiaries. However, CMS has consistently administered the program in such a way as to impose undue burdens on manufacturers seeking NTAP status, thereby creating obstacles to patient access to new breakthroughs.

As we have discussed in this and previous comment letters, BIO finds that in many instances, CMS fails to appropriately apply data in determinations of NTAP status, and may fail to provide appropriate coverage for new and innovative treatment options. BIO supports the alignment of the approach to reviewing NTAP with FDA's incorporation of patient reported outcomes by including patient-centric improvements in addition to process improvements to ensure timely and appropriate access to new treatments. BIO believes that CMS should work to incorporate these patient-centric elements to refine the criteria of "demonstrated substantial clinical improvements" and "newness" in determinations of NTAP status as new and more robust technologies and treatments are developed, improving patient outcomes and lowering overall costs to the healthcare system. Further, BIO urges

---

44 Morbidity and Mortality Weekly Report (August 22, 2014). *Update on Recommendations for Use of Herpes Zoster Vaccine*. Vol. 63. No.33. Accessed on 5/3/2017. https://www.cdc.gov/mmwr/pdf/wk/mm6333.pdf
45 Morbidity and Mortality Weekly Report (June 6, 2008). *Prevention of Herpes Zoster – Recommendations of the Advisory Committee on Immunizations Practices (ACIP)*. Vol. 57. No. RR-5. Accessed on 5/8/2017. https://www.cdc.gov/mmwr/PDF/rr/rr5705.pdf
46 Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Final Rule, 80 Fed. Reg. 68,678.

CMS to make process updates, such as reviewing NTAP applications on a quarterly basis, as is done with other payment rules,[47] applying the same full three-year NTAP status benefit across all approved therapies, and extending the timeframe for FDA approval deadline to align with the NTAP application year.

Moreover, the agency's regulatory impact analyses of these policies have failed to take into account the full economic impact of restricting access to new technologies—both on the manufacturers of these technologies as well as on society as a whole. BIO believes that restrictive NTAP policies have the potential to undermine the willingness of manufacturers of new technologies to continue investment in future breakthroughs. We would urge the agency to approach future economic impact analyses of NTAP decisions with this full context in mind.

II. CMS should further refine the MS-DRG system to appropriately account for and reflect patients with rare and orphan diseases, and to advance access to innovative treatment options.

As detailed in our comments above, BIO continues to encourage CMS in the FY 2018 Proposed Rule and in future policymaking to work to identify ways to best incorporate the treatment of rare diseases into the MS-DRG calculus, to help ensure appropriate coverage for these vulnerable patient populations in the hospital inpatient setting and to support additional mechanisms for treatment. CMS should further explore opportunities to adequately cover the treatment of rare diseases and novel therapies, particularly as we move to more personalized and targeted treatments. BIO believes CMS should explore means to best account for rare diseases in current MS-DRGs, and by creation of specific MS-DRGs, to address the needs of rare disease patients. CMS should work with stakeholders in this space, including centers of excellence and hospitals with experience in managing and treating certain subclasses of rare disease, to work to develop an MS-DRG that is appropriately reflective of the treatment requirements. Such considerations and updates will ensure that over time, the MS-DRG system keeps pace with advancements and changes in treatment and best serves Medicare beneficiary care needs.

III. CMS should consider means to appropriately account for uninsured and underinsured care in Disproportionate Share Hospital (DSH) eligibility criteria calculations.

Currently, CMS's foundation for DSH eligibility criteria is based on the number of Medicare and Medicaid inpatient days compared against the total number of inpatient days across all health coverage providers, calculated at the individual hospital level based on reports submitted by the facility. Current reports do not include amounts paid from either program, nor do they include appropriate accounting for inpatient days for uninsured or underinsured patients. This is problematic as it means DSH criteria do not appropriately account for these high cost patient populations in determining eligibility, and that a hospital may be benefitting from DSH eligibility, but not providing a sufficient level of care to the uninsured or underinsured population. BIO asks CMS to review and consider new means to account for

47 Hospital Outpatient Prospective Payment System Pass-Through Payments

such care in order to ensure DSH eligibility is appropriately reflective of the care being provided in each facility and to best serve patients.

* * *

BIO appreciates the opportunity to comment on the FY 2018 Proposed Rule for the Inpatient Prospective Payment System and Request for Information. We look forward to continuing to work with CMS in the future to address the issues raised in this letter. Should you have any questions, please do not hesitate to contact me at 202-962-9200.

Sincerely,

/s/

Laurel L. Todd
Vice President
Healthcare Policy & Research