Biotechnology Industry Organization

June 30, 2014

***BY ELECTRONIC DELIVERY***

The Honorable Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, 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 Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program; Proposed Rule [CMS-1607-P]**

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers 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 and Proposed Fiscal Year 2015 Rates Proposed Rule ("the Proposed Rule"), specifically with respect to the Hospital Inpatient Quality Reporting (IQR) Program and the Hospital Value-Based Purchasing (VBP) Program.[1] BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

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. BIO supports the development and use of appropriate, evidence-based quality measures throughout the healthcare system as a component of improving efficiency, short- and long-term clinical outcomes, and overall patient health. Immunization quality measures, as one example, help ensure that healthcare providers routinely discuss and offer recommended vaccines to their patients,

[1] 79 Fed. Reg. 27,978 (May 15, 2014).

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resulting in higher vaccine uptake, better health outcomes, and cost savings for the healthcare system.

Our comments focus on several proposals related to the Hospital IQR Program and the Hospital VBP Program, as well as to express concerns regarding both CMS's review of New Technology Add-on Applications and the Agency's implementation of the hospital transparency requirements enacted by the Patient Protection and Affordable Care Act (ACA). Discussed in detail below, we ask that CMS:

- Reinstate in the Hospital IQR Program the pneumococcal immunization measure (IMM-1), which was suspended from the IQR in FY 2014, as this measure would help improve pneumococcal immunization rates, public health, and patient safety;
- Finalize the proposal to adopt the hepatitis B vaccination measure for newborn infants in the Hospital IQR Program;
- Finalize the proposal to require reporting of central line associated blood-stream infections (CLABSI) for non-ICU settings no later than January 1, 2015;
- Continue efforts to adopt more clinical outcomes measures in the Hospital IQR program, while ensuring that such efforts do not result in the abandonment of critical process-based measures, including measures related to immunization;
- Finalize the proposal to align the Medicare Electronic Health Record (EHR) and IQR reporting and submission deadlines;
- Further develop the proposal to adopt new or updated measures for purposes of the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program in future rulemaking, "such as measures that assess the safety and efficacy of the diagnosis and treatment of cancer, measures that take into account novel diagnostic and treatment modalities, measures that assess symptoms and functional status, and measures of appropriate disease management";
- Finalize the proposal to readopt IMM-2, the influenza immunization measure, in the Hospital VBP Program and consider the adoption of additional immunization measures, particularly for adults, in the Hospital VBP program in future years;
- Finalize the proposal to include Methicillan-Resistant *Staphylococcus aureus* (MRSA) bacteremia and *Clostridium difficile* infection (CDI) standardized infection ratio (SIR) outcomes measures in the Hospital VBP beginning in FY 2017;
- Adopt Select NQF-Endorsed Stroke Chart-Abstracted Measures For Purposes of the VBP;
- Finalize the proposal to add the Care Transition Measure from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey to the Patient and Caregiver Centered Experience of Care/Care Coordination (PEC/CC) domain of the Hospital VBP Program beginning in FY 2018;
- Move forward with the proposal to add measures that supplement the Medicare Spending per Beneficiary (MSPB) measure within the Hospital VBP's Efficiency Domain in future rulemaking;
- Finalize the proposal to increase the weight of the Hospital VBP's Safety Domain beginning in FY 2017, provided that CMS takes steps to ensure that immunization measures are afforded sufficient weight in determining hospital value-based payments;
- Finalize the inclusion of a chronic obstructive pulmonary disease (COPD) measure in the Hospital Readmissions Program beginning in FY 2015;

- Review applications for new technology add-on payments on a case-by-case basis, taking into account the totality of the evidence and the unique nature of the product at issue;
- Either encourage or require that hospitals provide their cost-to-charge ratio together with their standard charges in implementing the ACA's hospital transparency requirements; and
- Further clarify appropriate inpatient versus outpatient reimbursement and billing for hospital drugs.

## I. Hospital Inpatient Quality Reporting (IQR) Program

### a. Proposal to Continue Suspension of IMM-1 Pneumococcal Immunization Measure (p. 28,223)

In the FY 2014 IPPS proposed rule, CMS proposed removal of IMM-1, Pneumococcal Immunization (NQF #1653), from the IQR Program.[2] BIO opposed removal of the measure, as did the Department of Health and Human Services (HHS's) National Vaccine Advisory Committee (NVAC). On June 25, 2013, Dr. Howard Koh, Assistant Secretary for Health, transmitted to Administrator Tavenner the NVAC recommendation to retain the IMM-1 measure in the IQR, as removal of the measure would "drive down pneumococcal immunization rates."

In the FY 2014 IPPS final rule, CMS decided to suspend the IMM-1 measure rather than remove it from the Hospital IQR Program,[3] and in the FY 2015 proposed rule, CMS proposes a continuation of this suspension.[4] BIO urges CMS to reinstate the measure as part of the FY 2015 IPPS final rule, as it plays a critical role in ensuring that patients are appropriately vaccinated against pneumococcal disease, thereby reducing the significant morbidity, mortality, and healthcare costs associated with the disease.

Pneumococcal disease is common in adults. Each year, approximately 175,000 people are hospitalized with pneumococcal pneumonia in the U.S., and these patients are at increased risk for concurrent cardiac events such as myocardial infarction, arrhythmia, and congestive heart failure.[5] In 2012, the total costs for Medicare beneficiaries during, and one year following, a pneumonia hospitalization were approximately $15,682 higher than those patients without pneumonia.[6] 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.[7]
Vaccination is the primary method for preventing pneumococcal disease, and it can also prevent the need for antibiotic treatments and the subsequent spread of antibiotic

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[2] See 78 Fed. Reg. 27,486, 27,680 (May 10, 2013).
[3] 78 Fed. Reg. 50,496, 50,780 (Aug. 19, 2013).
[4] 79 Fed. Reg. at 28,223.
[5] 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.
[6] Thomas CP, Ryan M, Chapman JD, et al. Incidence and Cost of Pneumonia in Medicare Beneficiaries. *Chest*. 2012;142(4):973-81.
[7] 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.

resistance. Despite the health and economic benefits, pneumococcal immunization rates are still suboptimal. In 2011, pneumococcal vaccination coverage among adults age 65 and older was only 62 percent, and among high-risk adults age 19-64, it was only 20 percent.[8] HHS's *Healthy People 2020* vaccination coverage targets for these populations are 90 percent and 60 percent, respectively.

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 quality measure data assessing pneumococcal vaccination) and 2010, the percentage of pneumonia patients who were assessed and received pneumococcal vaccine increased from 71 percent to 94 percent.[9]

Given the significant public health and economic impact of pneumococcal disease and the continued opportunities for improvement in vaccination rates, BIO urges CMS to reinstate IMM-1, the pneumococcal immunization measure, in the Hospital IQR Program. BIO appreciates CMS's efforts to align the quality measures used in the Hospital IQR Program with the latest clinical evidence, including recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC). In fact, BIO believes that the current IMM-1 measure is written broadly enough to enable hospitals to implement the updated ACIP recommendations and to successfully report on the measure, since CMS has already modified the measure description and specifications manual information to assess general pneumococcal vaccination status, and no longer stipulates that a specific pneumococcal vaccine be given to meet it. CMS has also developed Questions and Answers (Q&As) that are available on the Qualitynet website to facilitate hospitals' successful reporting on the measure. The suspension of the IMM-1 measure—currently the only pneumococcal vaccination measure included in this important program—undermines efforts to sustain and increase pneumococcal vaccination and promote high quality care. To ensure ongoing attention to the administration of pneumococcal vaccines to all eligible patients, BIO urges CMS to reinstate a comprehensive pneumonia measure for purposes of the Hospital IQR Program.

### b. Proposal to Adopt Measure of Hepatitis B Vaccine Coverage Among Newborns (p. 28,244)

CMS proposes to adopt several electronic clinical quality measures in the IQR with data collection beginning with October 1, 2016 discharges, including the immunization measure: Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge (NQF #0475). BIO fully supports the adoption of this important measure in the IQR.

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[8] Centers for Disease Control and Prevention. Noninfluenza Vaccination Coverage among Adults – United States, 2011. *MMWR Morb Mortal Wkly Rep*. 2013;63(04):66-72.

[9] 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.

The risk for developing chronic hepatitis B is highest for those infected at birth. Universal screening of pregnant women for HBsAg and case management of HBsAg-positive mothers and their infants has helped decrease perinatal hepatitis B infection; however, routine vaccination of all newborns is an important component in eliminating hepatitis B in the United States. The risk for perinatal acquisition of hepatitis B still exists for women who present for delivery without prenatal care, who acquire hepatitis B late in pregnancy after initial hepatitis B testing, or those who have an erroneous or delayed HBsAg laboratory result. Administration of hepatitis B vaccine and hepatitis B immune globulin within 12 hours of birth is 85 percent to 95 percent effective as post-exposure prophylaxis in preventing HBV infection in the infant. Importantly, and directly relevant to NQF Perinatal Measure #0475, is that the hepatitis B vaccine alone is 70 percent to 95 percent effective in preventing perinatal HBV transmission when the first dose is given within 24 hours of birth.[10]

### c. Proposal to Require Reporting of Central Line Associated Blood-Stream Infections (CLABSI) for Non-ICU Settings

Central line associated blood stream infections (CLABSI) are among the most common healthcare-associated infections (HAIs) and remain a significant cause of morbidity and mortality in the hospital setting, with a reported mortality of 12 percent to 25 percent.[11] In the United States, it is estimated that roughly 80,000 CLABSIs occur in the intensive-care unit (ICU) annually;[12] however, approximately *twice* this many CLABSIs occur in hospitalized patients outside of the ICU.[13]

In the FY 2014 IPPS Final Rule, CMS decided to delay the implementation date for expanding CLABSI reporting for the Hospital IQR program to non-ICU settings until January 1, 2015.[14] BIO urges CMS to avoid any further delays and to require hospitals to report CLABSI outside the ICU for FY 2015, which is consistent with NQF's re-endorsement update to this measure. We also recommend that CMS include non-ICU CLABSI reporting within the Hospital VBP and Hospital-Acquired Condition Reduction programs.

### d. Proposal to Move Towards the Inclusion of More Clinical Outcomes Measures (p. 28,219)

According to CMS, as the Agency continues "moving towards including more clinical outcomes measures as opposed to process-of-care measures in the Hospital IQR Program measure set, [CMS has] considered removing additional measures using [its] previously-adopted removal criteria."[15] BIO supports the movement to include more outcomes-based measures and commends CMS for its efforts to ensure that the IQR includes only the most current measures that accurately identify true differences in the quality of care provided across Medicare hospitals. That said, a sole reliance on outcomes measures is not necessarily appropriate; CMS itself states later in the Proposed Rule that "[p]ublic reporting should rely on a mix of standards, outcomes, process of care measures, and patient

[10] MMWR, August 1, 2008/57(30); 825-828.
[11] MMWR, March 1, 2011/**60(08);243-248**.
[12] Mermel LA, Prevention of intravascular catheter-related infections. *Ann. Intern. Med.* 2000 Mar. 7.
[13] Mayo Clin. Proc. 2006. Sept.;81(9).
[14] 78 Fed. Reg. at 50,787.
[15] 79 Fed. Reg. at 28,219.

experience of care measures, including measures of care transitions and changes in patient functional status."[16] Accordingly, we urge CMS to ensure that the move towards including more clinical outcomes measures does not ultimately result in the abandonment of process-of-care or patient-experience measures where they may be relevant and reflect important aspects of patient care. For instance, we believe it is critically important that CMS continue to include immunization measures in the Hospital IQR and other related programs to ensure that hospitals continue to provide these valuable services.

**e. Proposed Alignment of Medicare Electronic Health Record (EHR) and IQR Reporting/Submission Deadlines (p. 28,245)**

Currently, because of differences in the Hospital IQR and Medicare EHR Incentive Programs' schedules, hospitals that report quality measure data to both programs must do so multiple times a year. CMS is proposing to "incrementally shift the Medicare EHR Incentive Program reporting and submission periods for clinical quality measures to align with that of the Hospital IQR Program."[17] BIO supports finalizing this proposal, which we believe will help remedy the fact that the lack of alignment between these two programs "may create confusion and additional burden for hospitals attempting to report data to both programs."[18]

**f. Proposal to Add New or Updated Measures to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (p. 28,256)**

CMS outlines its intent to propose to adopt new or updated measures for purposes of the PCHQR in future rulemaking, "such as measures that assess the safety and efficacy of the diagnosis and treatment of cancer, measures that take into account novel diagnostic and treatment modalities, measures that assess symptoms and functional status, and measures of appropriate disease management."[19] BIO strongly supports this proposal and agrees that "such measures will help [CMS] further [its] goal of achieving better health care and improved health for Medicare beneficiaries who obtain cancer services through the widespread dissemination and use of quality of care information."[20]

We are particularly supportive of CMS's proposal to include "measures that take into account novel diagnostic and treatment modalities." We believe the inclusion of these measures in the PCHQR will help sustain incentives for U.S. cancer hospitals to deliver the most appropriate care for each individual patient and continue to lead the world in medical innovation. As with other measures included in this program, we urge CMS to ensure that such measures are endorsed by the National Quality Forum (NQF) or another consensus-based organization that uses similarly sophisticated processes for developing and endorsing measures. Additionally, because the aim of this proposal is to include measures that incentivize the use of novel means of diagnosing and treating cancer, we believe that particular attention should be made to ensuring that these measures are adopted in a timely manner and updated on a regular basis. We look forward to working with CMS to further develop this proposal moving forward.

[16] Id. at 28,254.
[17] Id. at 28,245.
[18] Id.
[19] Id. at 28,256.
[20] Id.

## II. Hospital Value-Based Purchasing (VBP) Program

### a. Proposal to Readopt Influenza Immunization Measure (p. 28,121)

CMS proposes to readopt IMM-2, the influenza immunization measure (NQF #1659), for the FY 2017 Hospital VBP Program. BIO supported the adoption of this measure for the FY 2016 Hospital VBP Program and we strongly support its readoption for FY 2017.

As CMS has stated, IMM-2 represents an "important component of quality improvement in the acute inpatient hospital setting."[21] Each year, influenza causes approximately 200,000 hospitalizations and 36,000 deaths in the United States.[22] Nosocomial influenza, which occurs when a patient develops symptoms after more than 72 hours of hospitalization,[23] results in longer hospital stays and greater morbidity and mortality among patients.[24] In addition, nosocomial influenza increases healthcare costs due to additional hospitalization and higher utilization of supplies, diagnostic tests, and treatments. One study reported mean excess healthcare costs of $7,545 per case of nosocomial influenza.[25]

Influenza vaccination is the primary method for preventing influenza infection and has been proven to be safe and effective.[26] For these reasons, the ACIP recommends annual influenza vaccination for all people age 6 months and older. Quality measures such as IMM-2 help drive immunization rates by ensuring healthcare providers offer recommended vaccines to their patients, reducing the number of missed opportunities to vaccinate patients and increasing vaccination rates.

The health and economic benefits of immunization measures became evident 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.[27]

As more healthcare providers adopt electronic health record (EHR) systems, the positive impact of immunization quality measures will become increasingly evident. According to new data released by HHS, 80 percent of eligible hospitals have now adopted EHR

[21] 78 Fed. Reg. at 27,486.
[22] 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(suppl 4):D27-30.
[23] 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.
[24] 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.
[25] 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.
[26] 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.
[27] 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.

systems.[28] BIO commends CMS for recognizing the value of immunization measures such as IMM-2 and readopting this measure in the Hospital VBP Program for FY 2017.

BIO also urges CMS to consider the adoption of additional immunization measures, particularly for adults, in the Hospital VBP program in future years. Despite the ACIP's recommendations and HHS's *Healthy People 2020* targets, adult immunization rates remain low,[29] and quality measures are an important tool to help increase vaccination rates in this population.[30] Adult immunization quality measures currently focus on influenza, pneumococcal, and hepatitis B immunization. BIO urges CMS to support the development and adoption of quality measures that increase adult immunization rates for all ACIP-recommended vaccines.

**b. Proposed Inclusion of Methicillan-Resistant *Staphylococcus aureus* (MRSA) Bacteremia and *Clostridium difficile* Infection (CDI) Standardized Infection Ratio (SIR) Outcomes Measures (pp. 28,119-28,120)**

BIO supports finalizing CMS's proposal to include both the MRSA Bacteremia and CDI SIR outcomes measures for the FY 2017 Hospital VBP Program. We, like CMS, "remain concerned about the persistent public health threat presented by MRSA infections" as well as "the seriousness of *C. difficile* infections," and agree that both measures are appropriate for the Hospital VBP "[b]ased on the continued danger" that both MRSA and *C. difficile* infections "present to patients and to the public health."[31] We believe that including these measures in the VBP—in addition to the IQR and *Hospital Compare* website—will further encourage hospitals to focus on avoiding and appropriately treating both MRSA and *C. difficile* infections, which will have important implications in terms of patient outcomes, as well as reduced overall healthcare expenditures.

**c. Adoption of Select NQF-Endorsed Stroke Chart-Abstracted Measures For Purposes of the VBP**

BIO appreciates CMS's commitment to advancing policies designed to ensure that all Medicare beneficiaries have access to care that reduces morbidity and the risk of disability. Stroke is the fourth-leading cause of death in the United States and a leading cause of disability.[32] Ischemic stroke affects hundreds of thousands and leaves many with new disability and at risk for complications, recurrent stroke, and clinical deterioration. In 2014, CMS highlighted the continued need for HHS to prioritize policy and program interventions to reduce stroke and disability in the United States.

We believe that CMS's adoption of the NQF-endorsed stroke chart-abstracted measure set (hereinafter, "STK measure set") into the IQR program was an important step in improving

[28] U.S. Department of Health and Human Services. "Doctors and hospitals' use of health IT more than doubles since 2012. News release. May 22, 2013. http://www.hhs.gov/news/press/2013pres/05/20130522a.html.
[29] MMWR, February 7, 2014/ 63(05); 95-10.
[30] 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.
[31] 79 Fed. Reg. at 28,119-20.
[32] Go AS, Mozaffarian D, Roger VL, Benjamin EJ, Berry JD, Borden WD, et al. Heart Disease and Stroke Statistics—2013 Update: A Report from the American Heart Association. *Circulation*. 2012:e-2-241.

stroke care.[33] The STK measure set was developed by the American Heart Association (AHA)/American Stroke Association (ASA), the Joint Commission, and physician groups as a complimentary component of a broader set of measures that reflect the treatment continuum of stroke patients. BIO is now recommending that CMS consider adopting select measures from the STK measure set for purposes of the Hospital VBP program.

The STK measures are strongly aligned with the Hospital VBP program's goals of rewarding better value and improved patient outcomes. A recent study found that hospitals participating in the *Get With the Guidelines*® stroke quality program, incorporating the AHA/ASA STK measure set, resulted in statistically significant reductions in all-cause mortality at 30 days, reductions in all-cause mortality at one year, and in higher rates of discharges directly to home for Medicare beneficiaries.[34]

Given the clinical and financial impact of stroke in the United States, we believe that CMS should prioritize quality measures related to stroke in the VBP program. In the absence of stroke outcomes-based measure that are accepted by providers, BIO believes that CMS should prioritize certain measures from the STK measures set for this purpose, specifically those that are directly tied to outcomes and endorsed by the Measure Application Partnership (MAP) for the Hospital VBP program.

Of the STK measures endorsed by MAP for the Hospital VBP program, BIO encourages adoption of the following measures: STK-1 (venous thromboembolism (VTE) prophylaxis); STK-2 (discharged on antithrombotic therapy); and STK-4 (percentage of eligible patients receiving thrombolytic therapy within 0-3 hours of symptom onset). As to this last measure, a recent study found that only four percent of the more than 370,000 Medicare patients who suffered a stroke in 2011 were treated with tissue plasminogen activator (tPA), the most commonly used drug for thrombolytic therapy, even though 81 percent of Americans live within an hour's drive of a hospital that can give the drug.[35] Furthermore, we see opportunity for hospitals to improve on the measure: Hospital Compare reported only a 63 percent national average for STK-4 for Q2 2013. As processes exist to improve performance on all of these measures, we believe that adopting them within the VBP would have a significant impact on stroke care, primarily by preventing strokes from occurring in the first instance.

### d. Proposal to Include a Care Transition Measure (p. 28,122)

CMS is "considering proposing to add the Care Transition Measure from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey to the Patient and Caregiver Centered Experience of Care/Care Coordination (PEC/CC) domain of the FY 2018 Hospital VBP Program."[36] BIO strongly supports this proposal and urges CMS to finalize it. Incentivizing hospitals to coordinate patient transitions to outpatient care settings will go a long way in decreasing readmissions and potentially mortality among the Medicare population.

[33] See 79 Fed. Reg. at 28,220, 28,242.
[34] Song S., et al. AHA Quality of Care and Outcomes Research (QCOR) Scientific Sessions, 2013.
[35] Adeoye, et al. ASA's International Stroke Conference, 2014.
[36] 79 Fed. Reg. at 28,122.

### e. Proposed Inclusion of Additional Measures in the Efficiency Domain (p. 28,122)

In the Proposed Rule, CMS notes that, "[i]n the interest of expanding the Efficiency domain to include a more robust measure set, including measures that supplement the Medicare Spending per Beneficiary (MSPB) measure with more condition and/or treatment specific episodes, as well as facilitating alignment with the Physician Value-Based Payment Modifier (VM) Program, we are considering proposing to add new episode-based payment measures to the Hospital VBP Program through future rulemaking." BIO agrees with this proposal in order to, as CMS notes, expand "the Efficiency domain to include such measures [which] would create incentives for coordination between hospitals and physicians to optimize the care they provide to Medicare beneficiaries."[37]

In terms of the proposal itself, we support that the Agency has included measures that assess both medical conditions and surgical episodes, as well as the criteria used to select the specific measures.[38] In particular, we believe it is critical that "standardized Medicare payments for services provided during the episode can be linked to the care provided during the hospitalization" to ensure that any applicable measures are assessing expenditures for which the hospitals are truly responsible. We also support that the measures will be risk-adjusted such that hospitals are not penalized based on the health status of their underlying patient population.

We believe, however, that certain aspects of the proposal require further clarification by CMS. For instance, while we support that these measures would only take into account related medical expenditures, CMS does not specify how the Agency will determine that a service is "clinically related to the health conditions treated during the hospital stay that triggered the episode" (for medical conditions) or "clinically related to the index admission" (for surgical episodes).[39] We believe this is a critical consideration that warrants further analysis by CMS. We also urge CMS to give further consideration as to whether the proposed 30-day measurement period is equally adequate to assess hospital performance on all six of the diverse proposed measures.

Additionally, we caution CMS in its stated goal of "increase[ing] alignment between the Hospital VBP and Physician VM Programs"[40] through this, or other, proposals. While BIO generally supports alignment between Medicare reporting requirements to decrease the administrative burden on providers, we reiterate the concerns we have expressed most recently in our response to the Calendar Year 2014 Medicare Physician Fee Schedule

[37] Id. at 28,122-23.
[38] Id. at 28,123 ("In selecting the six conditions around which we would develop episode measures for future expansion of the Efficiency domain, we considered the following five criteria: (1) The condition constitutes a significant share of Medicare payments for hospitalized patients during and surrounding the hospital stay; (2) the degree to which clinical experts consulted for this project agree that standardized Medicare payments for services provided during the episode can be linked to the care provided during the hospitalization; (3) episodes of care for the condition are comprised of a substantial proportion of payments for post-acute care, indicating episode payment differences are driven by utilization outside of the MS–DRG payment; (4) episodes of care for the condition reflect high variation in post-discharge payments, enabling differentiation between hospitals; and, (5) the medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioner types within each episode measure.").
[39] Id.
[40] Id. at 28,122-23.

Proposed Rule that the MSPB measure is inappropriate for inclusion in the Physician VM Program.[41] The physician groups subject to the Physician VM Program can differ significantly from each other in specialty composition as well as the setting in which they provide care. Applying the MSPB measure uniformly to these practices would not account for such differences and the impact on cost the clinical realities of these differences convey. Instead, BIO believes relative resource use measures[42] are better able to assess efficiency in outpatient care. Thus, we urge CMS to consider the important differences between the inpatient and outpatient setting before attempting to align reporting requirements that may not appropriately reflect the quality of care delivered in a specific care setting.

### f. Proposal to Increase the Weight of the Safety Domain (p. 28,131)

CMS proposes to revise the FY 2017 domain weighting by increasing the weight of the safety domain to 20 percent and reducing the weight of the clinical care process sub-domain to 5 percent.[43] BIO generally supports this proposal not only because it largely aligns with the National Quality Strategy's (NQS's) quality priorities, but because an increased focus on patient safety will help ensure that hospitals are committed to improve outcomes in this area.

That said, we believe that performance measures should remain an important component of the VBP program because they are actionable for hospitals and can therefore encourage the adoption of best practices that improve patient outcomes. Accordingly, we urge CMS to take steps to strike a balance between outcomes and process measures. Specifically, we urge CMS to ensure that the immunization measure described above (IMM-2)—and any immunization measures subsequently added to the VBP—is afforded sufficient weight in determining hospital value-based payments, such as by including this measure in the patient safety domain.

## III. Proposed Inclusion of a Chronic Obstructive Pulmonary Disease (COPD) Measure In the Hospital Readmissions Program (p. 28,113)

BIO supports the inclusion of an additional readmission measure for COPD in the Hospital Readmissions Program beginning in FY 2015.[44] COPD hospitalizations are among the most costly, but are also potentially preventable, and are thus appropriate targets for inclusion in the Hospital Readmissions Program. Specifically, BIO believes the adoption of this measure will encourage hospitals to focus more closely on avoiding negative outcomes for this potentially costly condition by more carefully managing the care of patients with COPD.

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[41] BIO. 2013. BIO Comments on the CY 2014 Physician Fee Schedule Proposed Rule. Washington, DC: BIO, Available at: http://www.bio.org/advocacy/letters/bio-comments-cy-2014-physician-fee-schedule-proposed-rule.

[42] Relative Resource Use Measures are defined by the National Committee for Quality Assurance (NCQA) as measures that: indicate how intensively plans use physician visits, hospital stays and other resources to care for members identified as having one of five chronic diseases; cardiovascular disease, COPD, diabetes, hypertension and asthma. When evaluated alongside quality measures, RRU measures make it possible to consider quality and spending simultaneously.
Source: NCQA. 2013. *Relative Resource Use Measures*. Washington, DC: NCQA, Available at: http://www.ncqa.org/Employers/RelativeResourceUseMeasures.aspx.

[43] 79 Fed. Reg. at 28,131. See also 78 Fed. Reg. at 50,702-04.

[44] 79 Fed. Reg. at 28,113. See also 78 Fed. Reg. at 50,657-50,664.

## IV. CMS Review of New Technology Add-On Payment Applications (pp. 28,036-48)

In CMS's review of the applications for new technology add-on payments for 2015, CMS appeared to be critical of the evidence presented by applicants in support of their claims that the new technology shows substantial clinical improvement over the standard of care.[45] Specifically, CMS appeared universally critical of all of the following sources of evidence: peer-reviewed literature; registry data; meta-analyses of clinical trials; single-arm studies; and non-inferiority studies. CMS also appeared to question studies in which the age of clinical trial participants is below the age of Medicare beneficiaries, or that lacked long-term outcome data.

In short, CMS is turning down a number of products based on what CMS perceives to be an insufficient level of evidence. But, while we understand that head-to-head clinical trials are generally the evidentiary gold standard, BIO is concerned that CMS is categorically dismissing the use of these other data sources without examining the circumstances of each particular application. To illustrate, there are instances in which a non-inferiority study may be particularly useful, such as where a product presents additional benefits (e.g., a simpler or less-frequent administration regimen that improves patient adherence) and a non-inferiority study is useful to demonstrate that the product is not worse than existing products in terms of both safety and efficacy. We also note that there are instances in which head-to-head studies may not be feasible, particularly for the most innovative products for which an adequate comparator may truly not exist. Accordingly, we would urge CMS to review applications for new technology add-on payments on a case-by-case basis, taking into account the totality of the evidence and the unique nature of the product at issue.

## V. Hospital Price Transparency (p. 28,169)

In the Proposed Rule, CMS reminds hospitals that the ACA requires that they make public a list of standard charges for hospital items and services.[46] Specifically, hospitals are directed to either make public a list of their standard charges or allow the public to view a list of standard charges in response to an inquiry. BIO strongly supports this requirement and commends CMS for reminding hospitals of their obligation to provide this information. We note, however, that the list of standard charges will be very difficult for patients and others to interpret in the absence of the hospital's cost-to-charge ratio, a data point that is not currently available to the public. In accordance with the Agency's encouragement of hospitals "to undertake efforts to engage in consumer friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain at the hospital, and to enable patients to compare charges for similar services across hospitals,"[47] BIO therefore urges CMS to either encourage or require that hospitals post this information together with their list of standard charges.

[45] See 79 Fed. Reg. at 28,036-48.
[46] Id. at 28,169 (citing ACA § 1001, enacting Public Health Service Act § 2178(e)).
[47] Id.

## VI. Inpatient Versus Outpatient Reimbursement for Hospital Drugs

It is our understanding that drugs used in an emergency department (ED) prior to inpatient admission are included in the DRG calculations under the IPPS, and are not to be paid separately under Medicare's Outpatient Prospective Payment System (OPPS). However, we have come across some alternative scenarios that are confusing. For instance, consider the following scenario: a patient comes into the ED, receives a drug, and then is subsequently admitted to that hospital. Under what circumstances would this entire episode be classified as an inpatient admission paid fully under the IPPS such that the hospital would not receive payment for the drug as a separately payable drug under the OPPS? Relatedly, under what circumstances, if any, may a hospital permissibly exclude charges for a drug normally included in the inpatient diagnosis-related group (DRG) calculation, or bill for that drug separately? BIO would greatly appreciate if CMS would provide further guidance with respect to how this scenario should be appropriately billed and reimbursed in issuing the IPPS final rule.

## VII. Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule regarding the Medicare IPPS, including the Hospital IQR and VBP Programs. We look forward to continuing to work with CMS to address critical issues related to the use of quality measures in the future. Please contact me at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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