Biotechnology Industry Organization

June 12, 2015

BY ELECTRONIC DELIVERY

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
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 Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program; Proposed Rule

Dear Acting Administrator Slavitt:

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 2016 Rates Proposed Rule (the "Proposed Rule"), including with respect to the Hospital Inpatient Quality Reporting (IQR) Program and the Hospital Value-Based Purchasing (VBP) Program.[1] 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 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, resulting in higher vaccine uptake, better health outcomes, and cost savings for the healthcare system.

[1] 80 Fed. Reg. 23,424 (April 30, 2015).

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6306 F
bio.org

Our comments focus on several proposals related to the Hospital VBP Program and the Hospital IQR program, as well as concerns regarding CMS's review of New Technology Add-on Applications and proposal to adopt a new, temporary category of codes. Discussed in detail below, we ask that CMS:

- Finalize the proposal to adopt a 3-item Care Transition Measure in the Hospital VBP Program for the FY 2018 Program Year;
- Finalize the proposal to adopt the Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization measure for the FY 2021 Program Year;
- Retain the IMM-2 Influenza Measure in the Hospital VBP Program;
- Move forward with the proposal to include selected ward (non-intensive care unit) locations in certain National Healthcare Safety Network (NHSN) measures beginning with the FY 2019 Program Year;
- Adopt select NQF-Endorsed Stroke Chart-Abstracted Measures for Purposes of the VBP Program;
- Retain the Clinical Care-Process Subdomain for the FY 2018 Program Year and Subsequent Years;
- Retain the Pneumococcal Immunization Measure in the Hospital IQR Program measure set for the FY 2018 Payment Determination and Subsequent Years;
- Finalize the proposal to retain the IMM-2 Influenza Immunization measure in the Hospital IQR program;
- Finalize the proposal to adopt the Centers for Disease Control and Prevention (CDC) NHSN Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure for the FY 2018 PPS-Exempt Cancer Hospital Reporting (PCHQR) Program;
- Finalize the proposal to adopt the CDC NHSN Facility-wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure for the FY 2018 PCHQR Program;
- Finalize the proposal to adopt the CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel (HCP) Measure for the FY 2018 PCHQR Program;
- Finalize the proposal to include select ward (non-intensive care unit) locations in certain CDC NHSN measures beginning in the FY 2018 program year for the Hospital-Acquired Condition (HAC) Reduction program;
- Consider, in implementing a new type of measure that utilizes core clinical data elements, the development of "hybrid" measures that include more than one data source, including clinical data found in electronic health records;
- Take into consideration three specific issues before making a determination of whether an expansion of the Bundled Payments for Care Initiative (BPCI) is appropriate;
- Further develop the proposal to adopt new, temporary Section "X" procedure codes within the ICD-10 procedure coding system; and
- 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.

I. Hospital Value-Based Purchasing (VBP) Program

A. Proposed New Measure for the FY 2018 Program Year: 3-Item Care Transition Measure (CTM-3) (p. 24,499)

In the FY 2013 IPPS final rule, CMS adopted the 3-item Care Transition Measure (CTM-3) in the Hospital IQR Program. In the FY 2015 IPPS final rule, CMS stated it was "considering proposing to add the CTM-3 measure from the [Hospital Consumer Assessment of Healthcare Providers and Systems] Survey to the Patient and Caregiver Centered Experience Care/Care Coordination (PCCEC/CC) domain of the FY 2018 Hospital VBP Program."[2] BIO strongly supported this proposal.

In the FY 2016 IPPS Proposed Rule, CMS is now proposing to adopt the CTM-3 for the Hospital VBP Program for the FY 2018 program year. BIO is supportive of this proposal and strongly urges CMS to finalize it. As we mentioned previously, including this measure would incentivize hospitals to coordinate patient transitions to outpatient care settings, effectively decreasing readmissions and potentially mortality, among the Medicare population.

B. Proposed New Measure for the FY 2021 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (p. 24,502)

BIO supports the inclusion of the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following COPD Hospitalization (MORT-30-COPD) in the Hospital VBP Program for the FY 2021 Program Year, as proposed. As CMS notes, COPD is one of the leading causes of death in the United States, and greatly contributes to Medicare costs. Indeed, COPD is the fifth most common reason for hospitalization of Americans over 65,[3] and the third-leading cause of death nationwide.[4] COPD is also associated with multiple comorbidities, as well as increases in healthcare resource utilization and spending.[5]

BIO believes that the inclusion of this measure will increase the likelihood that hospitals will spend the requisite time with patients presenting with COPD in order to advance the treatment, management, and care coordination that is required for this difficult disease, and will facilitate improvements in patient outcomes and reductions in overall healthcare costs. Thus, we ask CMS to adopt this measure as an important step in encouraging hospitals to improve outcomes for patients presenting with COPD in order to avoid complications that can result in increased mortality rates.

C. Proposed Removal of IMM-2 Influenza Immunization Measure (p. 24,499)

CMS is proposing to remove IMM-2, the influenza immunization measure, from the Hospital VBP Program, effective beginning in the FY 2018 performance year, based on an

[2] 79 Fed. Reg. at 28,122.
[3] Jemal A, Ward E, Hao Y, Thun M. Trends in the leading causes of death in the United States, 1970-2002. JAMA. 2005; 294:1255-1259.
[4] Centers for Disease Control and Prevention. National Center for Health Statistics. Final Vital Statiscits Report. Deaths: Final Data for 2009. Vol. 60, No. 4. January 2012.
[5] Dalal AA, Shah M, Lunacsek O, Hanania NA. Clinical and economic burden of patients diagnosed with COPD with comorbid vascular disease. Respiratory Medicine, 2011. 105: 10:1516-1522.

analysis that this measure has "topped out." Although CMS states its intention to keep this measure as part of the Hospital IQR Program, BIO believes it is equally as important for the IMM-2 to remain in the Hospital VBP Program as well.

Each year, influenza causes approximately 200,000 hospitalizations and 36,000 deaths in the United States.[6] Nosocomial influenza, which occurs when a patient develops symptoms after more than 72 hours of hospitalization,[7] results in longer hospital stays and greater morbidity and mortality among patients.[8] 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.[9]

Influenza vaccination is the primary method for preventing influenza infection and has been proven to be safe and effective.[10] For these reasons, the Advisory Committee on Immunization Practices (ACIP) recommends annual influenza vaccination for all people age 6 months and older. Quality measures such as IMM-2 help improve immunization rates by ensuring healthcare providers offer recommended vaccines to their patients, reducing the number of missed vaccination opportunities.

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.[11]

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 the Department of Health and Human Services (HHS), 80 percent of eligible hospitals have now adopted EHR systems.[12] Despite the growing evidence that vaccinations are one of the top methods for preventing illness, adult immunization rates remain low,[13] and quality measures are an important tool to help increase vaccination rates in this population.[14] For these reasons, BIO urges CMS not to

---

[6] 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.
[7] 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.
[8] 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.
[9] 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.
[10] 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.
[11] 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.
[12] 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.
[13] MMWR, February 7, 2014/ 63(05); 95-10.
[14] 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.

remove the IMM-2 influenza immunization measure from the Hospital VBP. Although this measure is currently "topped out", retaining it in the Hospital VBP is important to ensure that providers continue to administer this valuable vaccine.

D. Intent to Propose in Future Rulemaking to Include Selected Ward (Non-Intensive Care Unit (ICU)) Locations in Certain National Healthcare Safety Network (NHSN) Measures Beginning With the FY 2019 Program Year (p. 24,501)

In the FY 2016 proposed rule, CMS states its intention to propose, in future rulemaking, the inclusion of selected ward (non-ICU) locations in the Catheter-associated Urinary Tract Infections (CAUTI) and Central Line-associated Bloodstream Infection (CLABSI) measures beginning with the FY 2019 program year. BIO strongly supports this proposal. For the FY 2017 and FY 2018 program years, the Hospital VBP Program will use adult, pediatric, and neonatal intensive care unit data to calculate performance standards and measure scores for the CAUTI and CLABSI measures. Introducing these measures in non-ICU locations can help to prevent these costly and common hospital-associated infections. Additionally, as CMS notes, the "expansion of the measures will allow hospitals that do not have ICU locations to use the tools and resources of the NHSN" for their quality improvement efforts.[15] For these reasons, BIO encourages CMS to propose, in future rulemaking, to expand the CAUTI and CLABSI measures in non-ICU locations. In the interim, BIO asks CMS to consider, in the FY 2016 Final Rule, providing selected ward (non-ICU) locations with the mechanisms to begin voluntarily collecting data related to the CAUTI and CLABSI measures for purposes of calculating performance standards. Reducing the number of hospital-associated infections improves patient experiences and outcomes, while simultaneously reducing overall costs to the healthcare system.

E. Adoption of Select NQF-Endorsed Stroke Chart-Abstracted Measures for Purposes of the VBP Program

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 fifth-leading cause of death in the United States and a leading cause of disability.[16] Ischemic stroke affects hundreds of thousands and leaves many with a new disability and an increased 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 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 stroke care.[17] The STK measure set was developed by the American Heart Association (AHA)/American Stroke Association (ASA), the Joint Commission, and physician groups as a

[15] 80 Fed. Reg. at 24,502 (citing 78 Fed. Reg. 50,787).
[16] National Center for Health Statistics. Mortality in the United States, 2013, NCHS Data Brief Number 178, December 2014.
[17] See 79 Fed. Reg. at 28,220, 28,242.

complimentary component of a broader set of measures that reflect the treatment continuum of stroke patients. BIO is now recommending that CMS consider adopting STK-4 (percentage of eligible patients receiving thrombolytic therapy with 0-3 hours of symptom onset) 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 higher rates of discharges directly to home for Medicare beneficiaries.[18]

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 measures 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.

As part of the FY 2016 IPPS proposed rule, CMS recommended removing 3 additional STK measures from the IQR program that have reached the "topped out" criteria. Going forward, STK-4 would be the only measure from the STK measures set that hospitals would be required to report for IQR purposes. MAP has endorsed the STK-4 measure for the Hospital VBP program, and we see an opportunity for hospitals to improve on this measure: Hospital Compare reported only a 76 percent national average for STK-4 for Q2 in 2014. Furthermore, 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.[19] We believe that adopting STK-4 within the VBP program would have a positive impact on stroke care and patient outcomes.

F. Proposed Removal of Clinical Care-Process Subdomain for the FY 2018 Program Year and Subsequent Years (p. 24,500)

For the FY 2017 Hospital VBP Program, CMS had previously adopted three measures for the Clinical Care-Process subdomain. However, CMS is now proposing to remove two of those measures from the VBP Program and is not proposing to adopt any additional measures for the Clinical Care-Process subdomain. If the proposals to remove the AMI-7a and IMM-2 measures are finalized, CMS is proposing to move the final measure to the Safety domain and remove the Clinical Care-Process subdomain from the Hospital VBP Program beginning with the FY 2018 program year. While we understand that, if the stated proposals are finalized, there will be no process measures within the Clinical Care-Process subdomain, we nonetheless recommend that CMS maintain the subdomain and weight it at 0% for FY 2018. BIO supports CMS's desire to move toward outcomes-based measures, but

[18] Song S, et al. AHAQCOR Scientific Sessions, 2013.

[19] Adeove, et al. ASA's International Stroke Conference, 2014.

we continue to believe that process measures play an important role in improving patient outcomes and wish to not preclude the adoption of process measures within the Clinical Care-Process subdomain in the future. Therefore, we ask that CMS consider retaining the Clinical Care-Process subdomain to allow for the inclusion of additional process measures into the Hospital VBP Program in the future.

II. Hospital Inpatient Quality Reporting (IQR) Program

A. Proposal to Remove the IMM-1 Pneumococcal Immunization Measure (p. 24,558)

In the FY 2014 IPPS rule, CMS decided to suspend the IMM-1 measure rather than remove it from the Hospital IQR program, and in the FY 2015 proposed rule, CMS proposed a continuation of this suspension. BIO opposed the continued suspension of the measure and urged CMS to reinstate the measure. In the FY 2016 IPPS Proposed Rule, CMS proposes to remove IMM-1 from the Hospital IQR Program beginning in CY 2016 for the FY 2018 payment determination and subsequent years. BIO strongly urges CMS not to finalize this proposal and urges CMS to reinstate the requirement. The pneumococcal immunization measure plays a critical role in ensuring that patients are appropriately vaccinated against the pneumococcal disease, thereby reducing significant morbidity, mortality, and healthcare costs associated with the disease.

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 resistance. Reducing the need for antibiotic treatments has become especially critical given the current environment of anti-microbial resistance. 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 costs for Medicare beneficiaries during, and one year following, a pneumonia hospitalization were approximately $15,682 higher than those 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.[20]

In 2014, the Advisory Committee on Immunization Practices (ACIP) began recommending the routine use of PCV13 among adults aged 65 and older, in series with PPSV23.[21] Prior to this change, PPSV23 was the primary recommended pneumococcal vaccine for adults aged 65 and older, while PCV13 was predominantly recommended for individuals aged 19 to 64 with immunocompromising conditions.[22] CMS states that the complex nature of the new ACIP guidelines on pneumococcal vaccination makes it difficult

[20] 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.

[21] 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.

[22] Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromisng Conditions. MMWR Morbidity and Mortality Weekly Report. 2012; 61(40):816-819.

for hospitals "to implement the measure specifications that incorporate the new guidelines."[23] However, BIO believes that the new ACIP guidelines and would not require that hospitals gather the detailed data CMS thinks is necessary in order to effectively implement the IMM-1 pneumococcal immunization measure. Further, we believe there are mechanisms available to CMS to refine this measure to allow for more effective implementation

The new recommendations state that "adults aged ≥ 65 years who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first, followed by a dose of PPSV23."[16] For those adults who have already received a PPSV23 dose, ACIP recommends providing a dose of PCV13. CMS is concerned that an extensive history of each patient's pneumococcal vaccination status will be necessary in order to appropriately administer a pneumococcal vaccine. However, as previously mentioned, ACIP has provided a recommendation for when a patient's vaccination status is unknown. Given the narrower recommendation for PCV13 over the last few years, many of the beneficiaries who remember receiving a pneumococcal vaccination are more likely to have received PPSV23. Therefore, hospitals should be able to appropriately follow the new guidelines with regards to the pneumococcal vaccine in order to comply with IMM-1, without the detailed patient history that CMS writes providers would need.

Furthermore, based upon a preliminary analysis, the implementation of the new ACIP guidelines would "prevent an estimated 230 cases of invasive pneumococcal disease and approximately 12,000 cases of community-acquired pneumonia over the lifetime of a single cohort of persons aged 65 years."[16]

Despite the health and economic benefits, pneumococcal immunization rates are still suboptimal. 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.[24] 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 pneumococcal vaccine increased from 71 percent to 94 percent.[25]

Additionally, CMS states in the proposed rule that one of the key factors in determining whether a measure should be retained is whether it aligns with other CMS and the Department of Health and Human Services (HHS) policy goals. The removal of the IMM-

[23] 80 Fed. Reg. at 24,558.
[24] Centers for Disease Control and Prevention. Noninfluenza Vaccination Coverage among Adults – United States, 2011. *MMWR Morb Mortal Wkly Rep*. 2013;63(04):66-72.
[25] 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.

1 measure from the IQR program is in contradiction to other objectives and priorities established by HHS. Specifically, Health People 2020 established a goal of at least 90 percent of adults aged 65 or older ever receiving a pneumonia vaccine.[26] This goal was then reiterated at the 11th Scope of Work for the CMS Quality Improvement Organizations[27] and the draft National Adult Immunization Plan.[28] Given that pneumonia vaccination coverage of this population was only 60 percent in 2013, there is still progress to be made in pursuit of these goals. The removal of the IMM-1 represents a major impediment for HHS to meet its target and provide organizations with a mechanism for evaluating and tracking progress.

We believe the measure should be fully reinstated, and CMS can move quickly to make some minor modifications to the measure specifications that will address the concerns around accurate data collection and reporting. Specifically, we encourage CMS – as acting measure steward – to consider the following modifications to the existing measure.

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-aide in the form of a flow chart for use with adults, similar to the existing flow chart used in 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 pneumococcal vaccination (and which type) based on his or her vaccination history.

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 CDC/ACIP.[29] 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.

Although CMS asserts that "hospitals [will] continue to provide pneumococcal vaccinations for their hospital populations as appropriate," it offers no evidence to support this claim. Without evidence to support that assumption, it is not reasonable to remove the measure. Given the likely time and resource investment required for the development of an entirely new measure, BIO strongly encourages CMS to retain the IMM-1 measure with some minor modifications to enable accurate data collection and reporting.

Given the significant public health and economic impact of pneumococcal disease, the continued opportunities for improvement in vaccination rates, and the time and resource

---

[26] 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.
[27] 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.
[28] National Vaccine Program Office. National Adult Immunization Plan. February 5, 2015.
[29] National Quality Forum, Health and Well-Being, Phase 2, Draft Report for Comment, released May 29, 2015

investment required for the development of an entirely new measure, BIO urges CMS to reinstate IMM-1, the pneumococcal immunization measure, to the Hospital IQR Program and consider recommendations from NQF and other stakeholders for modifications to improve accurate data collection and reporting.

B. IMM-2 Influenza Immunization (p. 24,557)

We commend CMS for proposing to retain the influenza immunization measure (IMM-2) in the Hospital IQR Program, and for increasing the weight of the clinical process of care stratum as needed to include the influenza immunization measure. For reasons articulated in section (I)(C) of this letter, BIO believes that the continued inclusion of this measure in the Hospital IQR Program is critical to improving immunization rates for influenza among the Medicare population, which will have important benefits in terms of both improved public health and lower Medicare spending. As such, we urge CMS to finalize the proposal to include the IMM-2 influenza immunization measure in the IQR Program.

C. Proposed Modifications to the Existing Processes for Validation of Chart-Abstracted Hospital IQR Data (p. 24,589)

As stated in section (I)(C) of this letter, BIO strongly urges CMS not to finalize the proposal to remove the IMM-2 influenza immunization measure from the Hospital VBP. However, if CMS finalizes this proposal, and the IMM-2 is no longer included in the Hospital VBP Program, BIO understands the rationale behind removing the separate immunization measure stratum. In the FY 2015 IPPS final rule, CMS included a separate validation stratum for the Influenza Immunization measure: the immunization measure validation stratum. This action was intended to ensure validation of the influenza immunization measure with the Hospital VBP program, which also includes this measure. In the FY 2016 Proposed Rule, CMS is proposing to remove the influenza immunization measure from the Hospital VBP Program. CMS states that, if finalized, the proposal will negate the need to ensure validation of the measure between the two programs. For this reason, CMS is proposing to remove the separate immunization validation stratum and move the influenza immunization measure to the clinical process of care measure validation stratum, and BIO understands the justification behind this proposal.

D. Additional Considerations

AS CMS begins removing quality measures from the Hospital IQR Program that meet a "topped out" criteria, we encourage CMS to consider ways to improve scores for those measures that are slower to meet that criteria. With CMS focusing more on Outcomes measures in the VBP program, we believe that there is a need to put additional focus on the process measures that are tied to high quality data within IQR in order to support improvement of hospital quality and patient outcomes. We have observed recently that quality measures within some measure sets quickly reach the "topped out" criteria, while other measures in that set are slow to improve or have perpetually low scores. We recommend that CMS consider adopting such quality measures within the IQR program for a pre-determined time or work with stakeholders to identify other solutions to increase hospital focus on those measures.

III. PPS-Exempt Cancer Hospital Quality Reporting Program

For the FY 2018 PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, CMS is proposing to adopt three new quality measures. BIO strongly supports the inclusion of all three measures. We discuss each of the measures separately in more detail below.

A. Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717 (CDC NHSN CDI Measure) (p. 24,591)

BIO urges CMS to finalize the proposal to include the CDI measure for the FY 2018 PCHQR program. As noted by CMS, "these infections cost the U.S. healthcare system billions of dollars each year and lead to the loss of tens of thousands of lives."[30] We believe that including this measure will encourage hospitals to focus on avoiding and appropriately treating *C. difficile* infections. This becomes especially important in cancer hospitals, as cancer patients tend to be immunocompromised, increasing their risk of developing an infection. For this reason, BIO agrees with CMS that collecting data on CDI remains a priority in the hospital setting in order to improve patient outcomes, while also reducing overall healthcare expenditures.

B. CDC NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716) (CDC NHSN MRSA Measure) (p. 24,592)

BIO urges CMS to finalize the proposal to include the MRSA measure for the FY 2018 PCHQR program. As mentioned above, cancer patients are at an increased risk of infection due to their immunocompromised state. MRSA infections have become increasingly more common and present a significant public health concern. As CMS states, the adoption of this measure will allow hospitals to determine the efficiency of their infection control efforts. For this reason, we believe CMS should finalize the adoption of this measure as a way to continue to encourage hospitals to improve patient care and, in turn, patient outcomes.

C. CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel (HCP) Measure (NQF #0431) (CDC NHSN HCP Measure) (p. 24,592)

BIO urges CMS to finalize the proposal to include the vaccination coverage among HCP measure for the FY 2018 PCHQR Program. Vaccination is one of the most effective preventive measures against the spread of influenza, especially among sick individuals, such as cancer patients, who are already at an increased risk of developing infectious diseases. Increasing vaccination rates among healthcare personnel is an important step in protecting patients from developing nosocomial influenza. BIO commends CMS for proposing this important measure, which can help avoid preventable adverse patient outcomes, while also improving work productivity among HCPs.

IV. Hospital-Acquired Condition (HAC) Reduction Program (p. 24,333)

[30] 80 Fed. Reg. at 24,591.

For the FY 2018 HAC Reduction Program, CMS proposes to "include data from pediatric and adult medical ward, surgical ward, and medical/surgical ward locations" for the CLABSI and CAUTI measures.[31] In the FY 2014 IPPS final rule, CMS adopted the CLABSI and CAUTI measures in ICUs for the HAC Program beginning with FY 2015. As articulated in section (I)(D) of this letter, BIO supports the expansion of these measures to select ward locations in addition to ICU locations, and commends CMS for the thorough assessment as to when would be the most appropriate time to implement these measures. As CMS notes, delaying implementation until FY 2018 allows all hospitals, regardless of whether or not they have ICU locations, the opportunity to contribute two years of data for measure result calculation, in order to avoid bias within the program. The CAUTI and CLABSI measures are an important tool in measuring efficiency within hospitals in order to reduce costly hospital-acquired infections that can have detrimental effects on the patients who develop them. The inclusion of these measures is especially important in a program working to reduce preventable hospital readmissions. For this reason, BIO urges CMS to finalize this proposal.

V. Future Considerations for Electronically Specified Measures: Consideration to Implement a New Type of Measure that Utilizes Core Clinical Data Elements (p. 24,582)

In response to comments from the clinical community that data gathered directly from patients and used by clinicians to guide diagnostic decisions and treatment are preferable for the risk adjustment of hospital outcome measures, CMS is proposing: (1) to use core clinical data elements derived from electronic health records (EHR) for use in future quality measures; (2) the collection of additional administrative linkage variables to link a patient's episode of care from EHR data with his administrative claims data; and (3) the use of content exchange standards.

CMS has identified a set of twenty-one clinical variables, or core clinical data elements, which are routinely collected on hospitalized adults and feasibly extracted from hospital EHRs. CMS believes that the core data elements can be adapted for future use as part of specific quality measures. One way in which these data elements, in conjunction with other sources of data, can be used is the calculation of "hybrid" outcome measures, which are quality measures that use more than one source of data.

BIO supports the development of "hybrid" measures that include more than one data source, including clinical data found in electronic health records. The twenty-one core clinical data elements that CMS has identified and proposes to use have been shown to be captured during routine clinical practice on most hospitalized adults and, we believe, will not impose an additional burden on hospitals. Further, BIO supports the collection and use of these data elements for use in future quality measures; the collection of additional administrative linkage variables to link a patient's episode of care from EHR data with his administrative claims data; and the use of content exchange standards.

VI. Solicitation of Public Comments on Expanding the Bundled Payments for Care Initiative (BPCI) (p. 24,414)

[31] 80 Fed. Reg. at 24,512.

In the Proposed Rule, CMS requests feedback on operational issues related to a potential expansion of the BPCI initiative in the future. As the Agency states, the Secretary has the authority to expand, through rulemaking, the duration and scope of a model, if the following criteria are met: (1) the Secretary determines that the expansion is expected to either reduce Medicare spending without reducing the quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net Medicare program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of Medicare benefits.

BIO appreciates the Agency's solicitation of public feedback on potential operational issues associated with expanding the BPCI "in the event that the Secretary determines that findings from the evaluation of the initiative demonstrate that it meets all criteria for expansion."[32] BIO looks forward to the public release of data assessing the impact of the BPCI on patient access to quality care, as well as overall healthcare expenditures. Not only will this be an important step in understanding the Secretary's determination with regard to whether the BPCI meets the statutory criteria to consider expansion, but it also will be crucial to ensure that stakeholders are able to provide meaningful, specific feedback on potential changes to the program.

In the event that the Secretary does authorize the expansion of the BPCI, BIO recommends that CMS focus on specific principles of payment system reform, including but not limited to: protecting patient access to appropriate therapies; maintaining incentives to develop breakthrough therapies to address patients' unmet needs and to discover the cures of tomorrow; protecting high-quality care; and integrating "patient impact" assessment into the proposed changes.[33] These principles can be operationalized with regard to three specific aspects of the BCPI, and we urge CMS to consider each before making a determination of whether BPCI expansion is appropriate.

First, BIO urges CMS to preserve the existing exclusion of new technology add-on payments from the benchmarks and actual spending calculations within the BCPI models in any expansion of the demonstration. CMS should also consider excluding drugs and technologies that have received pass-through status designation under the Hospital Outpatient Prospective Payment System. Removing these payments when calculating BPCI target prices and Adjusted Aggregate Fee-for-Service payments will protect the financial stability of BPCI, while still promoting the advancement of new therapy regimens. In addition to protecting participants from volatile and unpredictable target prices, the exclusion of these payments ensures patient access to important new therapies. Access to all new technologies approved by the Food and Drug Administration is critical in order to continue to achieve the types of gains in survival, and other positive health outcomes, that have been seen in the last decade.[34] In addition to preserving this current methodology,

---

[32] 80 Fed. Reg. at 24417.
[33] *See* BIO. 2009. *Principles for Payment System Reform Policies*, available at: https://www.bio.org/articles/bios-principles-payment-system-reform-psr-policies.
[34] See, e.g., W. Yin, J.R. Penrod, J.R. Maclean, D.N. Lakdawalla; and T. Philipson, *Value of survival gains in Chronic Myeloid Leukemia*, American Journal of Managed Care (2012), http://www.ajmc.com/publications/supplement/2012/A386_12nov_Oncology/A386_12nov_Onclogy_Yin_S257to64#sthash.sPsCayRI.dpuf.

before expanding the demonstration, we urge CMS to work with stakeholders to consider mechanisms to take into account the value of innovative drugs and biologicals, including: the importance of patient access to the most appropriate therapy for them, as opposed to what may be appropriate for an "average" patient; the decreased spending on other types of health care (e.g., hospitalizations, surgical interventions) that results from the use of drugs and biologicals;[35] and the need to support an environment that fosters future innovation. A potential expansion of the BPCI will provide the opportunity for the Agency to develop these mechanisms more comprehensively, and to learn from the initial performance years, in order to ensure that patient access to innovative therapies is maintained or improved.

Second, we urge CMS to consider what additional quality measures need to be put into place to account for populations that may be included in an expanded demonstration population. Robust quality measures are a crucial aspect of any demonstration because they serve as a bulwark against the perverse incentives that can arise from a solitary focus on cost-containment (i.e., under-utilization of appropriate and medically necessary care). To be effective, quality measures must meaningfully evaluate whether an individual patient is receiving the most appropriate course of treatment, especially as medical science progresses toward truly personalized medicine. An expansion of the BPCI would mean the inclusion of a broader and likely inherently more diverse patient population. Thus, in considering an expansion, CMS must ensure that the quality measures utilized by the BPCI reflect the care individual beneficiaries are receiving, and include, to the extent feasible and appropriate, patient-reported outcomes and measures that assess outcomes rather than process.

Third, BIO urges CMS to consider how the Agency will ensure that any expansion of the BPCI is assessed in real time to understand the impact of expansion on existing and newly participating providers and the beneficiaries to whom they provide care. Ensuring robust assessment will allow the Agency to detect changes in patient experiences, for those patients whose providers are participating, including issues related to patient access to quality care more quickly. This, in turn, will allow the Agency to refine the structure of the BPCI's constituent models in a timely fashion. We are sensitive to striking a balance between the need for data to assess the impact of the demonstration and the need to avoid placing a high reporting burden on providers. However, we believe such a balance can be achieved through stakeholder engagement, and as such, BIO asks CMS to develop and allow public comment on additional assessment mechanisms that rely on a variety of data sources, not just claims data, before considering an expansion of the BPCI.

VII. New Technology Add-On Payments

A. Implementation of ICD-10-PCS Section "X" Codes for Certain New Medical Services and Technologies for FY 2016 (p. 24,421)

As discussed in prior guidance implementing the International Classification of Diseases, Tenth Revision (ICD-10) coding system—scheduled to go into effect at the

[35] Congressional Budget Office. 2012 (November). *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services*, available at: https://www.cbo.gov/sites/default/files/43741-MedicalOffsets-11-29-12.pdf.

beginning of the FY 2016 payment year—CMS is proposing to adopt new, temporary Section "X" procedure codes within the ICD-10 procedure coding system (ICD-10-PCS) to capture new technologies, particularly drugs, biologicals, and newer medical devices being tested in clinical trials. The stated purpose for the codes is to "identify and report these technologies and inpatient services for purposes of approving new technology add-on payment applications and initiating subsequent new technology add-on payments based on approval or tracking and analyzing the use of these new technologies or services."[36] These codes will be implemented on October 1, 2015. We note that CMS is making this proposal despite the fact that "several commenters have opposed including these types of technologies and services within the current structure of the ICD-10-PCS codes."[37] BIO shares many of these concerns.

As an initial matter, while we strongly support the creation of unique codes within the International Classification of Diseases system to identify products eligible for NTAP payments, we do not believe that it is necessary to create a separate category of codes for this purpose. For instance, even though there is currently a freeze on the creation of new ICD-9 codes—pending the transition to ICD-10—there is an exception to this freeze for new technologies. Moreover, once CMS transitions to ICD-10, there will be the opportunity to create new ICD-10 codes for these technologies.

BIO also is concerned that creating a separate category of temporary ICD-10-PCS codes for purposes of products that may, or have, obtained NTAP status is likely to create a new set of challenges. As addressed during the ICD-10 Coordinating and Maintenance Committee meeting, the premise of the "X"-code nomenclature appears to be very similar to the Current Procedural Terminology (CPT) Category III code sets, which also were designed to describe new and emerging technologies. The development of the CPT Category III codes has resulted in payment disparities for new and emerging technologies by serving as a "pseudo coverage" determination for services assigned to the Category III section of the CPT manual. We are concerned that, because CMS has not clearly established guidance to help coders and payors understand the intended use of the "X" codes, payors may treat "X" codes similar to CPT Category III codes, viewing those technologies assigned to the "X" code section as "investigational and experimental," which is likely to result in confusion, incorrect coding, and claims denials.

We also agree with the comments made by the American Hospital Association (AHA) during the ICD-10 Coordinating Committee Meeting that adding yet another layer of complexity to the challenges that the community has and will continue to face during the ICD-10 transition is likely to further confuse coders and payors and result in reimbursement hurdles. Accordingly, we urge CMS to create new ICD-10-PCS codes for new technologies granted NTAP status, rather than special, temporary "New Technology" codes.

Further, during the ICD-10 Coordinating Committee meeting, CMS stated that it was not yet certain how or if it would transition new technologies out of the "X" code section of the ICD-10 manual. Both the American Medical Association (AMA) and CMS have established processes and defined timelines for transitioning codes away from Category III CPT Codes, as well as Healthcare Common Procedural Coding System (HCPCS) codes that

[36] 80 Fed. Reg. at 24,421.
[37] 80 Fed. Reg. at 24,421.

are used on a temporary basis for purposes of products granted pass-through status under Medicare's Hospital Outpatient Prospective Payment System. The statutory and regulatory provisions that govern NTAP payments similarly contemplate that this special payment treatment for new technologies is to last only until such time as data are available to reflect that the cost of the technology in the DRG weights through recalibration—between two and three years—at which point, NTAP status is to terminate.[38] Therefore, if CMS were to assign new technologies to the "X" section of the ICD-10 codes for purposes of making NTAP payments, then it is reasonable that the technology be moved away from the "X" section of the codes immediately upon termination of the technology's NTAP status.

Therefore, to the extent that CMS nonetheless moves forward with the creation of "X" codes, we strongly urge the Agency to ensure that: (1) products that already have codes under the International Classification of Diseases system are not required to move to a new Section "X" code; (2) that the section X code be automatically deleted upon termination of NTAP status; and (3) a new, permanent ICD-10-PCS code is automatically created immediately upon the expiration of the Section "X" code for those new technologies coded under this temporary coding system. We note that, as described above, these requirements would track what occurs under the Outpatient Hospital Prospective Payment System's pass-through status provision; that is, once the permanent J-code is awarded, the C-code associated with pass-through status is automatically retired. We also continue to emphasize that clear guidance would be needed from CMS before implementing the "X" Section of the ICD-10 manual, if at all.

B. FY 2016 Applications for New Technology Add-On Payments (p. 24,428)

In the Proposed Rule, CMS discusses nine applications for New Technology Add-On Payment (NTAP) status in FY 2016. Pursuant to applicable federal regulations, in order to be eligible for NTAP status, a new medical 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.[39] We believe that CMS's approach to NTAP applications in recent years has taken an increasingly cramped interpretation of these regulatory criteria, and that the rationale employed by the Agency to reject granting NTAP status often appears either ad hoc or contrary to the available evidence. This year, CMS seemed to be particularly critical with respect to first and third of these three criteria in reviewing NTAP applications for drugs and biologicals, often for reasons that we believe miss the mark. We discuss CMS's approach to each of these criteria, in turn.

1. Newness Criterion

First, CMS called into question whether these products meet the "newness criterion." As CMS articulates in the preamble, the Agency is employing a three-part test to determine whether a product is new under this criterion, which asks: (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a

[38] See Social Security Act § 1886(d)(5)(K)-(L); 42 C.F.R. 412.87(b)(2).
[39] 42 C.F.R. § 412.87.

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 patient population.[40] In this year's Proposed Rule, CMS appears to have been particularly harsh in its application of the first and third prongs of this test.

As to the first prong, CMS has employed what appears to be an inappropriate standard in determining whether a product has a new mechanism of action. To illustrate, in the application for BLINCYTO® (Blinatumomab) , CMS stated that "[w]e believe that the feature that distinguishes the BLINCYTO® technology from these other bi-specific T-cell engagers is that it specifically targets the CD19 cell. However, we are concerned that the specificity of the mechanism of action may not be sufficient to distinguish the technology from other bi-specific T-cell engagers." We believe this statement evinces an overly broad interpretation of a "mechanism of action," focused solely on the downstream cellular response to a product. By contrast, the Food and Drug Administration (FDA)—which makes science-based determinations with respect to product approval and labeling on behalf of HHS—has defined a mechanism of action as the pharmacologic action at the receptor, membrane, or tissue level.[41] Indeed, BLINCYTO® itself was identified in a press release issued by the FDA as having a "unique mechanism of action."[42] We are concerned that the broad definition of "mechanism of action" employed by CMS is not only inconsistent with the FDA definition and application of mechanism of action, but also would lead to broad groupings of unrelated pharmacologic/biologic agents that target biochemically different receptors and trigger potentially unrelated cellular responses.

In questioning the newness of a product's mechanism of action, CMS also curiously employed comparisons between applicants and products *currently under investigation*.[43] This is not an appropriate standard. The question at issue should be whether an applicant therapy employs a new mechanism of action as compared to products that are already on the market. A comparison against the universe of potential future products, on the other hand, sets up an impossible standard; given the near limitless potential for advancements in biomedical science, virtually no products could be considered new under such a test.

As to the third prong, which asks whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, CMS appears to be taking a similarly restrictive view of what constitutes a new patient population. For example, CMS appears to reject treating as a new patient population those groups of patients that cannot be readily identified in claims data (e.g., patients for whom chemotherapy has not been successful, or patients who are not eligible for further chemotherapy treatments based on the risks associated with cumulative toxicities).[44] Given the potential for CMS to establish new International Classification of Diseases, Tenth Revision, Coordination & Maintenance (ICD-10 CM) procedure codes and/or modifiers to help identify these patient groups, we do not believe that this is a valid limitation.

---

[40] 80 Fed. Reg. at 24,431.
[41] See 21 C.F.R. § 201.57(a)(13)(A) (requiring that the contents of a product's label include information as to the mechanism of action, defined as "the established mechanism(s) of the drug's action in humans at various levels (e.g., receptor, membrane, tissue, organ, whole body)."
[42] FDA, FDA News Release: FDA approves Blincyto to treat a rare form of acute lymphoblastic leukemia (Dec. 3, 2014), http://www.fda.gov/newsevents/newsroom/pressannoucements/ucm425549.htm.
[43] 80 Fed. Reg. at 24,431.
[44] See 80 Fed. Reg. at 24,431.

2. Substantial Clinical Improvement

In the Proposed Rule, CMS also calls into question whether applicant products meet the "substantial clinical improvement" criterion. As in prior years, we believe that CMS is being overly critical of the data provided in NTAP applications to support the existence of a "substantial clinical improvement." Among other things, CMS took issue with the fact that studies were not randomized or blinded, and/or that they lacked a control group.[45] As we articulated in our comments in response to the FY 2015 Proposed Rule, while we understand that head-to-head, randomized control 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.

CMS also questioned the trial size, including whether a product's clinical trials included a sufficient number of Medicare enrollees. However, the Agency used a patient's age (i.e., whether they are at least 65 years old) as the only proxy for Medicare eligibility.[46] Yet, as CMS is aware, there are other pathways for obtaining Medicare eligibility, including disability and end-stage renal disease. Indeed, for some diseases, a disproportionate share of Medicare patients may actually qualify for Medicare based on these pathways, rather than age. CMS should take this into account when reviewing the data submitted with NTAP applications, as well as whether there are limitations on trial size inherent in the population or condition being treated (e.g., orphan or ultra-orphan diseases).

In sum, 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. We believe that CMS's evaluation of the first NTAP criterion should compare applicants only to products currently on the market as it is not appropriate to compare an applicant to a product that may or may not be approved in the future. We further believe that CMS's evaluation of the third NTAP criterion should take into account determinations already made by the FDA with respect to an applicant product. For example, we believe that CMS should examine whether the product in question received a breakthrough therapy designation from the FDA, which, by definition, requires preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

Finally, we take issue with CMS's assertion that the possibility of favorable safety and tolerability relative to other currently available therapy options may not represent a substantial clinical improvement.[47] Enhancing safety and tolerability over existing therapies has the potential to greatly improve patient outcomes by, among other things, improving

[45] See 80 Fed. Reg. at 24,434, 24,443.
[46] See 80 Fed. Reg. at 24,434, 24,438.
[47] 80 Fed. Reg. at 24,438.

rates of patient adherence to therapy. We do not believe that these benefits should be minimized or ignored.

VIII. 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 in the future to address critical issues related to the use of quality measures. 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/

Erin Estey Hertzog, J.D., M.P.H.
Director, Health Law and Policy