



June 16, 2016

BY ELECTRONIC DELIVERY

Mr. Andrew M. 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 and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Proposed Rule

Dear Acting Administrator Slavitt:

The Biotechnology Innovation 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 Policy Changes and Fiscal Year 2017 Rates Proposed Rule* (the "Proposed Rule"), including with respect to the Quality Reporting Requirements for Specific Providers and Hospital Notification Procedures Applicable to Beneficiaries Receiving Observations Services.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's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals. 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

¹ 81 Fed. Reg. 24,946 (April 27, 2016).

recommended vaccines to their patients, resulting in higher vaccine uptake, better health outcomes, and cost savings for the healthcare system.

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

- BIO is concerned that CMS's methodology used to calculate and recalibrate Medicare Severity Diagnosis-Related Groups (MS-DRG) relative weights does not adequately ensure appropriate payment for the treatment of patients with rare diseases. We therefore urge the Agency to explore opportunities to better account for these cases and emerging treatments within the MS-DRG system.
- BIO has ongoing concerns regarding CMS's review of New Technology Add-on Payment (NTAP) applications. The Agency has improved its review of NTAP applications for FY 2017, but BIO is concerned there were instances in which the agency applied both the "newness" and "substantial clinical improvement" criteria in an inconsistent manner. To address these and other concerns, BIO is supportive of the proposal to add certain patient-centric criteria to guide the Agency's NTAP application review, provided that these criteria are non-exhaustive, and each application is required to meet only one such criterion. BIO also urges CMS to provide further guidance regarding the use of the new Section "X" ICD-10-PCS codes.
- BIO supports CMS's decision to transition to the use of the S-10 Worksheet for purposes of determining the value of "Factor 3" in the multifactorial uncompensated care payment formula, which appears to provide for a better assessment of a hospital's uncompensated care than the current metric used.
- For purposes of the Hospital Value-Based Purchasing (VBP) Program:
 - BIO supports CMS's proposal to include selected ward (non-ICU) locations in the Catheter-Associated Urinary Tract Infections (CAUTI) and Central-Line Associated Blood Stream Infection (CLASBI) measures beginning with the FY2019 program year, and urges CMS, in the interim, to provide these locations with mechanisms to begin voluntarily collecting data related to these measures.
 - BIO supports CMS's proposal to add two new condition- or treatment-specific Medicare payment measures to the Hospital VBP beginning in FY2021; however, we urge CMS to adopt these measures instead of (not in addition to) the problematic Medicare Spending Per Beneficiary measure.
 - BIO urges CMS to reinstate the IMM-2 influenza immunization measure in the program, which CMS has removed beginning with the FY2018 performance year, as this measure helps ensure that providers continue to administer this important vaccine to patients in the hospital setting, where nosocomial influenza poses a significant threat to patient health and safety.
- BIO supports CMS's proposal to implement the NOTICE Act, which amended section 1866(a)(1) of the Social Security Act to require hospitals and critical access hospitals to notify individuals receiving observation services as outpatients for more than 24 hours. We believe that this provision will help prevent abuse and assist beneficiaries to better understand the financial and other implications of the care they receive.
- For purposes of the Hospital Inpatient Quality Reporting (IQR) Program:

- BIO supports CMS's proposal to refine the 30-Day Mortality Following Acute Ischemic Stroke Hospitalization measure to include the National Institutes of Health (NIH) Stroke Scale, which will help ensure that this measure accurately risk-adjusts for different populations.
- BIO also supports CMS's proposal to potentially include the National Healthcare Safety Network (NHSN) Antimicrobial Use Measure.
- BIO does not support the removal of the STK-4 measure.
- BIO commends CMS for retaining two important immunization measures in the IQR for the FY2018 payment determination and subsequent years—NQF #1659 "Influenza Immunization (IMM-2)" and NQF #0431 "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)"—but we again urge CMS to revisit the Agency's decision to remove IMM-1, the pneumococcal immunization measure, from the IQR program.
- For purposes of the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program:
 - BIO commends CMS for retaining the previously finalized measure NQF#0431 "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)."
 - BIO does not, however, support the proposed inclusion of the "Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy."
- For purposes of the Long-Term Care Hospital (LTCH) Quality Reporting Program, BIO supports the proposed revisions to the data collection period for NQF #0680 "Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)." BIO also is pleased that the previously adopted measure NQF #0431 "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)" will remain in the LTCH Quality Reporting Program for the FY2018 payment determination year and subsequent years.

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I. Proposed FY 2017 MS-DRG Relative Weights (p. 25,027)

As in prior years, CMS has proposed to calculate the Medicare Severity Diagnosis-Related Groups (MS-DRG) relative weights for FY2017 based on both claims data and hospital cost-report data from prior years. CMS also proposes to continue its policy of removing statistical outliers from the data used for this purpose.² While CMS has, in the past, "acknowledge[d] the importance of ensuring that patients diagnosed with a [rare disorder] have adequate access to care and receive the necessary treatment,"³ payment for cases involving patients with rare diseases continue to be inadequate to cover hospital costs and will often be subject to outlier payments. BIO is concerned that CMS's methodology used to calculate and recalibrate MS-DRG relative weights does not adequately ensure appropriate payment for the treatment of patients with rare diseases. BIO recognizes that there are inherent challenges to effectively incorporating orphan therapies into the current MS-DRG system, since by definition these cases are not common enough to significantly influence the relative weights of the MS-DRG to which they are assigned.

² Id. at 25,027-28.

³ 77 Fed. Reg. 52,258, 53,312 (Aug. 31, 2012).

In recent years, increasing numbers of treatment options have gained Food and Drug Administration (FDA) approval and have become available for a number of rare diseases. In light of this, BIO urges CMS to explore opportunities to better account for these cases and emerging treatments within the MS-DRG system. There are several approaches CMS could explore to determine how best to account for orphan disease treatments within the current system, including the creation of new MS-DRG(s) for specific patient sub-types which, though rare, demonstrate similar clinical needs, resource use, and lengths of stay. Such cases may be identifiable by both diagnosis and a targeted orphan drug intervention. It would behoove CMS to look at specific hospitals that serve as centers of excellence and/or specialize in the treatment of certain rare diseases, to see if within their patient populations there are groups of patients undergoing treatment protocols that warrant the creation of a new MS-DRG(s). We urge CMS to work with appropriate stakeholders to identify orphan diseases with patterns of inpatient care and treatment protocols that could be better incorporated into the current IPPS system, leading to better access to care for Medicare beneficiaries in need of acute inpatient services.

II. Proposed Add-On Payments for New Services and Technologies for FY 2017 (p. 25,031)

A. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments (p. 25,033)

In the Proposed Rule, CMS describes a general comment received in response to the Agency's published notice and town hall meeting regarding add-on payments for new medical services and technologies for FY2017, which urged the Agency to "broaden the criteria applied in making substantial clinical improvement determinations"⁴ as part of its New Technology Add on Payment (NTAP) application review. BIO generally agrees with this comment.

As articulated in prior BIO comments,⁵ as well as in the subsequent subsection of this letter, BIO is concerned that CMS has historically been overly critical of the data provided in NTAP applications to support the existence of a "substantial clinical improvement," and often has failed to take into account clinical improvements of particular relevance to Medicare beneficiaries as part of this assessment. We therefore believe that recognizing certain patient-centric improvements in assessing whether a new technology represents a "substantial clinical improvement," as the commenter recommends, would greatly enhance CMS's approach to NTAP applications, and also would align with the FDA's approach on incorporating patient-reported outcomes.

For this reason, we support three of the patient-centric "substantial clinical improvement" criteria suggested by the commenter, namely whether a new technology or medical service: (1) results in a reduction of the length of a hospital stay; (2) improves patient quality of life; or (3)

⁴ 81 Fed. Reg. at 25,033-34.

⁵ BIO, Comments Regarding FY2016 Medicare Inpatient Prospective Payment System Proposed Rule (June 12, 2015), available at <https://www.bio.org/advocacy/letters/bio-submits-comments-re-medicare-inpatient-prospective-payment-system-ipp-pps-proposed>; BIO, Comments Regarding FY2015 Medicare Inpatient Prospective Payment System Proposed Rule (June 30, 2014), available at https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments_FY15%20Hospital%20IPPS%20Proposed%20Rule_30%20June%202014.pdf.

creates long-term clinical efficiencies in treatment.⁶ Along these lines, we continue to urge CMS to also take into account whether a new technology has the possibility of an improved safety and tolerability profile relative to existing therapies (e.g., by incorporating adverse events and other hard, as well as functional, status endpoints from clinical trials). However, our support for these criteria extends only so far as they are viewed as a non-exhaustive list of ways to demonstrate a “substantial clinical improvement,” and so long as an applicant is required to meet only one such criterion. Furthermore, we recommend that CMS not adopt the remaining two criteria recommended by the commenter (i.e., whether a new technology or medical service: (1) addresses patient-centered objectives as defined by the Secretary; or (2) meets such other criteria as the Secretary may specify),⁷ as these criteria are too open-ended and ill-defined. In lieu of these criteria, we instead urge the Agency to solicit public comments regarding additional, specific patient-centric criteria for potential inclusion on this non-exhaustive list.

The commenter also suggested that “an entity that submits an application for new technology add-on payments be entitled to administrative review of an adverse determination made by the Secretary.”⁸ BIO also agrees with this recommendation. There is a need for these determinations to be administratively reviewable, as they currently cannot be reviewed as either a coverage appeal or a claims appeal—processes that, in other contexts, provide a fair hearing from external stakeholders—yet this determination can have a substantial financial impact on providers (as well as the uptake of promising new therapies). Relatedly, we remind CMS that paying providers 50 percent for a portion of the costs of a new technology that the Agency has determined represents a “substantial clinical improvement,” penalizes those providers that furnish better patient care. We believe that setting this additional reimbursement amount at 80 percent to 90 percent would better align CMS’s NTAP policy with the goal of providing high-quality care to Medicare patients.

B. Proposed FY2017 Applications for New Technology Add-On Payments

In the Proposed Rule, CMS reviewed nine NTAP applications for FY2017. We believe the Agency has made positive advancements in its application of the NTAP criteria in the Proposed Rule based on previous feedback, but still remain concerned regarding CMS’s application of the Agency’s regulatory NTAP criteria in certain instances. 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.⁹ While we believe that the Agency has improved its review of NTAP applications this year, including the FY 2017 new technology add-on payment (NTAP) application for Idarucizumab, there were instances in which the Agency applied both the “newness” and “substantial clinical improvement” criteria in an inconsistent manner.

⁶ 81 Fed. Reg. at 25,034.

⁷ Id.

⁸ Id.

⁹ 42 C.F.R. § 412.87.

1. Newness

As CMS articulates in the preamble to the Proposed Rule, the Agency is employing a three-part test to determine whether a product is “new,” which asks: (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS-DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population.¹⁰ We are particularly concerned regarding CMS’s application of the first and third prongs of this test in this year’s Proposed Rule.

As to the first prong, BIO supports that CMS has—in some instances—improved its standards for determining whether a particular product employs a new mechanism of action. For instance, we do feel the Agency accurately assessed Idarucizumab’s NTAP application against the three-part test “newness” criteria, including this first criterion. Idarucizumab was developed as a specific reversal agent to PRADAXA® (dabigatran), and represents a new pharmacologic approach to reversing the anticoagulant effect of dabigatran by directly inhibiting thrombin, thereby blocking the final step of the coagulation cascade. There were, however, instances in which CMS employed what appears to be an inconsistent standard. To illustrate, in its review of the NTAP application for Defitelio® (defibrotide), notwithstanding the fact that the FDA, in approving the therapy, recognized the mechanism of action as unique, CMS notes the Agency’s “concern[]” that the product’s “mechanism of action is not well understood by the manufacturer.”¹¹ We thus continue to be concerned that CMS has, at least in some instances, adopted a definition of “mechanism of action” that is inconsistent with the FDA’s definition and application of that term.

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 utilizing an appropriate set of standards to make this determination, such as the application for Idarucizumab, which CMS notes “is the only FDA-approved therapy available to neutralize the anticoagulant effect of Dabigatran.”¹² Indeed, prior to its approval, management of dabigatran patients who experience bleeding may often be managed by supportive care. Due to the mechanism of action of dabigatran, protamine sulfate and vitamin K, which are typically used to reverse the effects of heparin and warfarin, respectively, are not expected to have an effect.¹³ There were, however, instances, in which CMS has taken an overbroad view of what constitutes the “treatment” of a given disease. For instance, while CMS recognizes that Defitelio® is the only FDA-approved therapy to treat patients diagnosed with veno-occlusive disease (VOD) with evidence of multi-organ failure—other than supportive care, which CMS notes may not be effective and may cause a high risk of bleeding—the Agency notes its “concern[]” that Defitelio® may not produce outcomes that are significantly different than the outcomes of patients treated with supportive care.”¹⁴

¹⁰ 81 Fed. Reg. at 25,032.

¹¹ *Id.* at 25,053.

¹² *Id.* at 25,044.

¹³ Schiele F, et al. A specific antidote for dabigatran: functional and structural characterization. 2013. *Blood* 121 (18), 3554 – 3562.

¹⁴ 81 Fed. Reg. at 25,053.

2. Substantial Clinical Improvement

In the Proposed Rule, CMS also made improvements in the application of its “substantial clinical improvement” criterion. We are concerned, however, that these improvements are only seen in some instances with respect to products that are applying for NTAP status for the second time. This may stem from the fact that CMS has, and continues to, insist on real-world data as evidence that a product represents a “substantial clinical improvement”—yet such real-world evidence is not necessarily available when a product is first approved. We believe that requiring applicants to wait for these data to apply (or re-apply) for NTAP status—thus drawing out the period of time before a product is eligible for the add-on payments—is contrary to the purpose of the NTAP policy in the first place: to facilitate the uptake and adoption of promising new medical technologies for the treatment of Medicare inpatients.

We also are concerned that CMS has taken an overly critical view of certain data provided to support NTAP applications. For example, CMS took issue with the “historical control group used in pivotal trial 2005-01” used to support the Defitelio® application, pointing to “the discrepancy between the size of the treatment group (N=102) and the historical control group (N=32),” which, according to the Agency, “may skew the trial results in favor of the treatment group.”¹⁵ We are concerned with the Agency’s assessment of this trial design for two reasons. First, as the applicant noted “running a controlled, blinded, and randomized trial in a patient population with high mortality rates would be unethical.”¹⁶ Second, the Agency’s concerns with regard to the relative size of each study arm do not take into account the reality that the incidence of rare conditions may not afford the use of identically-sized study arms. Moreover, the Agency should consider, rather than just a comparison of the size of the study arms, whether “the observed effect is large in comparison to variability in disease course (e.g., substantial improvement in outcome is observed with treatment in a disease that does not naturally remit),” and other aspects of the trial that characterize the impact of the therapy on the outcomes measured.¹⁷

CMS also expressed uncertainty as to “whether the historical control group is representative of patients with VOD with multi-organ failure,” in light of “the small sample size and historical data used.”¹⁸ BIO is concerned that CMS’s skepticism of historically-controlled studies, if applied broadly across the Agency’s review of NTAP applications, may limit the ability of rare disease therapies that would otherwise qualify to actually obtain NTAP status. Given the challenges of developing therapies to treat small patient populations, the use of historical comparators can provide an important avenue to support drug development and approval, particularly when it is unethical or infeasible to employ a placebo control group, and there are no other therapies approved to treat the condition (which is often the case for rare conditions).

Finally, CMS notes that “[b]ecause of advancements in medicine” within the timeframe covered by the historical control group (1995 through 2007), the Agency is “concerned that the patients in the historical control group cannot be appropriately compared to patients in the

¹⁵ Id. at 25,055.

¹⁶ Id.

¹⁷ The U.S. Food and Drug Administration (FDA) identifies this as a critical criterion in evaluating the credibility of using a historical control. See FDA, *Rare Diseases: Common Issues in Drug Development Guidance for Industry; Draft Guidance*, available at: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm458485.pdf>

¹⁸ 81 Fed. Reg. at 25,055.

treatment group” and that “it is difficult to attribute improved survival and CR rates only to Defitelio® treatment.”¹⁹ As to this first issue, we point out that VOD is a well-characterized condition according to the applicant, thus the comparability of the control group to the treatment group should not hinge on when the patients were treated, but how reliable each patient’s diagnosis was. Additionally, we reiterate that the rare incidence of certain conditions may make it very challenging to identify the same number of historical comparators as treatment arm participants, but that this does not necessarily impact a reliable observation of the treatment impact itself. As to this second issue, particularly given that CMS has recognized the limitations of the existing treatment for VOD—namely, supportive care—we do not believe that attributing improved survival and CR rates to Defitelio® should be an issue under the study design.

C. ICD-10-PCS Section “X” Codes for Certain New Medical Services and Technologies (p. 25,034)

In the Proposed Rule, CMS describes its policy, finalized in the FY2016 IPPS Final Rule, to use new Section “X” codes for discharges beginning on or after October 1, 2015.²⁰ BIO continues to have concerns regarding CMS’s policy to implement ICD-10-PCS Section “X” codes. Specifically, while we support that CMS has issued some limited coding guidance regarding the use of Section “X” codes,²¹ we continue to urge the Agency to provide more detailed guidance regarding the use of these codes. We also continue to urge CMS to ensure that products that already have codes under the ICD system are not required to move to a new Section “X” code.

III. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2017 and Subsequent Years (§ 412.106) (p. 25,081)

In the Proposed Rule, CMS has proposed to transition to the use of the S-10 worksheet for purposes of determining the value of “Factor 3” in the multifactorial uncompensated care payment formula.²² BIO supports CMS’s decision to transition to the use of the S-10 worksheet for this purpose, as we believe that this metric appears to provide a better assessment of a hospital’s uncompensated care than the current metric used, which assesses low-income insured days. This is consistent with the Medicare Payment Advisory Commission’s (MedPAC’s) multiyear research on the correlation between the data reported on the S-10 worksheet, versus the actual audited analysis of hospital uncompensated care, which found that the S-10 worksheet has an 80 percent correlation to audit data of hospital uncompensated care.²³ This contrasts markedly with the relatively low, 50 percent correlation between low-income insured and audit data of hospital uncompensated care.

Given the large impact that the S-10 will have on distribution of the uncompensated care funds, we also agree with MedPAC that CMS should continually revise the S-10 form and instructions so that the S-10 worksheet can be completed as accurately and uniformly as

¹⁹ Id. at 25,055.

²⁰ Id. at 25,034.

²¹ <https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2016-Section-X-New-Technology-.pdf>.

²² 81 Fed. Reg. at 25,084-94.

²³ MedPAC, FY2016 IPPS/LTCH PPS Comment Letter, *available at* <http://www.medpac.gov/documents/comment-letters/medpac-comment-on-cms's-proposed-rule-on-the-hospital-inpatient-prospective-payment-system-and-long-term-care-hospital-prospective-payment-system.pdf?sfvrsn=0>.

possible. CMS also may wish to proactively monitor significant changes in hospital S-10 reports from year to year to determine if further explicit guidance is needed regarding how to accurately complete the form and to monitor any possible S-10 “creep.”

IV. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes for the FY 2018 Program Year and Subsequent Years (p. 25,099)

A. Proposed Inclusion of Selected Ward Non-Intensive Care Unit (ICU) Locations in Certain NHSN Measures Beginning with the FY 2019 Program Year (p. 25,101)

In the Proposed Rule, CMS proposes to include the selected ward (non-ICU) locations in the Catheter-Associated Urinary Tract Infections (CAUTI) and Central Line-Associated Blood Stream Infection (CLABSI) measures for the Hospital Value-Based Payment (VBP) Program beginning with the FY2019 program year.²⁴ BIO strongly supports this proposal. For the FY2017 and FY2018 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 noted in the FY2016 proposed rule, 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.²⁵

In the interim, BIO asks CMS to consider, in the FY2017 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.

B. Condition-Specific Hospital Level Risk-Standardized Payment Measures (p. 25,099)

In addition to the Medicare Spending Per Beneficiary (MSPB) measure, CMS is proposing to add additional measures to the VBP’s Efficiency and Cost Reduction domain. Specifically, CMS proposes to add two new condition- or treatment-specific Medicare payment measures to the Hospital VBP beginning in FY2021. According to CMS, these “risk-adjusted standardized Medicare payments, viewed in light of other quality measures in a program, are an appropriate indicator of efficiency because they allow [CMS] to compare hospitals without regard to factors such as geography and teaching status.”²⁶

BIO agrees with CMS that “payment measure results viewed in isolation are not necessarily an indication of quality.”²⁷ We therefore support CMS’s proposal to utilize payment metrics—particularly such metrics that are NQF-endorsed—“that can be directly paired with existing clinical

²⁴ 81 Fed. Reg. at 25,101.

²⁵ 80 Fed. Reg. at 24,502 (citing 78 Fed. Reg. 50,787).

²⁶ 81 Fed. Reg. at 25,102.

²⁷ Id.

outcome measures in the program” such that such information can be viewed “along with quality measure results” in order for stakeholders to be able to “better assess the value of care.”²⁸ We believe that this aim will be furthered to the extent that CMS also pursues its proposal to “adopt[] a scoring methodology for a future program year that would assess quality measures and efficiency measures in tandem to produce a tandem score reflective of value,” because, as CMS notes, “[w]ithout a measure or score for value that reflects both quality and costs, [the Agency’s] ability to assess value is limited.”²⁹ This is particularly important in light of recent evidence that CMS’s value-based purchasing programs have rewarded hospitals for providing mediocre care at lower cost.³⁰

We also support that these metrics have a three-year (as opposed to one-year) baseline period, which can more accurately account for the longer-term predictive value of certain health events, particularly for acute conditions, like acute myocardial infarctions. For example, a 2011 meta-analysis of the risk of stroke recurrence found that the cumulative risk of recurrence at 5 years after initial stroke was 26.4 percent and was 39.2 percent at ten years after initial stroke.³¹ A longer baseline period can better take this predictive value into account.

We are concerned, however, that—while CMS has proposed that the Efficiency and Cost Reduction domain remain weighted at 25 percent of the Total Performance Score³²—the addition of these payment metrics, on top of the existing MSPB metric, could put an undue emphasis on the efficiency of care for the conditions subject to the new measures, as the cost of those conditions would be double counted. We therefore urge CMS to consider replacing the MSPB metric—which we believe is flawed to begin with—with these new metrics. We also urge CMS to clearly articulate the methodology the Agency plans to use to risk-adjust these metrics, as risk-adjustment is a critical component of ensuring that hospitals are not inadvertently penalized for treating sicker and more complex Medicare beneficiaries.

C. CMS Should Reinstate the IMM-2 Influenza Immunization Measure in the Hospital VBP Program

Effective beginning in the FY 2018 performance year, CMS removed NQF #1659, “Influenza Immunization (Imm-2)”, from the Hospital VBP Program based on an analysis that this measure had “topped out.” BIO strongly urges CMS to reinstate this important measure in the Hospital VBP Program, as it helps ensure that providers continue to screen for and administer this vaccine to patients in the inpatient setting where nosocomial influenza is a significant threat to patient health and safety. BIO also disagrees that the measure has “topped out,” as influenza vaccination rates for all populations remain below Healthy People 2020 goals. According to the CDC, for the 2014-2015 Influenza Season, the vaccination rate for individuals sixty-five years of age and older was 66.7 percent, and for individuals 18- 64 years of age with high-risk conditions the rate was only

²⁸ Id.

²⁹ 81 Fed. Reg. at 25,105.

³⁰ <http://content.healthaffairs.org/content/35/5/898.abstract>.

³¹ Mohan, et. al., *Stroke* (2011).

³² 81 Fed. Reg. at 25,103.

47.6 percent. Additionally, there is more than a 20 percentage point range between states with the highest and lowest vaccination rates for adults.³³

Each year, influenza causes approximately 200,000 hospitalizations and 36,000 deaths in the United States.³⁴ Nosocomial influenza, which occurs when a patient develops symptoms after more than 72 hours of hospitalization,³⁵ results in longer hospital stays and greater morbidity and mortality among patients.³⁶ 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.³⁷

Influenza vaccination is the primary method for preventing influenza infection and has been proven to be safe and effective.³⁸ 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.³⁹

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.⁴⁰ Despite the fact that vaccinations are one of the top methods

³³ CDC. Flu Vaccination Coverage, United States, 2014-15 Influenza Season. <http://www.cdc.gov/flu/fluview/coverage-1415estimates.htm>.

³⁴ Tilbur 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.

³⁵ 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.

³⁶ 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.

³⁷ 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.

³⁸ 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.

³⁹ 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.

⁴⁰ 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>.

for preventing illness, adult immunization rates remain low,⁴¹ and quality measures are an important tool to help increase vaccination rates in this population.⁴²

For these reasons, BIO urges CMS to reinstate the Imm-2 influenza immunization measure in the Hospital VBP Program. Although CMS has kept 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.

V. Proposed Hospital and CAH Notification Procedures for Outpatients Receiving Observation Status (p. 25,131)

In the Proposed Rule, CMS is proposing to implement the NOTICE Act, which amended section 1866(a)(1) of the SSA to require hospitals and critical access hospitals (CAHs) to provide written notification, and an oral explanation of such notification, to individuals receiving observation services as outpatients for more than 24 hours at the hospitals or CAHs. BIO supports this proposal, as there is evidence to suggest that observation status has been abused by hospitals for many reasons, including in order to obtain access to 340B pricing, with detrimental effects on Medicare beneficiaries. We believe that patient notification, as required under the NOTICE Act, will help prevent abuse in this area, as well as assist beneficiaries better understand the financial and other implications of the care they receive. We also support many of CMS's proposals to implement this requirement.

For example, BIO supports CMS's proposal to create a standardized notice, referred to as the Medicare Outpatient Observation Notice (MOON). We agree with the Agency that requiring use of a standardized notice will provide an assurance that hospitals and CAHs "are providing all of the statutorily required elements in a manner that is understandable to individuals receiving the notice."⁴³ We also agree with the specific proposal that such notification "provide an explanation of the implications of receiving observation services furnished by a hospital or CAH as an outpatient, including services furnished on an inpatient basis, such as those related to cost-sharing requirements for the patient under Medicare, and post-hospitalization eligibility for Medicare-covered SNF care, in standardized language to ensure that all Medicare eligible individuals receive accurate information."⁴⁴

We also support CMS's proposal to require notification of *any* Medicare beneficiary who receives observation services as an outpatient for more than 24 hours, regardless of whether the services in question are payable under Medicare. In fact, it seems particularly critical that a beneficiary be notified if the practical result of their receiving care while in observation status (i.e., as an outpatient) is that Medicare will not pay for their care (i.e., for individuals eligible for Part A, but not enrolled in Part B).

⁴¹ MMWR, February 7, 2014/ 63(05); 95-10.

⁴² 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.

⁴³ 81 Fed. Reg. at 25,133.

⁴⁴ Id.

VI. Hospital Inpatient Quality Reporting (IQR) Program (p. 25,174)

A. 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure

BIO supports CMS's proposal to refine the 30-Day Mortality Following Acute Ischemic Stroke Hospitalization measure to include the National Institute of Health (NIH) Stroke Scale.⁴⁵ As an initial matter, we note that 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.⁴⁶ Ischemic stroke affects hundreds of thousands and leaves many with a new disability and an increased risk for complications, recurrent stroke, and clinical deterioration. And, as CMS notes, "[m]ortality following stroke is an important adverse outcome that can be measured reliably and objectively and is influenced by the quality of care provided to patients during their initial hospitalization."⁴⁷ We further believe that the more rigorous risk-adjustment facilitated by the proposed reliance on NIH's Stroke Scale will help ensure that the measure accurately risk-adjusts for different hospital populations, as this severity score is not only one of the strongest predictors of mortality in ischemic stroke patients, but also part of the national guidelines on stroke care. We also support CMS's efforts to make this refinement applicable as early as July 2017.⁴⁸

B. National Healthcare Safety Network (NHSN) Antimicrobial Use Measure

BIO also supports CMS's proposal to potentially include the National Healthcare Safety Network (NHSN) Antimicrobial Use Measure.⁴⁹ As CMS notes, this measure will help "advance national efforts to reduce the emergence of antibiotic resistance by enabling hospitals and CMS to assess national trends of antibiotic use to facilitate improved stewardship by comparing antibiotic use that hospitals use to antibiotic use that is predicted based on nationally aggregated data."⁵⁰ Antimicrobial resistance is a growing clinical and public health concern. We therefore support antimicrobial stewardship programs (i.e., programs dedicated to optimizing inpatient antibiotic use) as an evidence-based mechanism to slow the emergence of antibiotic resistance and improve the appropriateness of both antimicrobial use and patient outcomes.

C. STK-4 Measure

BIO does not, however, support removal of the STK-4 measure from IQR Program. First, we see an opportunity for hospitals to improve on this measure, as national averages remain well below 90 percent. Indeed, Hospital Compare reported only an 83 percent national average for STK-4 for the latest data available (through June, 2015).⁵¹ 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

⁴⁵ 81 Fed. Reg. at 25,196. *See also* NIH, Stroke Scale, *available at* <http://www.nihstrokescale.org/>.

⁴⁶ National Center for Health Statistics. Mortality in the United States, 2013, NCHS Data Brief Number 178, December 2014.

⁴⁷ 81 Fed. Reg. at 25,196.

⁴⁸ *Id.* at 25,197.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ CMS, Hospital Compare Dataset, *available at* <https://data.medicare.gov/Hospital-Compare/Timely-and-Effective-Care-National/isrn-hgvy/51> (last viewed May 24, 2016).

therapy, even though 81 percent of Americans live within an hour's drive of a hospital that can give the drug.⁵²

Second, BIO believes that removing STK-4 from the IQR program would have a negative impact on stroke care and patient outcomes and thus we do not support this proposal. As articulated in prior BIO comments, 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.⁵³ 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. 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.⁵⁴ Yet, in the FY2016 IPPS final rule, CMS removed 3 chart-abstracted STK measures from the IQR program, and removed STK-1 from the program entirely,⁵⁵ making it even more important to retain the remaining STK measures—including STK-4—in the IQR program.

D. Inclusion of Influenza Immunization Measures

BIO commends CMS for retaining two important immunization measures in the IQR for the FY 2018 payment determination and subsequent years. The first of these measures is NQF #1659 "Influenza Vaccination (IMM-2)." For reasons articulated in section (IV)(C) of this letter, BIO believes that the continued inclusion of this measure in the Hospital IQR Program is critical for driving influenza immunization rates among the Medicare population, which will have important benefits in terms of both improved public health and lower Medicare spending.

We are also pleased that CMS has retained NQF #0431 "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)." This measure encourages hospitals to ensure their healthcare personnel receive an annual influenza vaccine. Increasing vaccination rates among healthcare personnel is an important step in protecting patients from nosocomial influenza, particularly since sick and elderly patients are at an increased risk of contracting infectious diseases. BIO commends CMS for retaining this important measure, which can help avoid preventable adverse patient outcomes, while also improving work productivity among healthcare providers.

⁵² Adeove, et al. ASA's International Stroke Conference, 2014.

⁵³ See BIO Comments in Response to *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation* (June 25, 2013), https://www.bio.org/sites/default/files/files/BIO%20Final%20Comments_FY14%20Hospital%20IPPS%20Proposed%20Rule_25%20June%202013.pdf.

⁵⁴ Song S, et al. AHAQCOR Scientific Sessions, 2013.

⁵⁵ 80 Fed. Reg. 49,326, 49,645 (Aug. 17, 2015).

E. Pneumococcal Immunization Measure Needed in IQR

BIO again urges CMS to revisit the Agency's decision last year to remove NQF#1653, "Pneumococcal Immunization (Imm-1)," from the IQR program.⁵⁶ We remain very concerned that the removal of this measure is resulting in missed opportunities to vaccinate patients, thereby leading to avoidable morbidity, mortality, and healthcare costs associated with pneumococcal disease. Further, the removal of this measure contradicts the stated objectives and priorities of HHS. Specifically, *Healthy People 2020* established a goal of at least 90 percent of adults aged 65 or older ever receiving a pneumonia vaccine,⁵⁷ and this goal was reiterated as part of the 11th Scope of Work for the CMS Quality Improvement Organizations,⁵⁸ as well as the draft National Adult Immunization Plan.⁵⁹

Pneumonia has a significant public health and economic impact in the U.S. 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 rise of antimicrobial 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 cost for Medicare beneficiaries during, and one year following, a pneumonia hospitalization was approximately \$15,682 higher than the cost for patients without pneumonia. In 2004, pneumococci caused an estimated 4 million illness episodes, resulting in direct medical costs (inpatient and outpatient) of \$3.5 billion, and approximately half of these costs were for the care of patients 65 years and older.⁶⁰

Vaccines are an effective intervention against the high cost of medical care and rates of preventable death associated with this disease, particularly among medically vulnerable populations and the elderly. That is why ACIP recommends that all adults aged 65 years or older—and adults aged 19-64 with certain health conditions, such as a weakened immune system, HIV, and kidney disease—receive PCV13 and PPSV23.

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.⁶¹ 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

⁵⁶ *Id.* at 49,826.

⁵⁷ 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>.

⁵⁸ 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>.

⁵⁹ National Vaccine Program Office. National Adult Immunization Plan. February 5, 2015.

⁶⁰ 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.

⁶¹ Centers for Disease Control and Prevention. Noninfluenza Vaccination Coverage among Adults – United States, 2011. *MMWR Morb Mortal Wkly Rep*. 2013;63(04):66-72.

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.⁶²

For these reasons, BIO urges CMS to reassess its decision to remove the pneumococcal vaccination measure from the IQR. We ask the Agency to either: (1) develop and validate a new measure for the hospital inpatient setting that reflects the August 2014 ACIP recommendations;⁶³ or (2) reinstate the Imm-1 measure after making minor modifications to the measure specifications that address the Agency's expressed concerns around accurate data collection and reporting.

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-aid in the form of a flow chart for use with adults, similar to the existing flow chart used for high-risk children aged 5 to 18 years. This would provide hospitals with guidance as to how to evaluate if a patient needs to receive 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 the Centers for Disease Control and Prevention (CDC)/ACIP.⁶⁴ The Committee put forth these recommendations to NQF members and the public for comment, an effort reflective of support for continued use of the measure and in direct conflict with CMS's proposal to remove the measure. We urge CMS to consider these recommendations along with minor updates to the allowable values to account for minimum intervals between different types of pneumococcal vaccines, which will alleviate the feasibility challenges to implementing the measure.

Third, BIO suggests CMS include recommended measures for immunocompetent adults 19-64 who are at increased risk for pneumococcal disease because they have several specific chronic diseases enumerated by ACIP. This represents a large population group. Immunization rates for this group have been extremely low: CDC has reported that in 2013 only 21.2 percent of adults in this group had received a pneumococcal vaccination, and this number has been essentially unchanged for at least a decade.⁶⁵ Because of the large population in this group, the significant need for quality improvement efforts to increase their pneumococcal vaccination coverage, and the simplicity of measuring this activity, we strongly urge creation of a standard measure for this population group.

⁶² 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.

⁶³ 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.

⁶⁴ National Quality Forum, Health and Well-Being, Phase 2, Draft Report for Comment, released May 29, 2015

⁶⁵ (MMWR, Feb 6 2015, vol 64, pages 95-102).

Such a measure might best be structured similarly to the way in which the other pneumococcal vaccination measures are designed, including measurement of whether or not the pneumococcal vaccination status of patients in this risk group was assessed, whether or not those for whom immunization was appropriate were offered an immunization, and whether or not they were actually immunized.

Given the significant public health and economic impact of pneumococcal disease, the alignment of pneumococcal immunization with CMS and HHS policy goals, the continued opportunities for improvement in vaccination rates, and the time and resource investment required for the development of an entirely new measure, BIO recommends that CMS reinstate Imm-1, the pneumococcal immunization measure, within the Hospital IQR Program and consider recommendations from NQF and other stakeholders for modifications to improve accurate data collection and reporting.

VII. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (p. 25,205)

A. NQF #0431 "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)" Measure

BIO commends CMS for retaining the previously finalized measure NQF #0431 "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)" in the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program for the FY 2019 program year and subsequent years.⁶⁶ This measure encourages hospitals to ensure their healthcare personnel receive an annual influenza vaccine. Increasing vaccination rates among healthcare personnel is an important step in protecting patients from nosocomial influenza, particularly patients with cancer who are at an increased risk of contracting influenza and suffering from associated complications. BIO commends CMS for retaining this important measure, which can help avoid preventable adverse patient outcomes, while also improving work productivity among healthcare providers.

B. "Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy" Measure

We cannot, however, support the measure "Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy," which CMS has proposed to include in the PCHQR Program for the FY 2019 program year and subsequent years.⁶⁷ This measure requires further development before it can be applied in a federal payment program. For example, we agree with the Measure Applications Partnership (MAP) recommendations that this measure needs further consideration with respect to "the exclusions and risk-adjustment."⁶⁸ In particular, we believe that the exclusion list must be reviewed based on clinical evidence and should include other hematologic malignancies, such as lymphoma and multiple myeloma. There are a wide range of reasons for admission that are very different across these conditions and not appropriate to combine.

⁶⁶ 81 Fed. Reg. at 25,206.

⁶⁷ *Id.* at 25,206-07.

⁶⁸ Spreadsheet of MAP 2016 Final Recommendations, available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

VIII. Proposed Revision to Data Collection Period for Influenza Vaccine Measure in the Long-Term Care Hospital (LTCH) Quality Reporting Program (p. 25,230)

CMS proposes revisions to the data collection period for NQF #0680, "Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)" measure within the Long-Term Care Hospital Quality Reporting Program.⁶⁹ The objective of this revision is to help long-term care hospitals (LTCHs) better capture influenza vaccination data for patients in their hospital for one or more days during the influenza vaccination season (October 1 of a given year through March 31 of the subsequent year), regardless of the date(s) of their admission and/or discharge. This change thereby allows for the accurate calculation of data for the measure and ensures that LTCHs are receiving credit for recording the vaccination status of all patients in their care during the influenza vaccination season. BIO supports this revision and commends CMS for proposing modifications to the measure while retaining it in the LTCH Quality Reporting Program for FY 2019 payment determination and subsequent years.

BIO also is pleased that the previously adopted measure NQF #0431 "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)" will remain in the LTCH Quality Reporting Program for the FY 2018 payment determination year and subsequent years.⁷⁰

IX. Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule. We look forward to continuing to work with CMS in the future to address the issues raised in this letter. 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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⁶⁹ 81 Fed. Reg. at 25,230.

⁷⁰ Id. at 25,215.