Biotechnology Industry Organization

June 25, 2013

BY ELECTRONIC DELIVERY

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation [CMS-1599-P]

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates Proposed Rule ("the Proposed Rule"), specifically the Hospital Inpatient Quality Reporting (IQR) Program and the Hospital Value-Based Purchasing (VBP) Program.[1] BIO represents more than 1,100 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.

Our comments focus on several quality measures proposed for inclusion or amendment in the Hospital IQR Program and the Hospital VBP Program. Discussed in detail below, we ask that CMS:

[1] 78 Fed. Reg. 27486 (May 10, 2013).

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

1. Finalize the provision to include the influenza immunization measure for acute care hospitalized inpatients age 6 months or older (IMM-2, National Qualify Forum [NQF] #1659) in the Hospital VBP Program;

2. Reconsider the proposed removal of the pneumonia immunization measure (IMM-1) from the Hospital IQR Program, as this could adversely affect pneumococcal immunization rates, public health, and patient safety;

3. Finalize the provision to include Chronic Obstructive Pulmonary Disease (COPD) readmission and mortality rate measures in the Hospital IQR Program;

4. Include the American Heart Association(AHA)/American Stroke Association (ASA) Stroke (STK) measure set in the Hospital VBP Program, similar to its previous incorporation into the Hospital IQR Program, as a complimentary component of a broader set of measures that reflect the treatment continuum of stroke patients;

5. Finalize the proposal to move "drip and ship" cases (those in which Tissue Plasminogen Activator (tPA) (rtPA) administration occurs within 24 hours prior to admission) to a higher Medicare severity diagnosis-related group (MS-DRG) as a move toward recognizing the costs for comprehensive stroke care;

6. Finalize the proposal to expand the collection of central line associated blood stream infection (CLABSI) data to select non-intensive care unit (non-ICU) locations, and identify potential sources of variation leading to unreliable and inconsistent reporting of infection data; and

7. Finalize the proposed inclusion of a standardized infection ratio of hospital-onset *Clostridium difficile* Infection (CDI) in the Long-Term Care Hospital Quality Reporting (LTCHQR) Program and include this measure in the Hospital VBP Program as well.

I. Proposed Inclusion of IMM-2: Immunization for Influenza Measure (p. 27610)

CMS states that IMM-2, the influenza immunization measure for acute care hospitalized inpatients age 6 months or older, represents an "important component[] of quality improvement in the acute inpatient hospital setting."[2] CMS proposes to include the measure in the Hospital VBP Program, and BIO strongly supports this proposal.

Each year, influenza causes approximately 200,000 hospitalizations and 36,000 deaths in the United States.[3] Nosocomial influenza, which occurs when a patient develops symptoms after more than 72 hours of hospitalization,[4] results in longer hospital stays and greater morbidity and mortality among patients.[5] In addition, nosocomial influenza increases healthcare costs due to additional hospitalization and higher utilization of supplies,

[2] Id. at 27610.
[3] Tilburt J, Mueller P, Ottenberg A, Poland G, Koenig B. Facing the challenges of influenza in healthcare settings: The ethical rationale for mandatory seasonal influenza vaccination and its implications for future pandemics. *Vaccine*. 2008;26(suppl 4):D27-30.
[4] 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.
[5] 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.

diagnostic tests, and treatments. One study reported mean excess healthcare costs of $7,545 per case of nosocomial influenza.[6]

Influenza vaccination is the primary method for preventing influenza infection and has been proven to be safe and effective.[7] For these reasons, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommends annual influenza vaccination for all people age 6 months and older. Quality measures such as IMM-2 help drive immunization rates by ensuring healthcare providers offer recommended vaccines to their patients, reducing the number of missed opportunities to vaccinate patients and increasing vaccination rates.

The health and economic benefits of immunization measures became evident following the introduction of performance measures for influenza and pneumococcal vaccinations in the Veterans Health Administration (VHA) in 1995. Among eligible adults, influenza vaccination rates increased from 27 percent to 70 percent, and pneumococcal vaccination rates rose from 28 percent to 85 percent, with limited variability in performance between networks; pneumonia hospitalization rates decreased by 50 percent, and it is estimated that the VHA saved $117 for each vaccine administered.[8]

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 U.S. Department of Health and Human Services (HHS), 80 percent of eligible hospitals have now adopted EHR systems.[9] BIO commends CMS for recognizing the value of immunization measures such as IMM-2 and proposing to include this existing Hospital IQR measure in the Hospital VBP Program for FY 2016.

II. Proposed Removal of IMM-1: Immunization for Pneumonia Measure (p. 27680)

CMS previously adopted IMM-1, a pneumonia immunization measure, for the Hospital IQR Program for the FY 2014 payment determination. However, CMS now proposes to remove this measure due to "new guidelines on the administration of pneumococcal vaccination for various populations"[10] released by the ACIP in October 2012. BIO strongly urges CMS to reconsider this proposal, as this measure plays a critical role in ensuring patients are appropriately vaccinated to prevent pneumonia.

Pneumococcal disease is common in adults and is associated with significant morbidity, mortality, and healthcare costs. Each year, approximately 175,000 people are hospitalized with pneumococcal pneumonia in the U.S., and these patients are at increased risk for concurrent cardiac events such as myocardial infarction, arrhythmia, or congestive heart

---

[6] 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.
[7] 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.
[8] 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.
[9] 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.
[10] 78 Fed. Reg. at 27680.

failure.[11] 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.[12] 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.[13]

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. Despite the health and economic benefits, pneumococcal immunization rates are still suboptimal. In 2011, pneumococcal vaccination coverage among adults age 65 and older was only 62 percent, and among high-risk adults age 19-64, it was only 20 percent.[14] HHS' *Healthy People 2020* targets for these populations are 90 percent and 60 percent vaccination coverage respectively.

Immunization quality measures are an important mechanism for improving these rates, especially in hospitals where pneumococcal vaccines can be readily administered to vulnerable populations. Since the inclusion of quality measures evaluating the percentage of inpatients assessed for pneumococcal vaccination, large increases in vaccination rates have been observed. Between 2006 (when CMS first began reporting quality measure data assessing pneumococcal vaccination) and 2010, the percentage of pneumonia patients who were assessed and received pneumococcal vaccine increased from 71 to 94 percent.[15]

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

---

[11] 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.

[12] Thomas CP, Ryan M, Chapman JD, et al. Incidence and Cost of Pneumonia in Medicare Beneficiaries. *Chest*. 2012;142(4):973-81.

[13] 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.

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

[15] 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.

III. Proposed Readmission and Mortality Measures for COPD (p.27684-86)

BIO supports the proposed inclusion of the NQF-endorsed measures to assess 30-day, all-cause, risk-standardized readmission and mortality rates following COPD hospitalization. COPD hospitalizations are among the most costly, but potentially preventable, and thus are appropriate targets for rigorous outcomes measures in the Hospital IQR Program. Studying critical aspects of inpatient care as well as transitions to outpatient care settings—and the communication between providers during those transitions to prevent and respond to complications—will more comprehensively identify potential avenues to decrease readmissions and mortality in the COPD patient population. BIO urges CMS to finalize these measures for inclusion in the Hospital IQR Program for FY 2016 and subsequent years.

IV. Proposed Readmission and Mortality Measures for Stroke (p. 27686-87)

BIO commends the agency for recognizing the importance of ischemic stroke as a prevalent and costly health problem affecting Medicare beneficiaries. We agree with CMS that there are opportunities for improving care and there is unwarranted variation in outcomes at hospitals for stroke care.[16] Nonetheless, as the agency moves forward to potentially include measures of stroke mortality and readmission, we must reiterate the existing value of CMS' recent adoption of the AHA/ ASA STK measure set for Hospital IQR Program.[17]

BIO appreciates CMS' continued support of that STK measure set as it has been shown to explicitly drive improvements in patient outcomes. For example, a recent study found that hospital participation in the *Get With the Guidelines®-Stroke* quality program, incorporating the stroke measure set, resulted in statistically significant reductions in all-cause mortality at 30 days, reductions in all-cause mortality at one year, and in higher rates of discharges directly to home for Medicare beneficiaries.[18] We believe that given that these are clearly actionable measures tied to outcomes, the AHA/ASA STK measure set should be included in value-based payment for hospitals.

BIO agrees with CMS that the existing STK measure set, although robust as a means for improving inpatient care, does not include all of the components that are part of the treatment continuum for stroke patients. One of the potential approaches to increase treatment opportunities and improve stroke outcomes is to provide this treatment in a more timely fashion after patient arrival (reduce the door-to-needle time for intravenous rtPA). Results from clinical trials and registries have encouraged multiple organizations to set targets for timely initiation of thrombolytic therapy after hospital arrival. Therefore, BIO recommends that CMS include in the Hospital IQR Program measure 1952 "time to intravenous thrombolytic therapy," endorsed by the NQF last year.[19]

We also encourage CMS to support the development of new measures that are complimentary to the current STK measure set. For example, some ambulances text the Face-Arms-Speech-Time (FAST) symptoms to the hospital during transport enhancing the ability of the hospital to treat the patient during the critical "golden hour." Developing and implementing such measures would ensure that all parties—not just the hospitals—are held accountable for their contribution to the quality of patients' overall care.

---

[16] 78 Fed. Reg. at 27687.
[17] 76 Fed. Reg. 51476, 51634 (August 18, 2011).
[18] Song S, et al. Get With The Guidelines-Stroke program participation and clinical outcomes for Medicare beneficiaries. *American Heart Association QCOR Scientific Sessions*. May 2013; Abstract 008.
[19] National Quality Forum. 1952: Time to Intravenous Thrombolytic Therapy. November 2012. http://www.qualityforum.org/QPS/1952.

V. Proposed Change to MS-DRG Classification of Cases for tPA rtPA Administration Within 24 Hours Prior to Admission (p. 27513-14)

In the Proposed Rule, CMS reanalyzed the costs, number of cases, and average length of stay for cases where the administration of tPA occurs at one institution and the patient is then transferred and admitted to a comprehensive stroke center (i.e., "drip and ship," to assess the accuracy of MS-DRG classification for these cases).[20] Today, the "drip and ship" cases are not eligible for assignment in the higher-weighted tPA stroke MS-DRGs 61, 62, and 63. CMS determined that the average cost and length of stay of the "drip and ship" cases in MS-DRGs 64, 65, and 66 did not warrant an assignment to the higher-weighted MS-DRGs 61, 62, and 63. In addition, there are only a small number of "drip and ship" cases, making it impractical to add another set of MS-DRGs. However, CMS proposes moving the "drip and ship" cases in the lowest-weighted MS-DRG 66 to a higher-weighted MS-DRG 65. BIO supports the agency's proposal because it moves closer to recognizing the costs for comprehensive stroke care for these patients than the current policy.

VI. Proposed Expansion of the Collection of CLABSI Data to Select Non-ICU locations (p. 27684)

CMS proposes to expand the collection of the CLABSI measures to include several non-ICU locations, beginning with infections occurring on or after January 1, 2014.[21] CMS states that this proposal is consistent with NQF's re-endorsement update to this measure. BIO supports this recommendation.

In addition, we note CMS' concerns about ensuring reliable and consistent reporting of infection data. To that end, we ask CMS to assess if hospital variation in the use of mid-lines (given midlines are not reported in the CLABSI measure) might introduce an unintended source of variation in the CLABSI measure.

VII. Proposed inclusion of a standardized infection ratio of hospital-onset *Clostridium difficile* Infection (CDI) (p. 27725-26)

The Proposed Rule notes that CDI causes a range of potentially life-threatening symptoms in tens of thousands of patients each year and is responsible for over 14,000 deaths annually. With an increasing prevalence over the last decade in hospitals and facilities with longer lengths of stay, BIO agrees that robust CDI surveillance, identification, and reporting are crucial to reversing this trend. We support, and urge CMS to finalize, the inclusion of a standardized infection rate of hospital-onset CDI Laboratory-identified events among all inpatients in a facility in the LTCHQR Program for FY 2017, and subsequent, payment determinations. This measure was adopted by the Hospital IQR Program in 2011 and is NQF-endorsed. BIO further urges CMS to include the standardized infection ratio measure in the Hospital VBP Program beginning in FY 2017 to better secure prompt identification and treatment of CDI.

[20] 78 Fed. Reg. at 27513.
[21] Id. at 27684.

VIII. Conclusion

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

With sincerest regards,

/s/

Laurel L. Todd
Managing Director, Reimbursement
and Health Policy