June 25, 2018

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

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

Dear Administrator Verma:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS'/the Agency's) Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Proposed Policy Changes and Fiscal Year (FY) 2019 Rates Proposed Rule (the "Proposed Rule").

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's comments on the Proposed Rule are focused on the following areas:

- Proposed changes to the IPPS for coverage and payment of Chimeric Antigen Receptor T-cell (CAR T) Therapy and other Transformative Therapies;
- Updates to the Medicare Severity – Diagnosis Related Groups (MS-DRG) to appropriately account for care delivered, including for patients with rare diseases;

- Applications for FY 2019 New Technology Add-On Payments (NTAP) and the process for determination of receipt of NTAP status;
- Improving patient outcomes and reducing burden through meaningful measures and expanding access to vaccines through appropriate quality measures; and
- Requirements for hospitals to make public a list of their standard charges via the Internet.

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I. Proposed Changes to MS-DRGs for CAR T Therapy and other Transformative Therapies

BIO commends CMS for its efforts to ensure appropriate reimbursement and rate setting for CAR T therapies through proposed updates to the MS-DRG system in a manner than can be applied for FY 2019. We appreciate CMS taking this important step of engaging stakeholders through notice and comment rulemaking to help ensure appropriate patient access to these therapies and adequate reimbursement for providers who deliver these highly-specialized medicines.

CAR T therapies fall into a group of new, innovative treatments that represent a significant benefit and value for patient health outcomes and overall delivery of care – Transformative Therapies. These therapies generally address very serious diseases with high unmet medical need; serve small patient populations, including rare and orphan diseases; and can provide a substantial, durable health benefit. These therapies include cellular or gene therapies that are truly personalized medicines targeting treatment to specific patient populations or subsets of patient populations.

CAR T therapies are a type of treatment in which a patient's own T-cells are reengineered to attack cancer cells through a highly-specific manufacturing process producing a single patient dose for a subset of incredibly vulnerable and sick cancer patients. BIO believes that Transformative Therapies, including CAR Ts, present unique considerations in the inpatient reimbursement framework. The existing MS-DRG being used to reimburse delivery of CAR T therapy is not sufficient and leads to significant losses for providers and serious impediments to patient access. Updates to the current reimbursement system are critical in order to appropriately and accurately provide payment to ensure delivery of treatments for Medicare beneficiaries that meet the highest standard of care, and we again thank the Agency for recognizing this need for action.

BIO appreciates CMS' consideration of several options to improve reimbursement and ensure patient access to CAR T therapies including creation of a new MS-DRG, updates to an existing MS-DRG, and updates to the cost-to-charge ratio (CCR) for these therapies. In providing updates to account for these life-altering medicines, BIO believes that changes made should facilitate timely patient access in the most appropriate site-of-service based on each patient's healthcare needs as determined by the treating provider; provide sufficient, stable reimbursement for providers to be able to continue to deliver CAR T therapies;

provide sufficient flexibility for incorporation of future Transformative Therapies into the inpatient hospital reimbursement system; and serve as a model for addressing existing reimbursement and access challenges for other therapies, including for orphan and rare disease states.

First and foremost, we support the Agency's proposal to update the cost-to-charge ratio (CCR) used for CAR T therapies. BIO believes that the proposed CCR of 1.0 is critical to substantially improving the alignment between cost of care and payment for services within these MS-DRGs, as CMS articulates in the Proposed Rule[1]. These updates are fundamental alongside any MS-DRG pathway to move toward appropriate reimbursement for these medicines and their associated patient care services. We therefore urge CMS to finalize this approach.

One of the options outlined in the Proposed Rule is the creation of a new MS-DRG for procedures involving CAR T cell therapies. BIO believes this is the best approach for meeting the coverage and access goals described above. The creation of a new MS-DRG is consistent with the overall framework of the IPPS system, and over the long-term can provide stability for both providers and patients through the setting of a new rate rather than a reliance on temporary payments or payments intended for unpredictable situations (i.e. outlier payments).

However, this new approach works only so long as the rate is accurately and consistently reflective of both the therapy costs and associated care services required for the delivery of CAR T therapies. BIO also acknowledges that certain obstacles may need to be overcome to make a new MS-DRG viable and ensure that inadvertent disparities in provider payment rates are not created. We urge CMS to take the appropriate steps necessary to overcome such disparities and obstacles and to thereby protect patient access to innovative new CAR T therapies.

In particular, BIO recommends that CMS couple a new MS-DRG with adjustments that ensure that the MS-DRG payment formula does not create undue geographic disparities in CAR T therapy payment rates. Under the default MS-DRG rate formula, the geographic wage index adjustment likely would cause substantial differences in the payment rates for providers located in low versus high wage index areas. Hospitals with low wage indexes could suffer significant and unsustainable losses when furnishing CAR Ts, while some high wage index hospitals potentially could receive payment amounts well in excess of their costs. Such significant disparities ultimately could hamper patient access to CAR T therapies and disincentivize the adoption of CAR Ts for the appropriate patients.

[1] 83 Fed Reg. 20637 (May 7, 2018). For illustrative purposes, CMS details the following example of the use of CCR 1.0, "if a hospital charged $400,000 for a procedure involving the utilization of the CAR T-cell therapy drug described by ICD–10–PCS code XW033C3, the application of a hypothetical CCR of 0.25 results in a cost of $100,000 (=$400,000 * 0.25), while the application of a hypothetical CCR of 1.00 results in a cost of $400,000 (=$400,000 * 1.0)."

BIO urges CMS to use its adjustment authority to prevent these inequities and to ensure that payment rates under a new MS-DRG are reasonably consistent across the country. The Secretary has "broad discretion to make exceptions and adjustments as []he 'deems appropriate,'" under the authority granted under Section 1885(d)(5)(I) of the Social Security Act.[2] This "broad-spectrum grant of authority" to make adjustments and exceptions could be used to level the effect of the wage index for a new CAR T MS-DRG.[3] For example, CMS could adjust payments under the new MS-DRG to effectively set a wage index floor and ceiling for CAR T therapy procedures. This would prevent the wage index from causing inequitable payment differences.

We believe that the creation of a new MS-DRG will prove to be the best choice in the long-term to ensure all qualified hospitals and providers are able to deliver CAR T therapies without fear of significant budgetary constraints. While we understand there are technical challenges in setting a rate that provides adequate payment across the range of Medicare providers, we urge CMS to continue to work with stakeholders in this regard to incorporate the appropriate amount of the CAR T therapy cost into the new MS-DRG calculation to ensure appropriate reimbursement for providers.

As an alternative to the creation of a new MS-DRG, CMS suggests an approach to update an existing MS-DRG by assigning procedures involving CAR T cell therapy drugs (ICD-10-PCS procedure codes XW033C3 and XW043C3) to Pre-MDC MS-DRG 016 and to rename it "Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy" for FY 2019. BIO recognizes that this reassignment will increase payment rates to providers, but we have concern about the ability of this approach to adequately reimburse providers for CAR T therapy. The updates to MS-DRG 016 still represent a loss for providers and rely on NTAP and outlier payments to bring the payment amounts closer to the true cost of providing CAR T therapies. As we expressed above, here again the associated CCR of 1.0 is critical. However, we are concerned that over the long-term, this updated MS-DRG approach will continue to present access barriers for patients to CAR T.

We again appreciate the steps CMS has taken to seek feedback from stakeholders and develop a solution that can be implemented in FY 2019 for CAR T therapies. As stated above, BIO's preferred approach is the creation of a new MS-DRG and we urge the Agency to move forward on the creation of a long-term solution for adequate payment of these medicines. If such challenges are not able to be addressed in the near term, we would encourage CMS to look to a short-term solution as a temporary bridge that provides an improvement over the current payment rate, while continuing to work with stakeholders on a long-term solution.

Such short-term fixes could include a temporary bridge in the form of reassignment to MS-DRG 016, or similar, plus separate payment of the CAR T therapy's Average Sales Price (ASP). We believe that this type of "pass-through" mechanism is well within CMS' broad authority to respond to new technologies or reimbursement deficiencies associated with

[2] *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 256 (D.D.C. 2015).
[3] *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 692 (D.C. Cir. 2014).

established therapies. We suggest such an approach as an interim mechanism while the Agency and stakeholders work to refine payment for future years, ideally by creating a new, adequately paying CAR T MS-DRG. We ask that the Agency provide additional opportunity for comment in subsequent rulemaking cycles, no matter the path chosen for FY 2019. Such a process can help inform appropriate payment and patient access, particularly as new CAR T therapies come to market and providers gain additional experience in administering them.

Beyond making adjustments for CAR T therapies, we ask CMS to consider how to appropriately incorporate future therapeutic innovations, including other Transformative Therapies that are delivered in the inpatient hospital setting into the MS-DRG system. As BIO has previously expressed, we believe there are avenues that can achieve this, such as the creation of "new technology" MS-DRGs, similar to the Ambulatory Payment Classifications (APCs) made to account for new technologies in the Outpatient Prospective Payment System (OPPS),[4] and additional updates to the NTAP system, explored below. It is critical that such considerations include appropriate updates to the CCR, as we have encouraged the Agency to adopt CAR T. We also ask CMS, as we discuss further below, to address existing payment inadequacies through payment system updates in the inpatient setting (MS-DRG, CCR, and others) impacting patient access, including for rare diseases requiring administration of orphan drugs.

It is important that CMS consider how to use the existing components of the inpatient reimbursement system collectively to accurately reflect the value of new therapies that provide substantial benefit for patient health. The changes being proposed for CAR T are critical to addressing this goal, but must be considered for additional classes of treatments in the future and implemented as part of an overall commitment to ensuring adequate inpatient reimbursement for new and existing Transformative Therapies, rare disease treatments, and medicines that address high unmet medical need.

II. Updates to the MS-DRG to Appropriately Account for Care Delivered, Including for Patients with Rare Diseases

In addition to the changes for CAR T therapies, BIO continues to encourage CMS to revisit the methodology used to calculate and recalibrate MS-DRG relative weights to appropriately account for products that have substantial benefit to patient health, including in the treatment of rare diseases. CMS in the past has recognized the importance of ensuring patients with rare disorders have "adequate access to care and receive the necessary treatment,"[5] however this Proposed Rule and previous versions have not addressed adequate payments for necessary treatment through the MS-DRG system. In fact, a small patient population is a near-complete bar to MS-DRG reassignment, severity category

[4] In the Hospital Outpatient Prospective Payment System (OPPS) Final Rule published April 7, 2000, CMS created special Ambulatory Payment Classifications (APCs) to make accommodations for new technology services that could not be appropriately placed into existing APC groups. CMS created these "new technology APCs" in order to temporarily classify new technology services while gathering further data and gaining pricing experience. The rule notes that the new technology APC system gives a mechanism for initiating payment at an appropriate level within a relatively short time frame.

[5] 77 Fed Reg. 52,258, 53,312 (August 31, 2012).

establishment, or a separate MS-DRG. BIO encourages CMS to work to identify ways to best incorporate the treatment of rare diseases into this calculation.

While we recognize that there are inherent challenges to making such determinations, since by definition these cases are not common enough to influence the relative weights of the MS-DRGs to which they are assigned, BIO urges CMS to explore opportunities to better account for these cases, particularly in light of the continued innovative treatment advances discussed above. As has been proposed for CAR T, CMS could consider creation of additional MS-DRGs for specific patient subclasses with similar clinical needs, resource use, and length of stay. These cases may be identifiable by both diagnosis and targeted drug intervention.

Additionally, CMS could look to specific hospitals or centers of excellence in the management of certain rare diseases or subclasses of diseases to identify standards and protocols of care that are not accurately reflected within the MS-DRG system and would be best served by a new MS-DRG for a rare disease. For many rare diseases, particularly those for which an orphan drug creates a resource use disparity within an existing MS-DRG, each payment update maintains or exacerbates reimbursement deficiencies in centers of excellence with expertise in treating the disorder and a commitment to the standard of care. Compounding this problem is the fact that the financial shortfall translates to a reimbursement windfall for facilities in the form of above-cost reimbursement for the remaining conditions in the MS-DRG. We ask CMS to further explore how to set MS-DRGs appropriate to care provided for patients with rare diseases.

Further, the Agency should consider additional updates to the inpatient payment system, such as through MS-DRGs and associated CCRs, as discussed, for both existing and new therapies that further the ability of providers to deliver the most appropriate course of treatment to their patients. Examples include but are not limited to areas of high unmet medical need, such as antimicrobial resistance, or areas of significant public health focus, such as on pain and addiction treatment, in addition to rare diseases. It is critical that the inpatient system prioritize access to the most appropriate care and treatment to improve health outcomes in the long-term. BIO urges CMS to further investigate this issue and work closely with stakeholders to seek out opportunities to improve the MS-DRG system for patients, including those with rare diseases, to encourage quality, patient-centric care aligned with advances and innovations in treatment.

Although the Proposed Rule is part of CMS' annual updates for the Medicare program, we note that the policies, mechanisms, and structures CMS develops and refines impact provider reimbursement and patient access across payers. The MS-DRG system, for example, is used by 27 Medicaid programs and many commercial payers. Just as we ask that CMS approach changes to components of the IPPS in a holistic manner that appropriately provides payment for patient care in the inpatient setting, we hope the Agency will consider the broad reach of its policies and the potential for unintended consequences for non-Medicare populations, including pediatric rare disease patients.

III. FY 2019 Applications for NTAP and the Process for Determination of Receipt of NTAP Status

As innovation in medicines continues to address serious unmet medical need, provide more personalized treatment options for patients, and deliver sustained health outcomes, it is imperative that CMS reimbursement structures keep pace to ensure both sufficient provider reimbursement and adequate patient access to novel therapies. Consistent with the considerations detailed above for the MS-DRG system, and as expressed in previous comments, BIO believes updates to NTAP are critical – in determination criteria, payment rate, and the frequency of adoption – to ensure the program adapts alongside the considerable treatment advances since its inception.

With regard to the discussion of NTAP applications in the Proposed Rule, BIO expresses our support for granting NTAP status to the two CAR T products, KYMRIAH™ and YESCARTA™, and for PLAZOMICIN, a next-generation aminoglycoside developed to treat serious bacterial infections due to multidrug resistant Enterobacteriaceae and that commonly occur in the hospital setting.[6] These therapies represent substantial innovations and advancements in the treatment of serious diseases. In addition to expressing our support for granting NTAP to new innovations in treatment, we continue to highlight our concerns with the overall process for determination of NTAP for new products.

The purpose of the NTAP is to facilitate beneficiary access to new technologies. By statute, CMS is required to establish a mechanism to recognize the costs of new technologies under the Medicare IPPS.[7] CMS has itself recognized that Congress intended for this requirement to ensure the "adequacy of Medicare's payment systems in facilitating access to new technologies for Medicare beneficiaries"[8] because the IPPS otherwise would inadequately reimburse such technologies. In addition, studies on NTAPs have shown such add-on payments are effective at improving quality of care *and* reducing Medicare costs.[9] BIO accordingly believes that it is important that CMS administer the NTAP in a way that facilitates the patient-access promoting objectives underlying the NTAP.

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

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[6] Infections due to multidrug-resistant (MDR) gram-negative pathogens are a major public health concern and are increasing in the U.S. and worldwide. These infections are associated with increased morbidity and mortality compared to infections caused by susceptible organisms often due to limited therapeutic options (Falagas 2014, Lee 2017). As a result**,** there is an urgent need for new antibiotics to treat infections due to MDR gram-negative organisms (CDDEP 2015; WHO 2014). In 2013 and again in 2017, the Centers for Disease Control and Prevention (CDC) identified Carbapenem-resistant Enterobacteriaceae (CRE) as "nightmare bacteria" and an immediate public health threat requiring "urgent and aggressive action" (Daikos 2014, Tzouvelekis 2014). The FDA granted Fast Track designation for the plazomicin development program for the treatment of serious and life-threatening infections due to CRE, and designated plazomicin as a Qualified Infectious Disease Product (QIDP) in recognition of its intended use to treat serious or life-threatening infections in patients with limited or no alternative treatment options, including cases caused by resistant pathogens.

[7] SSA § 1886(d)

[8] 66 Fed. Reg. 46,902

[9] *See, e.g.*, Scott Gottlieb, American Enterprise Inst., *Restoring the Trust for All Generations* 2 (2016).

beneficiaries as part of this assessment. Further, CMS 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: to facilitate the uptake and adoption of promising new medical technologies for the treatment of Medicare inpatients. Moreover, CMS' implementation of the "newness" criteria would make it nearly impossible for any technology, much less one addressing an uncommon condition, to acquire sufficient real world data while simultaneously meeting the newness requirement.

BIO is supportive of making the NTAP process more patient-focused by broadening the criteria applied in making substantial clinical improvement determinations to include considerations such as: (a) results in a reduction of the length of a hospital stay; (b) improves patient quality of life; (c) creates long-term clinical efficiencies in treatment; (d) addresses patient-centered objectives as defined by the Secretary; or (e) meets such other criteria as the Secretary may specify.[10] It is BIO's belief that recognizing patient-centric improvements and accounting for the continued push toward personalized medicine when assessing a new technology would greatly enhance the approach to review NTAP applications, align with the Food and Drug Administration's (FDA) incorporation of patient reported outcomes, achieve previously stated CMS objectives in covering a new technology or service, and best serve Medicare beneficiaries.

BIO maintains concerns with CMS' application of the criteria for NTAP status eligibility, where a new service or technology must: (1) be new; (2) be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) demonstrate a substantial clinical improvement over existing services or technologies.[11] We believe that in certain instances, CMS has inappropriately applied these criteria in consideration of NTAP applications.

With regard to the "newness" criteria, the Agency employs three considerations that CMS says bear on whether the new product is too "substantially similar" to an existing product to be considered new: (1) whether a product uses the same or similar mechanism to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS-DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar type of patient population.[12] BIO is concerned that by taking an overly critical view in the case of the application of each component of the "newness" criteria, CMS may be stunting the benefit of the NTAP for truly new products in the space and creating barriers to access.

BIO continues to urge the Agency to make updates to NTAP that are in step with advances in technology for new, innovative treatment options and technologies. We remind the

[10] Id. at 19,871.
[11] 42 CFR 412.87.
[12] 82 Fed. Reg. 19,869 (April 28, 2017).

Agency that the overall intent of NTAP is to provide a bridge and ensure access until the relevant MS-DRG is updated, a process that can be lengthy. CMS should focus on ensuring that NTAP serves as a mechanism to allow Medicare beneficiaries to access new innovations that represent advances over the existing options for their disease or subset of disease.

IV. Improving Patient Outcomes and Reducing Burden through Meaningful Measures; Expanding Access to Vaccines through Appropriate Quality Measures

In the Proposed Rule, CMS discusses efforts to streamline quality measures and reporting across programs, including: the Hospital Inpatient Quality Reporting (IQR) Program, the Hospital Value-Based Purchasing Program, the Hospital-Acquired Conditions (HAC) Reduction Program, the Hospital Readmissions Reduction Program (HRRP) and the Electronic Health Records Incentive Program (Meaningful Use). The intent is to ensure measures are high-impact, patient-centric, and outcomes-based, while minimizing burden and adhering to statutory requirements.

BIO supports the overall goals of streamlining quality measures across programs and the six overarching quality priority areas and their associated meaningful measure areas. In particular, BIO applauds CMS for including the meaningful measure area of "care is personalized and aligned with patient's goals", a focus area that is ever the more critical as technologies and treatments advance to meet individualized patient health needs.

Further, we commend CMS' specific call around "prevention and treatment of opioid and substance use disorders." BIO is focused on the development of innovative treatment options for both pain and addiction, and appropriate associated quality measures are critical in ensuring patient access to novel and safer medicines. We applaud the Agency for making reference to the aims of the HHS five-point Opioid Strategy which includes (1) improving access to prevention, treatment, and recovery support services; (2) targeting the availability and distribution of overdose-reversing drugs; (3) strengthening public health data reporting and collection to inform real-time public health response; (4) supporting cutting edge research to advance the understanding of pain and addiction and the development of new treatments and public health interventions; and (5) advancing the practice of pain management. BIO is committed to be a partner in developing solutions to the opioid crisis, particularly through the advancement of new science and innovations in treatment for both pain and addiction.

In addition to support for these broad meaningful measure areas, as a part of the "preventive care" component, we urge the Agency to consider how to best incorporate appropriate quality measures to increase vaccination rates across quality programs. Vaccines are a critical component of preventive care and CMS, acting as measure steward, should maintain existing measures, develop and validate new measures, or reinstate measures that are reflective of the current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccine coverage of the Medicare population.

For instance, to this aim, CMS should not remove measures that still have value and benefit for increasing uptake of critical vaccines. CMS is proposing to remove the influenza immunization measure (NQF #1659) (IMM-2) from the IQR, stating that the measure has "topped out" based on limited differences between reaching the 75th and 90th percentile. Additionally, CMS is proposing to remove the influenza measure "Influenza Vaccination Among Healthcare Personnel" (NQF #0431), citing that costs associated with the measure outweigh the benefit of its continued use in the program.

BIO is concerned that removing these measures are inappropriate, as there is a demonstrated need to continue to improve influenza vaccination rates. Maintaining these measures is critical to achieving the Healthy People 2020 goal of a 70% immunization rate for influenza.[13] With current immunization rates for influenza around 40% for adults,[14] these measures can help improve delivery of preventive healthcare services and overall health outcomes for the vulnerable patients served in Medicare. Their removal will significantly impair assessment of influenza vaccine status in both acute and long-term care settings and have a negative impact in future hospital influenza outbreaks. BIO recommends CMS maintain these measures.

Additionally, BIO urges CMS to expand the use of a herpes zoster vaccination measure into the IQR program. Herpes zoster, also known as shingles, can be painfully debilitating[15] and can lead to costly treatments among older adults. The ACIP recommends the herpes zoster vaccine for adults 60 years and older, based on the vaccine's ability to reduce overall incidence, decrease pain associated with shingles, and the significant impact in the 60 year and older population. [16,17] BIO supported CMS' important steps to improve these vaccination rates in the 2016 Home Health Payment System and Value-Based Purchasing Rule[18] and encourage the Agency to take further steps to improve these rates across Medicare's most vulnerable populations.

Finally, CMS should reinstate the IMM-1 pneumococcal measure that was removed from the IQR in 2016. CMS removed this measure related to reporting challenges and alignment to the updated ACIP guidelines for pneumococcal vaccination. Rather than doing away with the measure, we encourage the Agency to make updates to the measure to best align with program goals and recommendations to help increase vaccination rates.

Further, BIO asks CMS to address gaps in outcomes and care delivery measures for multiple chronic conditions, including but not limited to Chronic Obstructive Pulmonary Disease

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[13] Office of Disease Prevention and Health Promotion. Healthy People 2020: Immunization and Infectious Disease Objectives.
[14] Centers for Disease Control and Prevention. Flu Vaccination Coverage, United States, 2015-2016 Influenza Season.
[15] Vaccines. Shingles *Herpes Zoster* – *What is Shingles (Herpes Zoster)?*
[16] Morbidity and Mortality Weekly Report (August 22, 2014). *Update on Recommendations for Use of Herpes Zoster Vaccine*. Vol. 63. No.33.
[17] Morbidity and Mortality Weekly Report (June 6, 2008). *Prevention of Herpes Zoster – Recommendations of the Advisory Committee on Immunizations Practices (ACIP)*. Vol. 57. No. RR-5.
[18] Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Final Rule, 80 Fed. Reg. 68,678.

(COPD) and diabetes. These are particularly important gap areas, as healthcare for patients with complex chronic and comorbid conditions extends beyond one setting of care. Many patients with multiple chronic conditions see multiple providers spanning several care settings. In a 2012 analysis, CMS identified that patients with comorbidities including asthma and COPD were associated with up to seven times higher costs than the average spending for Medicare beneficiaries. Additionally, patients with comorbid chronic conditions consume a significantly higher portion of healthcare resources.[19] We therefore believe CMS should focus on assessing and making recommendations for measures that address this gap area across all care settings, which can help ensure patients receive coordinated and continuous care, particularly since most Medicare patients suffer from co-occurring conditions.

We would also highlight a particular absence in measures for individuals with comorbid diabetes and cardiovascular disease.[20] According to the 2017 National Diabetes Statistics Report released by the Centers for Disease Control and Prevention (CDC), in 2014, 1.5 million patients with diabetes (or 70.4 per 1,000 persons with diabetes) were discharged from a hospital with major cardiovascular disease.[21] A 2014 CMS report on Medicare/Medicaid dual-eligibles noted that 45% of patients who had a heart condition were also diagnosed with diabetes.[22] Similarly, cardiovascular disease accounts for 28% of the costs of treating diabetes and associated complications.[23] At this time, no existing measure in any of the CMS quality reporting programs explicitly reports on identification or treatment of patients with these comorbid conditions. We encourage the Agency to focus on addressing this important measure gap.

Along these lines, BIO also notes a lack of measures focused specifically on outcomes related to cardiovascular mortality for individuals with comorbid diabetes and cardiovascular disease. Evidence shows that cardiovascular disease is highly prevalent in patients with diabetes, is associated with high rates of mortality, and is a source of high financial burden to patients, caregivers, and the health care system at large.[24] It is crucial that more focus is placed on developing measures that help ensure patients receive care that comprehensively meets their needs, both during and beyond the hospital stay.

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[19] Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition.
[20] American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2012. *Diabetes Care.* 2013; DC_122625. DOI:10.2337/dc12-2625.
[21] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017: Estimates of Diabetes and Its Burden in the United States
[22] Physical and Mental Health Condition Prevalence and Comorbidity among Fee-for-Service Medicare-Medicaid Enrollees. Centers for Medicare & Medicaid Services. Published September, 2014.
[23] Sander S, et al. Poster presented at American Academy of Managed Care Nexus; October 3-6, 2016; National Harbor, MD.
[24] This is especially evident in the diabetes patient population where incidence of myocardial infarction (MI) is eight times higher than the general population. Additionally, patients with diabetes are also 2.7 times more likely to experience death related to coronary heart disease with a prior MI. (Juutilainen A, Lehto S, Rönnemaa T, Pyörälä K, Laakso M. Type 2 diabetes as a "coronary heart disease equivalent": an 18-year prospective population-based study in Finnish subjects. Diabetes Care. 2005;28(12):2901-7.)

We ask the Agency to continue to work with stakeholders to develop measures in the core focus areas that appropriately reflect the full range of healthcare needs for Medicare, promoting quality, patient-centric care and treatment.

V. Requirements for Hospitals to Make Public a List of Their Standard Charges via the Internet

In the Proposed Rule, CMS references ongoing challenges for patients in understanding their hospital costs, including the 2015 requirements for hospitals to make a listing of their standard charges for items and services publicly available. The Proposed Rule further notes that the Agency is considering ways to improve transparency for patients and make additional updates, and calls for feedback on a number of questions intended to help patients better understand their financial liability for services obtained in the hospital and to compare charges for similar services across hospitals. BIO supports CMS' efforts to help patients better understand their financial liability for healthcare services. We believe that all cost transparency measures should be grounded in the goal of improving timely access to information that supports informed patient/provider clinical decision-making and that helps ensure smarter healthcare spending. Transparency components should facilitate access to timely initiation of the most appropriate course of treatment for patients.

In meeting the Agency's goals of providing better transparency and understanding of health costs and patient out-of-pocket cost burden, we believe there are elements of charge information that could be useful to patients who are either enrolled in health insurance exchange plans or are uninsured to better understand the basis of their associated out-of-pocket costs. For instance, CMS could provide information to exchanges and patient groups on hospital charges for the top 100 medicines used in the hospital outpatient setting. Consumers may then be able to compare what their health plan is paying their hospital, their own out-of-pocket costs, or what those without insurance are being asked to pay as compared with the hospital charges. Such efforts may have the effect of creating pressures for reductions in hospital charges and overall beneficiary cost burden.

Of the areas outlined, BIO has concerns around additional information being given to patients by providers around their out-of-pocket costs. There are a number of factors that affect patient out-of-pocket costs, such as what Medicare pays for particular services and how Medigap affects patient out-of-pocket costs. There is potential based on these factors for inaccurate information to be delivered which can negatively impact timely and appropriate initiation of care. Further, sharing such information places an additional burden on providers in accurately reflecting coverage details and out-of-pocket costs for each individual patient. While beneficiary understanding of associated costs, particularly their out-of-pocket burden, is useful information for patients, this may not be the most appropriate venue for delivery. We encourage the Agency to seek other opportunities to help beneficiaries understand their out-of-pocket cost liability for inpatient hospital services, as well as what other variables impact the amount they may pay.

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BIO appreciates the opportunity to comment on the FY 2019 Proposed Rule for the IPPS. We look forward to continuing to work with CMS in the future to address the issues raised in this letter. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Sincerely,

/S/

Crystal Kuntz
Vice President, Healthcare Policy & Research
Biotechnology Innovation Organization

/S/

Mallory O'Connor
Director, Healthcare Policy & Federal Programs
Biotechnology Innovation Organization