September 27, 2019

By Electronic Delivery

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: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals -Within-Hospitals [CMS-1717-P]

Dear Administrator Verma,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems 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 represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we closely monitor changes to Medicare's reimbursement rates and payment policies for their potential impact on innovation and patient access to drugs and biologicals. Our comments on the Proposed Rule are outlined below.

I. BIO remains concerned with CMS' continued use of packaging policies, as they have the potential to limit patient access to innovations in care and treatment.

While BIO believes that efficiency and flexibility are important goals of the Medicare program, packaging policies have the potential to create perverse incentives that could unintentionally limit patient access to certain services and care. Moreover, these potential access issues created by packaging are not necessarily ones that can be identified by a decline in volume of packaged services. Instead, these issues occur when patients do not receive the most clinically appropriate drug, biological, or service that could be provided as one component of a larger package of services because providers and practitioners could be incentivized under packaging policies to make choices that prioritize minimizing costs relative to their expected payment over clinically appropriate care personalized to the patient. These potential access issues are ever the more important as the healthcare system continues to move toward the delivery of more personalized medicine. BIO urges CMS to consider how to best account for and encourage the use of new innovations, including reconsideration of or updates to packaging policies. We believe CMS should provide continued opportunity for stakeholders to weigh in as new drugs, biologicals, and services come to market to ensure appropriate reimbursement rates in a manner that advances patient access to these innovations.

II. BIO Supports Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Packaged Drugs and Biologicals at ASP+6%.

For CY 2020, CMS proposes to continue the CY 2013 policy of paying for separately payable drugs and biologicals at ASP+6%, referred to as the "statutory default."[1] The SSA directs CMS to pay for SCODs at either the "average acquisition cost of the drugs for [the] year," as determined by the Agency using survey data,[2] or—if such survey data are not available—based on "the average price for the drug in the year" established under section 1842(o), section 1847A, or section 1847B, as applicable.[3]

BIO supports the Agency's proposal for CY 2020 because it is consistent with the statute and congressional intent. This approach also generates far more predictable payments for separately paid drugs and biologicals under the OPPS than the approach previously employed by CMS of adjusting pharmacy overhead costs. In addition, using the statutory default approach ensures that Medicare payment rates for drugs and biologicals are equivalent in both the hospital and physician-office setting, eliminating reimbursement incentives that can drive inappropriate shifts in the site of care and helping to ensure that patients are able to obtain care in the most clinically appropriate setting. CMS should finalize this proposal for CY 2020 to ensure that payments for separately payable drugs and biologicals continue to remain predictable and adequate.

Furthermore, BIO once again recommends that CMS make separate payment for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes in the OPPS, in the same manner as the Agency does for these therapies when they are

[1] 84 Fed. Reg. 39500 (August 9, 2019).
[2] SSA § 1833(t)(14)(A)(iii)(I).
[3] SSA § 1833(t)(14)(A)(iii)(II).

administered in a physician's office. We believe that factors such as the methods of administration or type of procedure in which it is used should not determine whether a drug or biological is considered a supply and result in subsequent packaging, as is the case for certain drugs and biologicals when used in a diagnostic or surgical procedure. We believe such policies are harmful to beneficiary access to appropriate treatment.

III. CMS Should Not Finalize Its Proposal to Use Prior Authorization (PA) for Services Provided in the OPD.

In the notice of proposed rulemaking (NPRM), CMS proposes to use prior authorization (PA) to manage utilization across five broad areas that, according to the agency, are generally associated with cosmetic procedures. BIO and its members agree that the Medicare program should not reimburse for services which do not currently meet Medicare coverage, coding and payment guidelines. We question, however whether implementing PA is the correct solution and may cause unnecessary disruption to care and poor Medicare beneficiary outcomes.

PAs are onerous, expensive and administratively burdensome on the healthcare delivery system. The American Academy of Dermatology recently stated:

> *"Prior authorization is a significant barrier to care that has harmed the patient-physician relationship. The Academy has long advocated for solutions that remove prior authorization policies that adversely affect patient care. For many skin diseases and conditions, medications are specialized and highly nuanced, and their efficacy is dependent on several patient factors. Prior authorization policies that place a third party in a decision-making position, with no knowledge of the complexity or full history of a patient's condition, are not only inappropriate; they also impede a patient's access to the most effective treatment, and a delay can cause irreparable harm."*[4]

We believe implementing as stringent a utilization management tool as PA is unnecessary and ignores the agency's existing claims review and provider education mechanisms designed to efficiently identify providers that are fraudulently submitting cosmetic claims for Medicare reimbursement and to address inappropriate billing. Indeed, MedPAC has similarly questioned this proposal, citing the Agency's "lack of experience in using prior authorization in fee-for-service Medicare, a lack of administrative structure for implementing this proposed policy, and a lack of guidelines through which providers would obtain prior authorization.[5]" The Commission also "is concerned that access to necessary care could be adversely affected."

CMS takes the position that Social Security Act § 1833(t)(2)(F) allows the agency to implement a PA requirement for botulinum toxin injections. This broadly worded section gives CMS the authority to develop "a method for controlling unnecessary increases in the volume of covered [outpatient] services"; however, BIO firmly believes that such language does not contemplate a PA program nor was it ever intended to.

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[4] Statement of Howard Rogers, MD, FAAD, on behalf of the American Academy of Dermatology, before the U.S. House of Representatives Committee on Small Business, "Utilization Management' Barriers to Care and Burdens on Small Medical Practice." September 11, 2019

[5] MedPAC, Comment Letter on, "RE: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals." September 13, 2019.

In fact, when Congress has previously intended to give CMS the authority to implement a PA requirement, it made that authority explicit in statute. For example, CMS's authority to impose a PA requirement on durable medical equipment comes from a statutory provision (Social Security Act § 1834(a)(15)) that expressly requires Medicare contractors to "determine in advance of delivery of an item whether payment for the item may not be made." BIO believe that if Congress had intended to give CMS the authority to subject other types of OPPS services to PA, it likely would have done so expressly.

For the reasons stated above and in the interest of beneficiary health outcomes, BIO urges the Agency not to finalize its proposal to implement PA, but rather, we recommend that the agency rely upon its existing internal systems to address suspected inappropriate utilization of services occurring in the OPD.

IV. CMS should not finalize the reduction in reimbursement for other drugs and biologics paid at the Wholesale Acquisition Cost when Average Sales Price data is not available.

For CY 2019, CMS finalized a proposal to reduce reimbursement for new drugs when Average Sales Price (ASP) is not available from the existing rate of Wholesale Acquisition Cost (WAC) plus 6 percent to WAC plus 3 percent. In our previously submitted comments, BIO opposed this policy stating that reducing the add-on payment during the timeframe when a drug is newly introduced to the market can have an impact on update of new innovations in treatment and ultimately patient access to new medicines that may be preferred for their given condition. For CY 2020, CMS has proposed to expand this policy to include reduction in reimbursement for other drugs and biologics that are paid at WAC because ASP data is unavailable. BIO continues to oppose the implementation of such a reduction in payment for drugs delivered in the Part B program.

As the Agency is aware, drugs delivered through this component of the Medicare benefit include those that require special handling and delivery, and administration under a physician's care and supervision (e.g., intravenous infusions, intraocular injections). Under the existing reimbursement structure, add-on payments to ASP and WAC are intended to reimburse hospitals for these associated care delivery and pharmacy services. Further, we remind CMS that this add-on payment would be 1.35 percent rather than 3 percent given the impacts of sequestration on Medicare payments.

Failure to provide a sufficient add-on payment to cover the associated administrative components of delivering Part B drugs and biologicals and not providing parity in payment policy between new and existing medicines will result in diminishing patient access to innovative treatments and potentially chill investment into new innovation. Additionally, while there may be differences between a product's WAC and ASP, the use of WAC is generally limited to the first two quarters while a product's ASP is being determined. Following that initial use of WAC-based payment, Medicare is able to benefit from the discounts negotiated in the private marketplace through lower ASP amounts.

The Proposed Rule also discusses the potential concerns raised around revenue generation from the ASP (and WAC) add-on by incentivizing the use of more costly drugs and biologicals. BIO believes there is no evidence to support the assertion that providers may be selecting therapies based on the potential to generate revenue based on the add-on to different products, rather than selecting and delivering the best treatment for each patient's disease state.

V. CMS Should Finalize its Proposed Payment Policy for Therapeutic Radiopharmaceuticals.

For CY 2020, CMS proposes to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6%, based on the statutory default, when ASP information is available. BIO supports this proposal and urges CMS to finalize it.

VI. CMS Should Finalize its Proposed Payment for Blood Clotting Factors.

BIO supports CMS' proposal to pay for blood-clotting factors at ASP+6%,[6] consistent with the Agency's proposed payment policy for other non-pass-through, separately payable drugs and biologicals. We also support CMS' proposal to continue its policy for payment of the furnishing fee using an updated amount, consistent with reimbursement in physician offices and in the hospital inpatient setting. We therefore ask CMS to finalize this proposal.

VII. BIO raises concerns with the agency's proposal to eliminate the differential between high cost and low-cost skin substitutes for 2020.

BIO raises significant concern with CMS' potential proposal to move to a single APC for payment of skin substitute products. Under this scenario, we are concerned that patient access to innovative skin substitute products will be impeded. Such a policy will impact both existing products and development of future innovations in skin substitute treatment. For products that would have previously met the high-cost threshold, care and treatment may shift to focus on use of lower cost products due to reimbursement losses. Further, investment in new innovations may suffer as a result of this new reimbursement proposal. We urge the Agency to continue with the existing high-cost and low-cost thresholds for coverage of skin substitutes and to continue to work with stakeholders on payment alternatives that appropriately reimburse innovations in the skin substitute space.

VIII. BIO supports payment for separately payable nonpass-through Drugs Acquired with a 340B Discount at ASP-22.5%.

For CY 2020, CMS is proposing to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at ASP-22.5%.[7] BIO appreciates CMS' continued efforts to address the exponential growth of the 340B program, and believe this policy is an important step.

However, we are concerned that the interaction of two policies – the 340B payment reduction and the exemption from this reduction for biosimilars with pass-through status - has the potential to create a disparity between federal reimbursement for biosimilars with pass-through status and their reference products. We believe the disparity created by these combined policies could cause an unlevel playing field in the competitive marketplace and lead to inappropriate financial incentives for prescribing in the context of 340B. BIO strongly supports a robust biosimilars market, and we encourage CMS to develop solutions to

[6] *Id* at 39502.
[7] *Id* at 39504.

address this disparity and ensure that biosimilars and their reference product are reimbursed equitably in Medicare.

Further, while these are important steps to managing the continued growth and abuse of the 340B program, additional policy changes are needed to address broader 340B reform. As BIO has expressed in the past, the exponential growth of the program and perverse incentives have led the program to stray from its original intent—to help uninsured and vulnerable patients gain greater access to prescription medicines. BIO urges CMS to continue to work with stakeholders on changes to help refocus the program toward its intended purpose.

IX. CMS should finalize and seek to expand into the OPPS setting the policy that provides separate payment in the ASC setting for pain management drugs that function as surgical supplies, and consider additional separate payment that facilitates patient access to innovations in treatment and the most appropriate care.

For CY 2019, CMS had proposed unpackaging and paying separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. BIO previously submitted comments supporting this proposal, as we believe this can help advance timely and appropriate patient access to novel pain treatments, reducing the number of opioid prescriptions. For CY 2020, the agency stated it has "not found compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives are necessary for CY 2020."[8] CMS seeks comment on whether separate payment would further incentivize appropriate use of such drugs in the hospital outpatient setting.

BIO supports CMS' efforts to appropriately cover and pay for innovation in pain treatment, and encourages continued consideration of additional policies that make separate payment for pain management drugs where they can help reduce use of opioids in appropriate patient populations. We encourage CMS to expand this policy in the ASC setting beyond non-opioid pain treatments to include all those pain treatments that can help improve the treatment of pain while lessening addiction potential. We similarly encourage CMS to examine and alleviate barriers to appropriate treatment options for specific diseases that can help reduce the duration or impact of acute pain episodes in certain instances. For example, BIO members have and will continue to advance treatment options for chronic, often rare, diseases (e.g., sickle cell disease) for which severe pain is a hallmark symptom. Similar adjustments around bundled payment for therapies that ameliorate these attacks are critical to reducing incidence of pain for these patient populations and help to reduce unnecessary opioid prescriptions. These patients are not likely to be treated in the ASC setting, but may require care in outpatient and inpatient facilities where barriers to incorporation of drug costs into bundled payments are particularly problematic.

As detailed above, BIO believes that a critical component to addressing the opioid crisis is ensuring patient access to novel and safer treatment options for pain. By facilitating reimbursement for these products in the ASC and other delivery settings (inpatient and outpatient), CMS can help provide patients with appropriate pain treatment based on the

[8] *Id* at 39427

procedure they've received and helping to prevent additional abuse or addiction to opioids. BIO urges CMS to apply this new policy beyond the surgical context and ASC setting. Further, we encourage CMS to examine and alleviate barriers to appropriate treatment that may reduce or mitigate acute pain episodes in chronic diseases across care settings.

By providing appropriate reimbursement for innovations in pain treatment, CMS can help facilitate future investment into additional innovations that can help address both acute and chronic pain. Therefore, BIO strongly encourages the Agency to apply this separate payment policy for innovations in pain treatment incident to surgical procedures in the inpatient and outpatient setting as well. Additionally, we encourage the Agency to continue to apply such a policy in these settings for innovations in pain treatment beyond the CY 2019 payment year, as continued appropriate reimbursement will help facilitate uptake of existing and future innovations for pain treatment.

As we have previously discussed with the Agency, we believe there are a number of other policy updates that CMS can make to both advance access to the most appropriate course of care for pain and addiction treatment, while reducing the number of traditional opioids prescribed to beneficiaries. These include: reviewing coverage and reimbursement policies in other areas of the Medicare program to prioritize access to current and innovative medications that either deter, mitigate, or assist in the treatment of addiction (the outpatient setting, in the physician office setting, and Medicare prescription drug benefit and Medicare Advantage programs); ensuring that providers and patients are educated on appropriate use of existing and innovative pain and addiction treatments; and incorporating scientific advances in the understanding of the treatment of pain and addiction into the continuum of care. BIO is committed to continuing to work with the Agency on these broader efforts to address the issues in the pain and addiction treatment space for Medicare beneficiaries.

X. CMS should incorporate the Adult Immunization Status measure in the final rule to prioritize prevention quality measurement.

BIO has noted CMS has proposed to remove several critical immunization measures for influenza and pneumococcal from quality reporting programs under this rule. We believe the adult immunization status (AIS) represents an opportunity for CMS to prioritize quality measurements for vaccine prevention.

The AIS is a composite of several age-recommended vaccines for adults, comprising influenza, pneumococcal, zoster, and Tdap vaccines. It aims to provide a sound, reliable, and comprehensive means to assess the receipt of routinely recommended adult immunizations while also reducing reporting burden on providers. It will enable robust immunization status monitoring and reporting and inform critical preventive service benchmarks that can account for the value immunization under new payment models. The AIS has also been proposed for adoption under the MIPS/MSSP as well as several primary and specialty areas in the CY2020 Physician Fee Schedule rule.[9]
The AIS will facilitate more opportunities to assess the immunization status of Medicare beneficiaries by the range of clinicians who care for them, both primary care and specialty providers. Reducing the number of missed immunization opportunities, particularly among

[9] https://www.regulations.gov/document?D=CMS-2019-0111-0092

Medicare beneficiaries, is critical to improving health and reducing the burden of vaccine preventable disease.

XI. CMS Should Not Finalize the Proposal to Limit the Laboratory Date of Service Exception Policy Only to Advanced Diagnostic Laboratory Tests (ADLTs) That Have Been Granted ADLT Status by the Agency.

Under the original CMS 14-Day Rule, reference and independent laboratories were barred from billing Medicare directly for molecular pathology tests ordered less than 14 days after an outpatient was discharged from the hospital.

In addition to the administrative challenges this created for both labs and hospitals, there was also clinical concern voiced over potential delays in patient testing, access to test results, and implementation of treatment plans as the 14-day timeframe is accommodated. That changed recently when the agency published its Outpatient Prospective Payment System Final Rule for 2018.

In 2018, CMS finalized exceptions to the 14-day rule to allow labs to bill Medicare directly under the Clinical Laboratory Fee Schedule for molecular pathology tests and advanced diagnostic laboratory tests (ADLTs) that are excluded from OPPS packaging rules and ordered fewer than 14 days after a patient's outpatient hospital discharge. If the specified criteria were met, the date of service (DOS) for the excepted tests would be the date of testing rather than the date of specimen collection.

The DOS has been the date the test was performed instead of the date the specimen was obtained if these conditions were met:

- The physician orders the test following the date of a hospital outpatient's discharge from the hospital outpatient department.
- The specimen was collected from a hospital outpatient during an outpatient encounter.
- It was medically appropriate to collect the sample from the hospital outpatient setting during the hospital outpatient encounter.
- The results of the test do not guide treatment provided during the hospital outpatient encounter.
- The test was reasonable and medically necessary for the treatment of an illness.

In creating the exception beginning in 2018, the agency acknowledged that it had received concerns and agreed that the provisions of the 14-day rule could cause inappropriate delays for molecular pathology tests and advanced diagnostic laboratory tests (ADLTs). Specifically, CMS reported in the preamble to the Final Rule,

> "We have heard from commenters that because ADLTs are performed by only a single laboratory and molecular pathology tests are often performed by only a few laboratories, and hospitals may not have the technical ability to perform these complex tests, the hospital may be reluctant to bill Medicare for a test it would not typically (or never) perform. As a result, the hospital might delay ordering the test until at least 14 days after the patient is discharged from the hospital outpatient department or even cancel the order to avoid the DOS policy, which **may restrict a patient's timely access to these tests**. In addition, we have heard from commenters that the current laboratory DOS **policy may disproportionately limit**

> **access for Medicare beneficiaries under original Medicare fee-for-service** (that is, Medicare Part A and Part B) because Medicare Advantage plans under Medicare Part C and other private payors allow laboratories to bill directly for test"[10](emphasis added).

For CY 2020, the agency is now considering limiting the exception as finalized in 2018, which as proposed would again restrict the ability of molecular pathology laboratories and ADLTs from billing Medicare directly. As CMS itself acknowledged when creating the exception, the 14 day rule as it previously existed caused delays in critical testing which informs treatment plans and helps to ensure that patients are able to access the most appropriate therapy in a timely manner.

In the CY 2020 Proposed Rule, CMS is considering three potential revisions to the to the DOS provision:

1. Specifying that a molecular pathology test or ADLT is a hospital service (and thus falls outside the DOS exception) unless the ordering physician determine that the test does not guide treatment during the current or a future hospital outpatient encounter;
2. Limiting the DOS exception to ADLTs; and
3. Excluding blood banks and blood centers from the DOS exception.

BIO appreciates CMS's detailed consideration of the DOS exception policy. However, we disagree with CMS's proposals to limit the 14-day rule exception policy by requiring physicians to certify that the test does not guide treatment, as well as the proposal to limit the exception only to ADLTs, and thus to revoke the exception for molecular pathology tests.

In the 2018 final rule, CMS cited that the original 14-day rule DOS policy had the real potential to restrict timely access to laboratory tests and could limit access to treatments for Medicare beneficiaries enrolled in the traditional Medicare program. For these reasons, BIO supported the exception for molecular pathology tests. These tests are critical to determining the most appropriate therapy for a patient, and often many therapies require companion diagnostics in order for a physician to prescribe that approved treatment. As we increasingly reach an era of personalized medicine, it is vital that patients have timely access to the most appropriate therapy for their given condition.

BIO urges CMS not to implement the proposed revisions to the 14-day rule exception, and ensure molecular pathology tests and ADLTs are able to continue billing Medicare directly by maintaining the previously finalized exception policy. Patients needing such tests are very sick and timing of their treatments can mean the difference between death or survival.

XII. BIO raises concerns with certain aspects of the agency's proposal to require hospitals to make publicly available their standard charges for all items and services.

BIO raises concern with certain aspects of the agency's proposal to require hospitals to make publicly available their standard charges for all items and services as part of its ongoing focus on bringing down health care costs through hospital costs and charge transparency. The proposal would include in this requirement charges that have been negotiated between hospitals and third-party payers.

[10] 82 Fed Reg 59397 (December 14, 2017).

In the Proposed Rule CMS lists several reasons why it believes that seeing hospital charges negotiated with third parties can benefit consumers. One example is that if a health care consumer's coinsurance amount is a percentage of the charges for a hospital service, the hospital with the lowest negotiated charges will result in the lowest coinsurance amount. CMS also states a growing number of insured consumers are choosing to pay cash out-of-pocket for some services as opposed to paying the coinsurance, and this information can help them with making that determination.

CMS acknowledges the potential impact resulting from the release of negotiated rates is largely unknown, and it is interested in comments expressing views on the potential impact. Several healthcare organizations such as the American Hospital Association have expressed concerns regarding this proposal, stating the proposal "could seriously limit the choices available to patients in the private market and fuel anticompetitive behavior among commercial health insurers." [11]

Market competition is a vital aspect of the US healthcare system, and all patients should benefit from the value that results from healthy competition. The reliance on private negotiations among many individual and sometimes competing stakeholders is a hallmark of this system. There are certainly aspects of the US healthcare system where improvements are possible, and improved price transparency that is relevant for healthcare consumers is a very important part of improving the system. However, we are generally concerned about certain proposals that may threaten some of the fundamental aspects of a competitive market relying on individual third-party negotiations. The competitive nature of market-based negotiations rely on confidentiality to protect the interests of the parties involved. Requiring these negotiated rates to be made public risks fundamentally (and perhaps irreversibly) changing the nature of this heretofore competitive market. BIO supports alternatives to "payer-specific standard charges" that would minimize anti-competitive incentives or create unintended consequences in the marketplace associated with releasing payer-specific information.

Therefore, BIO urges CMS to proceed cautiously as it considers policies that may create unintended consequences for patients in existing competitive healthcare markets.

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BIO appreciates the opportunity to comment on the proposals in the Medicare Hospital Outpatient Prospective Payment System Proposed Rule. 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

[11] https://www.aha.org/press-releases/2019-07-29-aha-statement-proposed-cy-2020-opps-rule