Biotechnology Innovation Organization

September 11, 2017

BY ELECTRONIC DELIVERY

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

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program; Proposed Rule [CMS-1676-P]

Dear Administrator Verma:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the calendar year (CY) 2018 Physician Fee Schedule (PFS), other revisions to Part B, and Medicare Shared Savings Program (MSSP) Proposed Rule (Proposed Rule),[1] published by the Centers for Medicare & Medicaid Services (CMS) on July 21, 2017.

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 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 biological. In this letter, BIO responds to CMS's proposals in the order in which the Agency addresses each issue in the Proposed Rule, for ease of

[1] 82 Fed. Reg. 33,950 (July 21, 2017).

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reference. However, there are several issues of particular importance to our members given the goal of ensuring patient access to necessary vaccines, treatments, and therapies.

These include the following recommendations:

- CMS should not finalize its proposed reduction in payment under the PFS for services provided in off-campus provider-based departments (PBDs) of hospitals and should maintain payment at 50 percent of the OPPS rate until a lower rate is justified by thorough analyses of the cost of such services.
- CMS should not finalize the proposed reduction for Current Procedural Terminology (CPT®)[2] code 96372 (subcutaneous or intramuscular injection), which will reduce patient access to drugs administered under this code, and, if implemented, should phase in any significant reduction over time.
- CMS should create a unique Healthcare Common Procedure Coding System (HCPCS) code and separate payment for each individual biosimilar product, including those that are based on a common reference product, to foster a robust market for biosimilars.
- CMS should finalize its proposal to establish separate payment for additional chronic care management and behavioral health integration services.
- CMS should ensure that it expands the Medicare Diabetes Prevention Program model only by exercising appropriate authority under the Center for Medicare and Medicaid Innovation (CMMI) waiver and in accordance with the statutory criteria for expansion of CMMI demonstration models.

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[2] CPT is a trademark of the American Medical Association.

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I. CMS should not finalize its proposed reduction in payment under the PFS for services provided in off-campus PBDs of hospitals and should maintain payment at 50 percent of the OPPS rate until a lower rate is justified by thorough analyses of the cost of such services. [p. 33,978]

Under sections 1833(t)(1)(B)(v) and (t)(21) of the Social Security Act (SSA), certain non-excepted items and services furnished by off-campus PBDs are not considered outpatient department services and must be paid under a payment system other than the OPPS. In the CY 2017 OPPS rulemaking and a separate interim final rule for CY 2017, CMS determined that it would pay for such items and services under the PFS, at a rate of 50 percent of the applicable OPPS rate. CMS arrived at this "PFS relativity adjuster" of 50 percent by comparing the OPPS payment rate and PFS payment rate for the service most frequently billed by hospitals using the PBD modifier, which was HCPCS code G0463 for clinic visits for assessment and management of a patient. For this code, CMS estimated that PFS payment was between 21 percent and 28 percent of OPPS payment. CMS then compared the OPPS payment rate for the next 24 most frequently billed services under the OPPS against the most nearly applicable PFS payment rate for those services. The percentage of OPPS payment for each individual service varied from zero percent to 137.8 percent, but the volume-weighted average was about 45 percent. Although CMS recognized that the data used to perform this analysis were imperfect and incomplete, it established the 50 percent adjuster "until such time that we had more precise data to better identify and value non-excepted items and services furnished by non-excepted off-campus PBDs and billed by hospitals."[3]

For CY 2018, CMS proposes to reduce the adjuster to 25 percent of the OPPS rate. BIO is deeply concerned that this reduction will result in unjustified payment disparities between physician offices and PBDs and between drugs that are separately payable under the OPPS and those that are not, and will inappropriately influence providers' decision-

[3] *Id.* at 33,980-82.

making and limit patients' access to treatment. We urge CMS to maintain the adjuster at 50 percent until a lower payment rate is supported by a comprehensive analysis of the data.

Although CMS has expressed general concern that the 50 percent adjuster might result in higher "overall" payments to hospitals for services in non-excepted off-campus PBDs than CMS otherwise would pay under the PFS in the non-facility setting, its proposal to reduce the adjuster to 25 percent is not based on a comprehensive analysis of whether any such disparity actually exists. Nor does CMS cite any new, "more precise" data to justify such a significant reduction. Rather, CMS states that it compared payment in non-excepted off-campus PBDs to an analogous PFS payment rate for a single service – clinic visits reported using HCPCS code G0463 – and arrived at an estimate that PFS payment was about 25 percent of the OPPS payment for that service.[4] CMS proposes to use this comparison as the basis for the revised adjuster although it previously recognized that the OPPS and PFS payment rates for these services are "not entirely comparable" "due to the more extensive packaging that occurred under the OPPS for services provided along with clinic visits relative to the more limited packaging that occurred under the PFS for office visits."[5]

CMS freely acknowledges that its new estimate is based on comparison of rates for a single service, that this comparison does not reflect the fact that PFS payment for other services is significantly higher than 25 percent of the analogous OPPS payment, and that certain PBDs will furnish more of these higher-paying services than others. Nevertheless, CMS states that "we must set the PFS Relativity Adjuster prior to studying the CY 2017 claims data that might allow us to consider and incorporate many more factors" – that is, the factors that would make the estimated adjuster accurate – and therefore CMS simply just disregards those factors.[6]

Even assuming that a comprehensive analysis of claims data is not possible for CY 2018, CMS does not attempt to explain why it believes 25 percent (based on the clinic visit service) is a "better proxy" for the actual relative PFS payment than the 50 percent adjuster it established a year ago. CMS simply states that, "[f]or CY 2018, we are focused on ensuring that we do not overestimate the appropriate overall payments for these services."[7] CMS does not explain why, in general, it believes that payment to off-campus PBDs under the PFS is too high, as opposed to about right, or too low. Nor does CMS explain why, in particular, the 50 percent adjuster is too high and the 25 percent is closer to right, or why the estimate that it performed for CY 2018 (based on clinic visits) is better than the estimate it performed for CY 2017 (based on clinic visits and a range of other services). Although CMS may not be able to arrive at a comprehensive analysis and precise estimate this year, it must at least justify the rough estimate that will be the basis for payment in CY 2018, and in particular it must justify the significant departure from the estimate that it chose for CY 2017. In the absence of an adequate explanation of CMS's rationale, the change in the adjuster is arbitrary and should not be finalized.

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[4] *Id.* at 33,982-83.
[5] *Id.* at 33,980.
[6] *Id*.
[7] *Id.*

BIO is also deeply concerned about the practical effects of the proposed reduction in payment for non-excepted items and services in non-excepted PBDs. We believe that the primary goal in establishing payment under the PFS for PBDs should be to maintain parity of payment between PBDs and physician offices, which is the only way to ensure that patients continue to have access to the most clinically appropriate therapy in all settings of care. CMS's decision to apply a uniform adjuster for all items and services creates a significant risk that patients will be denied access to certain treatments in the PBD setting when the adjuster is too low for the PFS payment to cover the hospital's costs in providing that particular item or service. Many drugs and biological therapies, for example, are not paid separately under the OPPS and therefore would be subject to the adjuster in the PBD setting. If CMS finalizes the proposed reduction to 25 percent of OPPS rates, the PFS payment for those drugs and biologicals is likely to be too low for many hospitals to cover their costs, potentially harming beneficiary access to care. CMS also is proposing to begin conditionally packaging payment for Level I and II drug administration codes under the OPPS, which would mean the adjuster would apply to those services as well and would expose even more patients to a denial of access to critical treatments if the adjuster is not high enough to cover hospitals' costs.

BIO is committed to working with CMS to perform the necessary data analyses and establish accurate and adequate payment rates for non-excepted items and services provided in off-campus PBDs. An analysis of drug administration codes comparing OPPS and PFS payment rates demonstrated that the proposed 25 percent rate is not justified and the current 50 percent rate represents appropriate, site-neutral payment.[8] Until CMS is able to perform additional analyses and establish payment rates that do not risk potentially limiting patients' access to treatment, we urge CMS to maintain the adjuster at 50 percent of OPPS rates.

II. CMS should not finalize the proposed reduction for CPT code 96372 (subcutaneous or intramuscular injection), which will reduce patient access to drugs administered under this code, and, if implemented, should phase in any significant reduction over time. [p. 34,056]

The Proposed Rule includes revisions to payment under the PFS for a number of services, including for CPT code 96372 (injection beneath the skin or into muscle for therapy, diagnosis, or prevention). CMS's proposed revisions to the practice expense inputs for this service would result in a payment reduction of approximately 19 percent from CY 2017 to CY 2018.[9]

BIO urges CMS not to impose this drastic reduction in payment, which could create a significant barrier to patient access to necessary and clinically appropriate treatment. The proposed reduction appears to be aimed primarily at conforming changes in clinical labor time or with labor activity for other codes in the family. But we believe that the proposed reduction goes too far and fails to account for the totality of time and work required to

[8] The Moran Company conducted analyses comparing volume and payment rate between OPPS and PFS for Drug Administration Codes with the PO modifier. That analysis showed that for drug administration codes with material volume, 25% of OPPS payments would represent a material cut compared to the physician office.
[9] *Id.* at 34,056.

perform this type of drug administration, including the time required to comply with post-regulatory reporting requirements. As we have noted in the past, CMS should consider carefully not only the time required for clinicians to perform the actual drug administration but also the increased time and effort spent by clinicians in complying with Risk Evaluation and Mitigation Strategies (REMS) requirements imposed by the Food and Drug Administration (FDA) on a growing number of drugs and biological products. This extra time and effort distinguishes drug administration from analogous codes and must be accounted for in payment rates under the PFS.

Imposing such a large reduction in payment may force physicians to reduce the use of drugs and biologics administered under this code, potentially curtailing beneficiary access to care. Accordingly, we urge CMS to maintain payment for CPT code 96372 at its current level. At a minimum, if CMS chooses to finalize a reduction in payment, the agency should phase in the reduction over a number of years to allow physicians time to prepare and, to the extent possible, mitigate the negative effect on patients.

III. Payment for Biosimilar Biological Products Under Section 1847A of the SSA – CMS should create a unique HCPCS code and separate payment for each individual biosimilar product, including those that are based on a common reference product, to foster a robust market for biosimilars. [p. 34,090]

Medicare Part B currently pays for biosimilar products under the PFS based on the Average Sales Price (ASP) of all biosimilar products within the same HCPCS code, which means that biosimilar products with the same reference product are grouped together for purposes of calculating an ASP and physicians are reimbursed the same amount under Part B for all such biosimilar products. In the Proposed Rule, CMS does not propose to revise payment for biosimilar products under the PFS, but asks stakeholders to assess and comment on whether CMS's previously finalized payment policy is "fostering a robust and competitive marketplace and encouraging the innovation that is necessary to bring these products to the marketplace."[10] Further, CMS expresses interest in "better understanding if and how the innate differences in biological products and their current regulatory environment should be reflected in Medicare payment policy for biosimilars, particularly as it relates to biosimilars that are licensed for fewer than all indications for which the reference product is licensed or situations where different biosimilars may be licensed for different subsets of indications for which the reference product is licensed."[11]

BIO has long advocated for separate payment for each biological and biosimilar product under the PFS, most recently in our comments on the CY 2016 PFS rulemaking in which CMS adopted its current payment policy.[12] We opposed that policy because:

(1) It is inconsistent with the statutory reimbursement methodology in section 1847A(b)(8) of the SSA;

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[10] *Id.* at 34,090-91.
[11] *Id.* at 34,091.
[12] BIO, Comment Letter regarding Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 [CMS-1631-P] (Sept. 4, 2015), available at: https://www.regulations.gov/document?D=CMS-2015-0081-1766.

(2) It creates an incentive for providers to choose less costly biosimilars within the same reference product rather than prescribing the biosimilar product that is most medically appropriate for that patient's condition; and

(3) It creates unnecessary confusion for providers and dispensers seeking to ensure that they are administering or dispensing the correct product and unnecessary difficulty in tracking adverse events and other safety information, both of which could cause harm to patients.

BIO appreciates the opportunity to reiterate our firm belief that a separate HCPCS code and separate payment rate for each biosimilar product, even within the same reference product, is the best policy to maximize patient safety and access to appropriate therapies and to foster a competitive, innovative market for biosimilars. In particular, we appreciate CMS's request for comment on whether Part B payment policy should reflect "the innate differences in biological products," particularly where biosimilars within the same reference product are licensed for different indications, or for different indications than the reference product itself. This request highlights the concern expressed by BIO and others that biosimilars are, by definition, not identical, and should not be treated as identical in setting payment rates under Part B, for all of the reasons cited above.

Finally, we would like to draw CMS's attention to the interaction between the biosimilar payment policy under the PFS and the newly proposed OPPS policy to reduce payment for 340B drugs from ASP plus six percent to ASP minus 22.5 percent. Under current policy, CMS reimburses biosimilars by paying the ASP (based on all biosimilars with the same reference product, as noted above) plus six percent of the ASP of the reference product. It is unclear how this payment policy would apply to the new and reduced payment for 340B drugs, that is, whether CMS would pay the blended ASP minus 22.5 percent of the reference product's ASP, or the blended ASP minus 22.5 percent of the blended biosimilars' ASP. In any event, the proposed reduction in 340B payment provides another example of why it is important and appropriate to assign a separate code and separate payment to each biosimilar product. Blending the ASPs of biosimilars with the same reference product is problematic enough when physicians are reimbursed at ASP plus six percent because the policy results in underpayment for a biosimilar that has a higher ASP than the blended average. That effect would be exacerbated by blending the ASP of biosimilars with the same reference product and then reducing that blended ASP by a further 22.5 percent. For this and all of the other reasons we have raised in these and past comments, we urge CMS to establish a separate code and separate payment for each individual biological product.

IV. Payment for Care Coordination and Care Management Services – CMS should finalize its proposal to establish separate payment for additional chronic care management and behavioral health integration services. [p. 34,010]

As part of its ongoing effort to establish separate and adequate payment under the PFS for care coordination and care management services, CMS proposes to establish payment rates for three new billing codes for psychiatric collaborative care management services (CPT codes 994X1, 994X2, 994X3) and one billing code for general behavioral

health integration services (HCPCS code G0507).[13] Relatedly, CMS proposes a new general care management code for Rural Health Clinics and Federally-Qualified Health Centers under the PFS (HCPCS code GCCC1) that would be paid based on the average of the national non-facility PFS payment rates for three care management and behavioral integration codes.[14]

BIO supports these proposals and generally supports CMS's continued efforts to increase the availability and use of care coordination and care management services. We believe that making these services more widely available will promote better outcomes for patients and more efficient delivery of care. We encourage CMS to establish and implement payment for these important services in a manner that ensures patients continue to have appropriate access to innovative therapies in all settings and at all points during their treatment.

V. Medicare Diabetes Prevention Program (MDPP) Model – CMS should ensure that it expands the MDPP model only by exercising appropriate authority under the CMMI waiver and in accordance with the statutory criteria for expansion of CMMI demonstration models. [p. 34,129]

In the CY 2017 PFS rulemaking, CMS finalized a nationwide expansion of the existing CMMI MDPP model, including a delay in the start date, at least with respect to MDPP payments, from January 1, 2018 to April 1, 2018. The Proposed Rule includes detailed proposals to continue implementation of this expansion.[15]

BIO closely follows the work of CMMI given its potential impact on patient access to needed healthcare interventions. In particular, we note that the MDPP model will be one of the first to be expanded nationally under existing statutory criteria, and thus, may be precedent setting with regard to how other CMMI models are expanded. As a general matter, we support the expansion of the MDPP given its potential to improve patient health outcomes through thorough, evidence-based education. As described by the U.S. Centers for Disease Control and Prevention (CDC), without intervention, 15-30 percent of people with pre-diabetes will develop type 2 diabetes within five years.[16] Treating diabetes costs Medicare over $100 billion annually in direct medical costs, and results in $69 billion in reduced productivity across the board.[17] Prevention, in addition to ever-improving treatments, is the two-pronged approach to combatting what many have termed an epidemic. Additionally, under the proposed expansion, we urge CMS to consider how to best support access to influenza and pneumococcal vaccinations through vaccine status assessment and education measures, as these diseases have a more pronounced effect on patients with diabetes.

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[13] 82 Fed. Reg. at 34,010.
[14] *Id.* at 34,083.
[15] *Id.* at 34,129-72.
[16] CDC, Facts, Figures & Registry of Recognized Organizations (rev. May 2017), available at: https://www.cdc.gov/diabetes/prevention/facts-figures/index.html (last viewed August 12, 2017).
[17] American Diabetes Association, *The Cost of Diabetes* (Mar. 2013), available at: http://www.diabetes.org/advocacy/news-events/cost-of-diabetes.html (last viewed August 12, 2017).

As we expressed in our comments on the CY 2017 PFS proposed rule,[18] however, we have serious concerns about CMS's lack of wavier authority under Phase II models and the need for greater clarity with regard to how CMS assessed the Diabetes Prevention Program (DPP) Model against the statutory criteria for expansion of CMMI demonstrations.

A. As a general matter, the statute does not authorize CMS to use waivers to expand Phase I models to Phase II, but waivers are not necessary to expand the DPP model.

BIO continues to have serious concerns and legal doubts about whether CMS's waiver authority permits an expansion of the DPP model as an "additional preventive service."[19] We believe that CMS is not authorized to use any waivers in the context of the Proposed Rule since the Medicare statute limits waivers to "Phase I" testing. Specifically, the Section 1115A waiver authority is available only "as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)."[20] In addition, subsection (b) describes the testing of models under "Phase I." The expansion phase of CMMI's demonstrations, on the other hand, is described in subsection (c) of the statute. Thus, even when a model is properly expanded in accordance with the statutory provisions, CMMI's waiver authority ends with Phase I, because it applies "solely for purposes of carrying out [Phase I testing]."[21]

However, we also reiterate our belief that waiver authority is not necessary to expand the MDPP model. As we described in detail in our comments on the CY 2017 PFS proposed rule,[22] the MDPP model does not require CMS to waive SSA section 1861(ddd)(1)(B) because creation of a new supplier class is not inconsistent with use of the National Coverage Determination (NCD) process required by that provision. We refer CMS to our comments on the CY 2017 PFS proposed rule for a detailed explanation of why waiver is unnecessary to implement the expanded MDPP model.

B. CMS should more comprehensively articulate the Agency's rationale for proposing to expand the DPP model.

BIO also continues to have serious reservations about CMS's articulation of why the statutory criteria for expansion of a CMMI model are met with respect to the MDPP expansion. These criteria are that:

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[18] BIO, Comment Letter regarding Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model (CMS-1654-P] (Sept. 5, 2016), available at https://www.regulations.gov/document?D=CMS-2016-0116-4138.
[19] 82 Fed. Reg. at 34,130.
[20] SSA § 1115A(d)(1) (emphasis added).
[21] SSA § 1115A(d)(1).
[22] BIO, Comment Letter regarding Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model (CMS-1654-P] (Sept. 5, 2016), available at https://www.regulations.gov/document?D=CMS-2016-0116-4138.

(1) The Secretary determines that expansion of the model is expected to reduce spending without reducing the quality of care or improve the quality of patient care without increasing spending;

(2) The CMS Chief Actuary certifies that such expansion would reduce (or would not result in any increase in) net program spending; and

(3) The Secretary determines that such expansion would not deny or limit the coverage or provision of benefits for beneficiaries.[23]

Each of these criteria should take into account the evaluation requirements the SSA establishes for all CMMI models.[24]

In proposing the expansion under the CY 2017 PFS rulemaking, and in continuing implementation of the expansion in the Proposed Rule, CMS has described the history of the model and the sources of evidence on which the Agency relied in deciding to expand the model, but has not provided a detailed, comprehensive account of its assessment of that evidence, simply stating the conclusions declaratively. Although BIO continues to agree with CMS's implicit conclusion that the statutory criteria are met, we strongly urge CMS to better articulate its reasoning in final rule before the expansion takes place. A detailed analysis should be the Agency's standard for demonstrating that a Phase I model has met the statutory criteria for expansion in order to allow stakeholders to easily follow CMS's logic and understand how the Agency categorized or ranked the available evidence to arrive at the decision to propose expansion.

In particular, BIO reiterates its request that CMS expand upon its rationale and evidence that each of the statutory criteria are met, as follows:

(1) With regard to the first criterion, by providing further detail on how expansion will "improve the quality of care," including various elements of quality of care assessment, including patient experience;

(2) With regard to the second criterion, by confirming that the Office of the Actuary will, as standard practice, make its determination with regard to impact of the model's expansion on future spending publicly available several months ahead of the proposed expansion date, and by clarifying how stakeholders can engage with this process in the future;

(3) With regard to the third criterion, by providing more detail on CMS's assessment of the impact of the model on patient access to covered items and services based on a broad evaluation of the direct and indirect barriers to care that may result from the model's expansion, and by making this detailed assessment a standard practice when CMS considers expanding CMMI models in the future.

[23] SSA § 1115A(c).
[24] SSA § 1115A(b)(4).

VI. CMS should advance access to vaccines through the Medicare Shared Savings Program [41,104]

The Medicare Shared Savings Program (MSSP) represents a critical opportunity to advance access to vaccinations and improve quality of care for beneficiaries. Measures within the MSSP help to ensure patients are receiving the recommended standard of care, particularly for immunizations. BIO commends CMS for maintain inclusion of the modified Annual Influenza Vaccination (ACO #14) and Pneumonia Vaccination Status for Older Adults (ACO #15) measures within the MSSP. These measures serve a crucial role in determining access, or lack of access, to influenza and pneumococcal vaccinations.

In addition to this critical measure, we ask CMS to advance vaccination access in the future by including a robust set of immunization quality measures that are reflective of the full spectrum of adult immunizations recommended by the Advisory Committee for Immunization Practices (ACIP). For example, CMS should consider the addition of a measure around receipt of herpes zoster vaccination. The inclusion of additional quality measures would help improve immunization rates and health outcomes for the Medicare population.

VII. CMS should procced with the new payment system for ADLTs as scheduled, but take additional measures to ensure data accuracy and integrity before implementing the payment system changes for clinical diagnostic laboratory tests [34,089]

BIO urges CMS to proceed with implementation of the new payment structure as planned on January 1, 2018 for tests designated as advanced diagnostic laboratory tests (ADLTs). ADLTs are a new category of tests that are performed by a single laboratory and are (1) cleared or approved by the FDA, or (2) at a minimum "an analysis of multiple biomarkers of DNA, RNA, or proteins combined in a unique algorithm to yield a single patient specific result."

ADLTs represent an important segment of laboratory testing where there is significant innovation. ADLTs and other novel diagnostics hold great promise as tools that allow physicians to differentiate patient-specific characteristics, design personalized treatment approaches, and ultimately improve patient outcomes. A market-based reimbursement system for ADLTs will help continue to spur investments in novel diagnostic tests and the field of personalized medicine. Furthermore, data collected from sole source clinical tests are reasonably expected to be accurate given the limited test menus and that they are considerably easier to validate. Proceeding with implementation of the ADLT payment structure as described in the final rule will help ensure that patients will have continued access to new, innovative diagnostic tests to guide medical and treatment decisions in the 21st century.

BIO's goal, similar to CMS and other stakeholders, is to ensure that Medicare beneficiaries maintain access to critical diagnostic laboratory testing services. BIO is concerned that the implementation of changes to the payment process for other clinical diagnostic laboratory tests (CDLTs) that are not ADLTs may not accurately reflect market rates. As a result, there could be a negative impact to the network of clinical laboratories that play a critical role during infectious disease outbreaks and efforts to remove barriers to testing through near patient testing could be undermined (including physician office-based and regional testing clinical laboratories).

BIO believes CMS should give consideration to concerns from other stakeholder groups (including the laboratory and physician communities) regarding the impact on patient access if the current payment changes for CDLTs were to proceed as planned. BIO recommends CMS take steps to ensure the integrity and accuracy of the data collected and used to calculate payment rates before fully implementing the extensive revisions to Medicare payment, coding, and coverage for CDLTs to mitigate the risk of reducing patient access to important testing services.

VIII. Conclusion

BIO greatly appreciates the opportunity to comment on the important issues raised by the Proposed Rule, and we look forward to continuing to work with CMS to ensure that Medicare beneficiaries have access to critical drug and biological therapies. Please contact me at 202-962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Mallory O'Connor
Director, Healthcare Policy & Federal Programs