Biotechnology Industry Organization

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BY ELECTRONIC DELIVERY

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Centers for Medicare & Medicaid Services
Mail Stop S3-02-01
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Baltimore, MD 21244

Re: Draft Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development in the Context of Coverage Decisions

Dear Dr. Jacques:

The Biotechnology Industry Organization (BIO) is pleased to submit the following response to the Centers for Medicare and Medicaid Services' (CMS) Draft Guidance for the Public, Industry, and CMS Staff on Coverage with Evidence Development (CED) in the Context of Coverage Decisions (Draft Guidance).[1] BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

As the representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO shares CMS's desire to use evidence to accelerate Medicare beneficiaries' access to innovative items and services. Our members invest billions of dollars each year in clinical research to develop and disseminate evidence to help guide the effective use of their therapies. This investment continues long after the Food and Drug Administration's (FDA's) stringent approval requirements for each of our therapies are met. We also support Medicare policies, such as the Clinical Trial Policy (CTP),[2] which encourage beneficiaries to participate in clinical research.

As CMS recognized when it first developed principles for applying CED, the need to provide for a predictable coverage and reimbursement environment is still critical today. The additional costs incurred as a result of a poorly designed and vague CED policy or inappropriate application of CED may culminate in a chilling effect on innovation, harming patient care both now and in the future. In addition, if manufacturers are unclear about the rationale for CMS's application of CED, investment in new medical technologies may be deterred and patient access to new and improved therapies may be delayed. Our comments are provided with these concerns in mind, to ensure that the CED policy achieves its goals without creating unpredictability or hampering future medical innovation.

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[1] Draft Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development in the Context of Coverage Decisions, Nov. 29, 2012, http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=23 (hereinafter "CMS Draft Guidance").
[2] National Coverage Determination (NCD) Manual, § 310.1.

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1. CMS Should Reiterate the Principles of CED in the Guidance Document.

CMS first provided guidance regarding the use of CED in 2006.[3] That guidance included principles that were developed after careful consideration of stakeholder comments. The eight principles governing the application of CED as articulated in the 2006 guidance document are: [4]

1. National Coverage Determinations (NCDs) requiring CED will occur within the NCD processes, which is transparent and open to public comment.
2. CED will not be used when other forms of coverage are justified by the available evidence.
3. CED will in general expand access to technologies and treatments for Medicare beneficiaries.
4. CMS expects to use CED infrequently.
5. CED will lead to the production of evidence complementary to existing medical evidence.
6. CED will not duplicate or replace the FDA's authority in assuring the safety, efficacy, and security of drugs, biological products, and devices.
7. CED will not assume the NIH's role in fostering, managing, or prioritizing clinical trials.
8. Any application of CED will be consistent with federal laws, regulations, and patient protections.

BIO strongly supports these principles because they protect beneficiary access to appropriate care; encourage development of useful clinical evidence; ensure that any applications of CED use the limited resources of CMS, providers, and manufacturers efficiently without unnecessary duplication of efforts; and were developed with the support of a broad set of stakeholders. CMS decided to remove these principles from the Draft Guidance, and the Agency does not propose alternate principles to guide the application of CED in the future. BIO continues to believe that all of these principles are relevant to the application of CED and that without them CED would impose significant burdens on beneficiaries, healthcare providers, and manufacturers. Therefore, BIO urges CMS to incorporate all of them into the final CED guidance document that the Agency issues. Once CMS recommits to these principles, it should focus on mechanisms to strengthen adherence to them, especially to those that focus on the evidentiary threshold for applying CED, the intended infrequent use of CED, and the requirement to produce evidence through CED that is complementary to existing medical evidence.

In the Draft Guidance, CMS indicates that it excluded the principles from the 2006 guidance document because "some of the 'principles' are now moot."[5] It does not, however, identify which of the principles it considers to be moot or why. If CMS continues to believe that some of these principles are moot, BIO asks that CMS identify those specific principles and the basis for its determination that those principles are obsolete or unnecessary. This will allow stakeholders to provide specific input to CMS on whether and why those principles continue to be relevant or not.

[3] Guidance for the Public, Industry, and CMS Staff, National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, July 12, 2006.
[4] Id.
[5] CMS Draft Guidance at 12.

2. CED Should Rarely Be Applied to Drugs, Biologics, and Diagnostics.

In the Draft Guidance, CMS indicates that CED is appropriate where there are "reasonable grounds, based on the available evidence, to question whether improved health outcomes reported in narrower settings" would be realized by Medicare beneficiaries as well as where "new research or evolving scientific thought raises important questions about the clinical usefulness, and thus the medical necessity, of older established technologies."[6] Although BIO agrees that CED can and should be applied to provide more immediate patient access to promising technologies, we urge CMS to proceed cautiously in applying CED to "older established technologies." CMS surely recognizes the need for predictability in coverage and reimbursement. BIO is concerned that the application of CED to older established technologies would create a less predictable coverage and reimbursement environment, which can discourage continued innovation. Moreover, applying CED to older established technologies is unnecessary since there is an evidence base on which to draw by virtue of these therapies having been utilized over a period of time already.

In addition, BIO urges CMS to state specifically that, with regard to drugs and biologics, CED will be limited to off-label uses of FDA-approved products. Drugs and biologics are subject to a rigorous FDA review process, and their approved prescribing information clearly describes the population for which each therapy is approved and includes the data supporting each indication. CMS should not second-guess the FDA's decisions by requiring additional post-approval studies of a drug or biological for its approved indications. By that same measure, CED should not be applied to Premarket Approval (PMA)-approved diagnostic products. Moreover, the Social Security Act's (SSA) definition of "drugs or biologicals" requires that each drug or biological be included or approved for inclusion in the United States Pharmacopoeia or other listed compendia or be "approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital."[7] These requirements, combined with FDA approval, provide additional assurance that the therapy has been thoroughly reviewed by independent experts prior to coverage.

In addition to FDA approval and compendia support, the Medicare statute and long-standing Medicare policy approve the use of these products for medically accepted indications. In the case of drugs and biologics used in anti-cancer chemotherapeutic regimens, "medically accepted indications" include the FDA-approved uses as well as uses that are listed in certain compendia or are supported by peer-reviewed literature.[8] Medicare also has long granted its contractors authority to determine that unlabeled uses of other drugs are "medically accepted" based on "the major drug compendia, authoritative medical literature and/or accepted standards of medical practice."[9] By using authoritative compendia and medical literature to define "medically accepted indications," the statute and Medicare's guidance protect beneficiaries' timely access to drugs and biologicals while also ensuring that Medicare's coverage policies are truly evidence-based. CMS also has previously recognized physicians' authority to prescribe drugs off-label, stating that "medical decisions are best made by the physician treating the patient. FDA rules do not prohibit physicians from ordering off-label uses of a drug. Current accepted medical practice may include the use of drugs for indications that are not covered by the FDA label but are supported by clinical evidence in peer-reviewed medical literature."[10]

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[6] Id. at 2-3.
[7] Social Security Act (SSA) § 1861(t)(1).
[8] SSA § 1861(t)(2).
[9] Medicare Benefit Policy Manual, ch. 15, § 50.4.2.
[10] CMS, Letter to Chairman Bill Thomas, Committee on Ways and Means, December 4, 2006.

Many types of conditions for which physicians use products off-label are rare diseases where compendia or literature supporting their use is difficult to build, even though the products provide clinical benefit to the patient.[11] The difficulty in securing an adequate number of patients for a trial and/or conducting effectiveness studies poses a major hurdle given the rarity of certain diseases. CMS should not use the CED policy to create access barriers for these patients, but instead should rely on the judgment of the clinician using an FDA-approved product within the standards of medical practice.

In general, BIO believes CMS should initiate CED only as an alternative to otherwise limiting coverage. Specific circumstances under which we believe CED may be appropriate include:

1. When the alternative is national non-coverage based on limited evidence;
2. When there is considerable non-coverage at the local level, creating a de facto national non-coverage policy;
3. When the final NCD will be more restrictive than current use, as signaled by the draft NCD; or
4. Prior to removing coverage for an item or service that was previously covered by Medicare.

3. CMS Should Consider the Applicability of the Standards of Scientific Integrity and Relevance on a Case-by-Case Basis to Address Feasibility.

BIO largely supports the standards of scientific integrity and relevance to the Medicare population that CMS included in the Draft Guidance, which generally mirror the standards included in the 2006 guidance document. CMS has, however, added new standards that are of concern to BIO because they may not always be feasible to achieve and therefore could limit the applicability of CED where it otherwise would be justified and provide expedited patient access to innovative therapies.

a. *Subpopulations*

In particular, BIO is concerned that the requirement that a CED study protocol must "explicitly discuss subpopulations affected by the item or service under investigation"[12] may limit the feasibility of conducting CED studies. For example, including a subpopulation of Medicare beneficiaries may be difficult because many are ineligible to participate in clinical trials due to age, comorbidities, or complications. This difficulty is compounded for therapies treating patients with rare diseases due to their unique vulnerabilities, an already narrow population, heterogeneity, and other issues characteristic of those patient groups. Similarly, the standard requirement of head-to-head studies would be infeasible for these therapies. Study criteria under a CED policy that are defined too narrowly, and therefore unnecessarily restrict the study's population, risk denying access to care for such beneficiaries. Therefore, BIO recommends that CMS apply these standards flexibly as circumstances require.

b. *Method and Timing of Public Release of CED Studies*

The draft guidance suggests specific standards for the method and timing of public release of CED studies, including a requirement that results be made public within 24

[11] National Organization for Rare Diseases, Comments Submitted to the Patient Centered Outcomes Research Institute, July 18, 2011. Today, there are 375 orphan products that treat an estimated 200 rare conditions. Since there are nearly 7,000 rare diseases, most patients are currently being treated off-label.
[12] CMS Draft Guidance at 7.

months of the end of data collection. BIO does not believe that an inability to make study results publically available within 24 months of the end of data collections should be used to inhibit the application of CED if it is otherwise warranted. Our members adhere to accepted standards for the methods and timing reporting of results from studies of drugs and biologics. These standards provide consistency and predictability for manufacturers in their pre-and post-market clinical studies, and therefore should serve as the standard for CED studies. BIO believes that mandating a separate 24-month standard for the method and timing of public release for CED studies is unnecessary and would require manufacturers to comply with multiple, and potentially conflicting, sets of rules potentially without enhancing scientific integrity.

4. Additional Guidance Is Needed Regarding Coverage After CED Ends.

BIO appreciates that CMS has provided guidance on when CED will end. It is important that CED have a definitive resolution in order to avoid unnecessary burdens on beneficiaries, healthcare providers, and manufacturers. BIO believes that more guidance is needed, however, on what specifically will happen after the CED study ends. The Draft Guidance does not clearly articulate the process under which CED studies will be evaluated for "graduation" to a new or revised coverage determination, if any. For example, the Draft Guidance is silent with regard to who will review the CED studies, what opportunities will be available for manufacturer input, and whether the decisions will be available for public comment. BIO urges CMS to include a more complete discussion in the final guidance document of the process it will follow for making a coverage determination after CED ends and believes strongly that this process should include an opportunity for public comment.

As part of its discussion of ending CED, CMS acknowledges the potential for a period of noncoverage between the end of a CED study and the Agency's review of the study results, and indicates that it "may address the issue of ongoing coverage by working with investigators to develop integrated research strategies during the planning of CED studies."[13] Although BIO appreciates that CMS has acknowledged the potential for a coverage gap during the period between the end of the CED study and a new or revised coverage determination and has recognized that it should take steps to ensure continued patient access during this period, BIO is concerned about CMS's proposed approach. Specifically, CMS says that it may design CED studies "to accommodate the complementary roles of randomized controlled trials (RCTs) and practical observational studies to close outstanding evidence gaps and allow coverage after an RCT ends where appropriate."[14] BIO is troubled by the potential for CED to involve multiple, overlapping studies that may not produce necessary data and that may result in a situation where the study requirements for a technology seem to be never-ending. This is of particular concern in situations involving therapies that treat rare or ultra-rare diseases for which no other treatment options are available. In these situations especially, any gap in coverage could be life-threatening to beneficiaries. BIO asks CMS to consider whether there are less burdensome means of enabling continued coverage until CMS issues a new or revised coverage determination following the end of a CED study. Continuous coverage is critical for our patients, particularly those battling cancer or fighting a chronic disease, and must be a top priority for the agency. In the final guidance, CMS should explicitly provide for continuous coverage between the end of CED and the issuing of a new or revised coverage determination.

We urge CMS to ensure patient access to necessary therapies during the review period by including the scientific "review period" and time needed to make a coverage

[13] Id. at 8.
[14] Id.

determination as part of the total CED study period under which uninterrupted coverage of the therapy would be available.

5. CED Should Not Be Applied Where a Product Is Subject to an FDA Post-Market Study.

In the Draft Guidance, CMS addresses coordination with the FDA by mentioning the memorandum of understanding (MOU) between CMS and the FDA, as well as the Federal Register notices on parallel review. FDA and CMS each have separate and distinct mandates that CMS must adhere to in its application of the CED guidance. Although BIO supports the two agencies working together to ensure patients have access to needed therapies, it is critical that the unique missions of these two agencies remain distinct and not be comingled or compromised in the course of the application of CED. Congress deliberately bestowed FDA and CMS with distinct authorities and standards for approval and coverage decisions respectively, consistent with the different missions and constituencies of the agencies. FDA has the appropriate combination of expertise and resources to review and approve study design and results of clinical trials needed to demonstrate that drugs and biologics are safe and effective. CMS should not attempt to use its limited resources to duplicate this mandate.

CMS also notes that "FDA has at times required ongoing research and data submission as a condition of approval," and "[w]hile the alignment of CED with an FDA post-approval study requirement presents an opportunity for greater research efficiency, we believe that this is simply an example of a CED application rather than a new CED paradigm."[15] BIO appreciates this clarification, but we also believe that patients and manufacturers should not be put into a "double jeopardy" situation in which CED is applied to those products that are already subject to Risk Evaluation and Mitigation Strategies (REMS) or other post-market studies required by the FDA. CED should not be used to limit access to care using therapies subject to a REMS if the FDA approval allows patients to receive the therapy without participating in a study. If therapies already subjected to REMS or other FDA post-market studies are also subject to CED, manufacturers—especially the often smaller manufacturers of orphan drugs—may face significant resource burdens associated with conducting multiple studies, which could potentially impose delays in conducting the FDA post-market research. Similarly, there is the potential that a CED study may directly conflict with the requirements of the FDA post-market study. In all of these instances, imposing CED on products or services already subject to FDA post-market requirements could inappropriately interfere with the division between the roles of the FDA and CMS, and could directly threaten patient access to innovative and novel therapies. Therefore, BIO urges CMS to prohibit the application of CED to products already subject to an FDA post-market study.

6. CMS Should Clarify the Role of the Agency of Healthcare Research and Quality (AHRQ) in the Application of CED.

CMS indicates that its authority to use CED is based on the provision of the SSA that permits coverage of items and services in the context of research conducted and supported by AHRQ.[16] Section 1142 of the SSA describes the authority of AHRQ to conduct and support research on outcomes, effectiveness, and appropriateness of services and procedures, among other things.[17] Although CMS discusses how ARHQ's "authority and resources complement CED," it does not describe AHRQ's role in identifying, conducting, or

[15] Id. at 9.
[16] Id.
[17] SSA § 1142.

supporting CED studies, but rather says that that "AHRQ's role will continue to develop as both agencies gain more experience with CED."[18] BIO believes that AHRQ's role should be limited to activities that support, as appropriate, the goal of expanding patient access to novel therapies through CED. Thus, CMS must clarify this role given that the statutory authority for CED is premised on AHRQ's research activities.

In particular, BIO believes that it is crucial for CMS to clearly explain how it plans to fund CED studies and the role AHRQ will play in such funding. CMS fails in the Draft Guidance to address the costs of CED and who bears them. The drug development and FDA review and approval processes require significant investment by manufacturers. Imposing additional clinical research requirements on manufacturers may limit the ability to support continued innovation, especially for therapies for the Medicare population. Provider and patient costs also must be taken into consideration. CMS does indicate that AHRQ has the ability to establish public/private partnerships to financially support CED studies. Thus, concerns regarding the costs of CED studies and the effect of those costs on patient access remain. To address these issues, BIO urges CMS to more clearly articulate the types of partnerships that AHRQ may establish and the public funding that will be available to minimize the financial burdens of CED whenever possible.

CMS also indicates in the Draft Guidance that AHRQ "has the ability to invoke certain confidentially protections regarding certain uses of data."[19] Although BIO agrees with CMS regarding the need for confidentiality of sensitive data, we urge CMS to use the final guidance document to identify how data ownership and patient confidentiality will be protected, and how other usage issues inherent in CED will be addressed. This is particularly important to ensure that manufacturers who sponsor research under CED have timely and complete access to the data the research produces.

7. As Exemplified in the Case of Diagnostic Products, Evidentiary Criteria for Invoking CED Should Vary Based on Expert Evaluation.

In developing its Draft Guidance, CMS convened the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) to evaluate, among other things, how to define the evidentiary criteria for the application of CED.[20] CMS discusses the MEDCAC's findings in the Draft Guidance, but provides no guidance regarding the evidentiary criteria it intends to use. BIO recommends that CMS provide additional information regarding the types of evidentiary standards it intends to use; however, BIO believes that it would be inappropriate for CMS to apply a single evidentiary threshold to invoke CED for all types of items and services because the coverage determination process involves complex judgments and values, and interventions are highly variable. For example, the level of evidence that CMS may require for drugs, biologics, devices, diagnostics, or medical procedures will vary based on the characteristics of these interventions. Even within the drugs and biologics categories, orphan therapies may require unique evidentiary standards because of the small size of these patient populations and the resulting data limitations. Similarly, novel therapies that fulfill unmet needs in disease areas such as cancer should be judged by a higher threshold before invoking CED. As discussed in detail above, BIO continues to believe that CED is inappropriate for FDA-approved drugs and biologics used on-label and for medically accepted off-label uses. Additionally, BIO believes that the appropriate focus of CED studies for diagnostic products (*e.g.*, molecular diagnostic tests)

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[18] CMS Draft Guidance at 9.
[19] Id.
[20] MEDCAC Meeting, May 16, 2012, Evidentiary Characteristics for Coverage with Evidence Development (CED), at http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=63&bc=AAAIAAAAAAAA&.

should be on whether the diagnostic test meaningfully alters clinical decision-making, rather than measuring impacts on clinical outcome.

In the Draft Guidance, CMS states that "adherence to the following standards of scientific integrity and relevance to the Medicare population should be demonstrated in all CED studies… [including that] the principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of patients who are represented by the enrolled subjects."[21] BIO cautions CMS in application of evidentiary standards for all medical products uniformly, without attention to the unique characteristics for appropriate clinical utilization.

BIO recognizes that payers, including CMS, have expressed concerns that some diagnostic tests in the market are superfluous, and may be ordered by a provider despite the fact that the result will not meaningfully alter how the provider will treat the patient. However, the above language included in the Draft Guidance—a focus on impacting clinical outcomes—is a metric more appropriately applied to a therapeutic intervention. In that case, there is a one-to-one, direct relationship between administration of the therapeutic intervention and the clinical outcome; that is, there is nothing downstream of the therapeutic intervention that cannot be controlled for in the study.

In contrast, diagnostic tests provide information for physicians to use to guide the course of treatment. In a clear case, such as for a companion diagnostic test that specifies a particular drug/biologic in its labeling based on the results, this evidentiary burden of meaningful impact on clinical decision-making is met *per se*. However, many clinically useful diagnostic tests are 1) used in the context of other clinical information; and 2) may produce different courses of action for patients with the same result, either due to other contextual clinical information or based on the individual experience of the physician. There exists variability downstream from administration of the diagnostic test that cannot practically be controlled for in the real world use of these products. Accordingly, the most appropriate metric for clinical utility should be whether the results of the test meaningfully alter clinical decision-making.

BIO encourages CMS to explore evidentiary standards for diagnostic tests that are more appropriate and valid to measure the clinical utility of these products. To this end, CMS should consider whether diagnostic tests exist that would fall into a *per se* category of meeting this evidentiary burden. For example, as mentioned above, companion diagnostic tests include labeling that direct the use of a particular drug/biologic based on the result of the test. Such diagnostic tests have a meaningful alteration of clinical decision-making, and thus meet this evidentiary burden, *per se*. As mentioned in other sections of this comment, BIO believes that CED is not appropriate for products that have been through a rigorous clinical review by the FDA, such as those approved under a new drug application (NDA), biologics licensing application (BLA) or a PMA. A more appropriate focus for the evidentiary standard for coverage of diagnostic tests will ensure that Medicare beneficiaries have access to tests that are used in a clinically meaningful manner by providers.

Stakeholders previously recommended that a MEDCAC meeting be convened prior to each proposed application of CED. CMS rejected this recommendation in the Draft Guidance.[22] BIO maintains, however, any application of CED requires input from stakeholders with relevant expertise, including manufacturers and those with public and private sector expertise in designing and conducting clinical trials. In order to determine the

[21] CMS Draft Guidance at V(A)4a.
[22] CMS Draft Guidance at 10.

appropriate evidentiary threshold for each application of CED and to determine whether a particular item or service meets that threshold, CMS should work collaboratively with stakeholders representing the full range of expertise and values—manufacturers, providers, and relevant academia—in evaluating the existing evidence, assessing the need to collect additional evidence, and constructing studies that can be used for CED. Because this process would be sensitive to the unique issues raised by each particular intervention, it is critical that CMS work closely and transparently with all stakeholders involved.

8. CED Should Be Implemented Only At the National Level.

The Draft Guidance does not clearly articulate the mechanism CMS intends to use to apply CED. BIO continues to believe that CED should occur within the auspices of an NCD and therefore, only be implemented at the national level. Any application of CED must be developed in a clear and predictable manner, with opportunity for public comment, to ensure that CMS reaches an appropriate decision. This can be accomplished by using the NCD process, which has well-established procedures to garner input from stakeholders and has protections in place to ensure that inappropriate coverage determinations do not occur. In addition, by implementing CED at the national level, CMS can overcome a number of potential challenges related to small study sample sizes, limited agency resources, and duplicative clinical trials.

9. CMS Should Ensure that the CED Process is Transparent and Inclusive.

In the Draft Guidance, CMS says that it expects that "all CED approved studies will be analyzed and published in peer-reviewed clinical journals," and that CMS "intends to maintain information on ongoing CED research studies on its website along with links to the ClinicalTrials.gov" website.[23] CMS's Draft Guidance fails to ensure transparency regarding the decision to initiate CED, end a CED study, and evaluate CED for purposes of making a new or revised coverage determination. It also fails to make specific provisions for ensuring meaningful manufacturer engagement in the creation, governance, and implementation of CED.

It is critical that CMS establish a well-defined, transparent, and inclusive CED policy that encourages innovation and that is initiated only after clearly communicating the reasons for applying CED and identifying the research questions justifying the application of CED. These communications should occur early in the coverage review process and be understood by all interested stakeholders. BIO urges CMS to engage manufacturers in determining how to define and implement technology-specific CED studies and in governing the approved CED registry or clinical trial. Without this engagement, CED may impose significant and unnecessary burdens on manufacturers and providers and may not productively complement and enhance existing medical evidence. The timeline for sufficient evidence development also should be part of the ongoing dialogue between CMS, stakeholders, and appropriate expert advisors, such as clinical epidemiologists and scientists. CED should describe CMS's proposed process for communication with manufacturers and other relevant stakeholders prior to the opening of a national coverage analysis and the potential application of CED, and its proposed process for involving them in an open and transparent dialogue as the issue is considered and the research questions are generated. In addition, CMS should describe in more detail the process it will use to apply the CED study results to a coverage decision. BIO recommends that decisions relating to applying and ending CED should be subject to public notice and comment. Finally, CMS

[23] Id. at 11.

should be transparent in how it defines metrics—such as 'last patient last visit'—that govern progression through the CED process, especially those used to determine its conclusion.

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BIO appreciates the opportunity to comment on the Draft Guidance. We look forward to continuing to work with CMS to address this and other important issues in the future. Please feel free to contact me at 202-962-9220 if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd
Managing Director, Reimbursement and Health Policy