December 18, 2006

BY ELECTRONIC DELIVER

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-4119-P (Medicare Program; Medicare Part D Data; Proposed Rule)

Dear Administrator Norwalk:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding collection of and access to claims data under Part D of the Medicare program (the "Proposed Rule").[1] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States.

BIO's members are strongly committed to increasing the body of quality evidence available to further the clinical decision making process. Our members invest millions of dollars each year on clinical studies, both before and after Food and Drug Administration (FDA) approval to produce high-quality clinical evidence to support appropriate medical decision-making. BIO is committed to ensuring appropriate beneficiary access to innovative biological therapies, and we look forward to the opportunity to

[1] 71 Fed. Reg. 61445 (October 18, 2006).

work with CMS to ensure that the collection and usage of Part D claims data furthers this access for all Medicare beneficiaries.

BIO continues to support a rigorous research process that encompasses all aspects of a disease, from examining how a disease affects the body to studying the costs and benefits of therapies. Our members' research initiatives advance the understanding of disease pathology and therapeutic mechanisms of action, clinical effectiveness in naturalistic settings, health-related quality of life, and health economic impacts of therapies, as well as clinical safety and efficacy. The development of evaluation of therapies is part of this broader research process and must be considered in context.

As we have noted in previous comment letters, such as our comments on the "Coverage with Evidence Development" (CED) policy, BIO's members are committed to the development of high-quality evidence about diseases and their treatments.[2] While we are uncertain about the statutory authority for the data usage CMS has proposed, we agree with CMS that the usage of the Part D information presently being collected could offer significant benefits to the public health, particularly in the area of pharmacosurveillance. The value and limitations of claims data, however, are also well known. While BIO commends the Secretary for considering expanded usage of Part D claims information, we are concerned that there is not enough information in the Proposed Rule about the procedures that will be put in place to account for limitations in the use of this information and to allow interested parties to provide input on specific uses, particularly those involving coverage and payment decisions. These substantial concerns underlie all of BIO's comments to the Proposed Rule.

The highlights of BIO's comments are as follows:

- The use of Part D claims information by the government to establish coverage and reimbursement policy raises a series of questions about the use of the data that are not answered in the Proposed Rule. Specifically, BIO urges CMS to recognize the limits of claims data and describe in detail the process it expects to use to solicit and consider public input on various uses of the data,

[2] See, for example, BIO Comment Letter to Steve Phurrough Re: "Guidance for Public, Industry, and CMS Staff: National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development" (September 22, 2006).

particularly with regard to studies designed to influence plan coverage and payment decisions;

- The Part D claims data should be available to researchers outside the federal government in much the same manner that claims data from Parts A and B are available currently. The capacity to use this data to enhance medical knowledge will be greatly enhanced by public access to Part D claims information, provided that access is available in an organized and transparent way.
- The definition of "commercial purposes" must be narrowly construed so that the integrity of the use of the data is not compromised but access to the information is not unduly hindered.

I. Statutory Considerations

The proposed rule contains extensive commentary on the statutory authority that CMS proposes to exercise in using Part D claims information for a variety of purposes. CMS proposes to use the contracting authority provided under section 1857(e)(1) of the Social Security Act ("the Act"), incorporated into Medicare Part D by section 1860D-12(b)(3) of the Act as the basis for using the claims information for a variety of proposed purposes beyond the payment issues for which it was originally being collected, delineated in section 1860D-15.

BIO supports efforts to ensure that accurate and comprehensive information about health care is available to facilitate high quality research on appropriate treatments using biotechnology therapies. As we will discuss further in the balance of this letter, we are generally supportive of efforts to assure that all researchers have access to Part D claims information, which is a rich source of data regarding the role played by medicines in the health and well being of Medicare beneficiaries. However, we have not completed a review of all of the legal questions raised by the proposed rule and accordingly do not take a position on CMS' statutory authority.

The balance of our comments focus on the importance of careful use of the Part D claims information, but BIO asks that the agency, in its final rule on these issues, provide more guidance on how it interprets the various statutory provisions at issue here.

II. The Value and Limitations of Claims Data

While the collection and development of Part D claims data has tremendous potential to further clinical knowledge and enhance clinical decision-making, BIO urges CMS to recognize the limitations of Part D claims data and to exercise extreme caution in using this data to establish coverage and reimbursement policy. Part D claims data alone provides only a very partial picture of a patient's health care and health outcomes. Even when used in conjunction with Part A and B claims data, this data has significant limitations and should not be used in isolation to establish coverage and reimbursement policy.

As CMS indicates in the Proposed Rule, the Part D data that the agency proposes to use for a variety of purposes were originally designed to assure accurate payment of Part D plans, reflecting "True Out of Pocket Costs" (TrOOP). While BIO agrees that the data could prove to be quite useful for a number of other purposes, the data elements available will not always be exactly on point for the questions that CMS and other agencies will be seeking to answer. Often the information will provide only surrogates for the actual information being sought. As indicated in the Proposed Rule, the usage of particular products, for instance, will only be suggestive of the presence of a particular diagnosis. While this will in some circumstances expand the diagnostic information as compared to what are currently available using Medicare claims, it also illustrates some of the limitations facing researchers using this claims data.

As a result of these limitations, working with claims data for the purposes that CMS has described—whether from existing Part A and B claims, or the proposed use of Part D information—will require substantial creativity. In some instances, the information provided by claims data will be all that is required, and research using only the information available on Part A, B and D claims may produce viable and highly interesting results. In many cases, however, this claims data will not give informative results, but rather indicate the need for additional research that would require data not available in Part A, B and D claims datasets.

Given the complexity of these issues, BIO believes that more information is needed for the public to evaluate the uses of Part D payment information that CMS has proposed. BIO believes that a more clearly delineated process is necessary before the proposed dataset can be used for many purposes, particularly those that may inform coverage and payment

decisions. In the Proposed Rule, CMS references a number of potential uses of the data that could have profound effects on coverage under either Parts D or B. However, CMS does not offer detail on the process that will be used to allow for public analysis of the results of any of the proposed research projects and input into any of the regulatory or legislative proposals that may result. BIO urges CMS to release more detailed information about the specific initiatives it has proposed and as well as more information about how the agency intends to approach these and other uses of the data given the limitations of the data in question. In addition, BIO urges CMS to allow for a process for outside analysts to review, comment on and critique the study methodology and the results of the research of CMS and other agencies using Part D claims data, along with a process for public input prior to the use of these data in legislative and regulatory proposals.

Particularly if the Part D claims information is to be used as the basis for coverage and payment decisions, a detailed framework describing the process by which these decisions will be made is required. This structure should detail:

- The evidentiary standards that will be used;
- The process for appeals from adverse decisions; and
- Assurances that the process will be fully transparent.

The Proposed Rule does not address these issues. BIO believes that if CMS is to move forward with its proposal to use Part D claims information, particularly as the basis for decisions related to coverage and payment, the agency has an obligation to develop and disclose procedural safeguards along these lines.

This process should include provisions for public comment on specific coverage and payment decisions—with adequate time for replication of the analyses on which these decisions are based—along with an appeals process that is open to manufacturers of products for which coverage is restricted or denied. The process should also include time for public meetings to provide detail on the analyses performed using Part D and other claims information that results in coverage and payment decisions, including the methodologies used, detailed findings and potential limitations of these findings.

The evidentiary burden for any effort to restrict coverage and payment on the basis of Part D claims information must lie with CMS, and

any such decisions should not be effective until the entire process, including appeals, is completed.

III. The Importance of Public Access to the Data

BIO agrees with CMS that the Part D data the agency proposes to collect could be extremely valuable to CMS and other federal agencies in their efforts to protect the public health and provide health care services to Medicare beneficiaries. This claims data also has the potential to benefit public health more broadly by furthering understanding of disease and treatment options, as well as for purposes such as pharmacosurveillance. We believe that this data, linked to currently available claims data from Medicare Parts A and B, could greatly enhance efforts to research and develop new drugs and biologicals and to improve the safe and effective use of existing products.

As an association, BIO has long believed that drugs and biologicals can be highly cost effective alternatives to other medical interventions, potentially reducing the need for surgical interventions and hospitalizations while offering significant improvements to quality of life. While our members have been able to produce evidence to support these contentions, the availability of Part D claims information would provide a rich new resource for researchers interested in these issues. In order for BIO and its members to conduct such research, as well as offer fully informed comments on any initiatives of CMS and other agencies based on data collected under this proposal, we must be able to independently analyze the data. Consequently, BIO urges CMS to ensure that the data it proposes to collect are available to the public in much the same manner that claims data from Parts A and B are available currently.

In order to facilitate analysis by outside researchers, BIO urges CMS to release a summary file parallel to the current Physician Supplier Procedure Summary Master file along with a 5% sample Standard Analytical File (SAF) that can be linked to encrypted identifiers on Part A and B claims, in addition to other releases that may be necessary to allow the public to be fully informed about and comment on any regulatory actions based on the proposed dataset. These claims should be drawn from the same 5% sample used for existing SAFs, even though some sampled beneficiaries will not be enrolled in standalone Prescription Drug Plans (PDPs). This will allow for a complete picture of the health care interventions needed for

sampled beneficiaries, creating the most detailed dataset available to date on the medical value of drug and biological therapies.

In constructing these files, we would urge CMS to include as many data elements from the Part D claims information as possible, without jeopardizing beneficiary privacy, to ensure research can control for as many confounding elements as possible. For example, detailed information about Part D plan formulary and tiering structures will be particularly useful in this regard.

CMS may also wish to consider constructing a mechanism to allow outside researchers to access Part D claims information for pharmacosurveillance purposes. Such a mechanism would require an investment of time and resources materially greater than a SAF release, but could generate significant improvements in the safe utilization of drugs and biologicals by expanding the pool of researchers attempting to identify and prevent potential adverse events.

In summary, BIO agrees with CMS that the data it proposes to collect could produce significant benefits for the public health, benefits that can be compounded by assuring that the data are available for public use that can improve the safety and effectiveness of current uses of drug and biologicals while also aiding in the development of further innovations.

IV. Defining "Commercial Purposes"

In the Proposed Rule, CMS requested comments on whether it should consider additional restrictions to guard against "the potential misuse of data for non-research purposes, commercial purposes or to ensure that proprietary data or confidential beneficiary data is not released."[3] BIO believes that the current protections for claims data released under Parts A and B, through the use of a privacy board for claims data that are considered fully identifiable, and research protocols with data use agreements for Limited Data Set (LDS) releases provide adequate protection of beneficiary privacy. We assume that LDS releases of Part D claims information will remove or encrypt data elements in much the same way that the current SAF LDS files are constructed, effectively preventing the re-identification of individual beneficiaries. However, we would again urge the agency to

[3] 71 Fed. Reg. at 61453.

release as many data elements as possible without compromising beneficiary privacy.

Given our desire to assure that the data in question—and the benefits these data offer—are available to the public for a broad range of beneficial analyses, BIO believes that CMS should construe "commercial purposes" as narrowly as possible. We believe that any analyses concerning the use of claims information in the legislative, regulatory, administrative or judicial processes cannot be considered a commercial purpose, even though the BIO members that may wish to conduct these analyses either directly or through a contract with outside researchers that are commercial entities. Due to the legitimate research and public health purposes that research using Part D claims information may offer, BIO believes that manufacturers should be able to access the data directly, and not merely through intermediaries or within the context formal judicial or administrative proceedings.

We do agree with CMS, however, that some potential uses of the data should be impermissible; we believe that these uses can be prevented with a targeted definition of "commercial purpose." We urge CMS to limit restrictions based on commercial uses to those situations where entities are seeking to use Part D claims information to identify beneficiaries or pharmacies in order to solicit commercial transactions. These sorts of uses of the data can be restricted through the use of encrypted pharmacy and plan identifiers—in much the same way that Physician identifiers are encrypted in current SAF files.[4] We are concerned that a broader definition of "commercial purpose" could create undue restrictions on use of this information by manufacturers, health insurers, pharmacy benefit managers and physicians, even where such uses have the potential to provide tremendous benefit to medical research or may be used by CMS as the basis for coverage and reimbursement restrictions. BIO believes that by narrowly defining those uses of Part D claims information that are prohibited will serve to provide the greatest benefit to Medicare beneficiaries, allowing manufacturers and outside researchers the flexibility to obtain the data while seeking to improve the safe and effective usage of prescription drugs and biologicals for Medicare beneficiaries and the healthcare system as a whole.

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[4] If the agency does decide to encrypt pharmacy and plan identifiers, we are hopeful that some descriptive information will be released. For instance, information about the nature of the pharmacy (mail order, retail, specialty, and/or geographic regions) would be necessary to control for possible confounding factors in outcomes studies.

We agree that commercial uses of the data should be restricted, but that this restriction should allow adequate flexibility for a wide range of research that has the potential to improve the safety and effectiveness of current drug and biological usage while also aiding in the search for new innovations in health care.

V. Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact Jayson Slotnik at 202-312-9273 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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