October 28, 2005

BY FEDEX DELIVERY

Walter Stone
CMS Privacy Officer
Mail Stop N2-04-27
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Notices of New Systems of Records: "Data Collection Secondary to Coverage Decision System," "Anti-Cancer Chemotherapy for Colorectal Cancer System," and "Carotid Artery Stenting System"

Dear Mr. Stone:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) notices of new systems of records (SORs) for data collection secondary to coverage decision (DCSCD),[1] anti-cancer chemotherapy for colorectal cancer (CRC),[2] and carotid artery stenting (CAS).[3] 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 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial, and environmental biotechnology products.

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1 70 Fed. Reg. 53667 (Sept. 9, 2005).
2 70 Fed. Reg. 55133 (Sept. 20, 2005).
3 70 Fed. Reg. 55137 (Sept. 20, 2005).

BIO has been pleased to work with CMS as it develops its approach to coverage with evidence development (CED). Through our comments on the national coverage determination (NCD) on anti-cancer chemotherapy for colorectal cancer[4] and the draft guidance document regarding factors CMS considers in making a determination of CED,[5] BIO consistently has urged CMS to ensure that its efforts to define CED and to apply CED to specific technologies are open, transparent, and predictable. The use of SOR notices is an important element of CMS' communications with stakeholders about CED. As CMS explained in the draft guidance and the CED fact sheet, the agency plans to use SOR notices to announce the data collected under CED, its authorized uses, and the conditions for use of the data.[6]

We are concerned that CMS has not sufficiently described these SORs and its policies regarding CED in general to allow beneficiaries and other stakeholders to understand what data the agency would collect and how precisely the data would be used by the agency. To ensure that individuals can determine what data pertaining to them are collected, maintained, used, or disseminated by the government, the Privacy Act requires agencies to announce the content, uses, and sources of data for each new SOR as well as the safeguards in place to protect that data from inappropriate disclosure.[7] In these three notices, CMS' descriptions of these SORs are so vague that beneficiaries cannot determine what data will be collected, the purposes for which it will be used, or when their data will be disclosed to other entities. The notices' ambiguity also raises concerns for other stakeholders, including physicians, institutional providers, researchers, and manufacturers, about CMS' use of CED. Accordingly, we urge CMS to withdraw these notices, continue to develop the guidance document for CED, and reissue the SOR notices only after that guidance document has been finalized.

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4 Letter from M. Werner, BIO, to S. Phurrough, CMS, regarding the draft decision memorandum for anti-cancer chemotherapy for colorectal cancer, Dec. 23, 2004, available at http://www.bio.org/healthcare/medicare/20041223NCD.pdf.

5 Letter from J. Greenwood, BIO, to S. Phurrough, CMS regarding the Draft Guidance for the Public, Industry, and CMS Staff: Factors CMS Considers in Making a Determination of Coverage with Evidence Development, June 6, 2005, available at http://www.bio.org/healthcare/medicare/20050606.pdf.

6 Draft Guidance for the Public, Industry, and CMS Staff: Factors CMS Considers in Making a Determination of Coverage with Evidence Development, at 13 fn. 6, available at http://www.cms.hhs.gov/coverage/download/guidanceced.pdf; Fact Sheet: CMS Responds To Stakeholder Feedback Regarding Coverage With Evidence Development, at 2-3, available at http://www.cms.hhs.gov/coverage/download/guidfactsheet.pdf.

7 5 U.S.C. § 552a(e)(4); Pub. L. No. 93-579, § 2(b) (Congressional findings and statement of purpose).

Our first concern is that these notices do not adequately describe the data to be collected or the protections against their misuse. According to the notices, these data collections will include "baseline patient characteristics," including, but not limited to, name, address, telephone number, health insurance claim number, geographic location, race/ethnicity, gender, date of birth, and "background information relating to Medicare or Medicaid issues."[8] CMS does not define "baseline patient characteristics" or "background information relating to Medicare and Medicaid issues," however, leaving unexplained the full breadth of the data that might be used.

We understand that, despite the broad descriptions provided in the notices, the data collected and sources used might be substantially narrower. We were informed by CMS staff that, in the case of the CRC SOR, CMS intends simply to ask the National Cancer Institute to verify that the beneficiary is enrolled in a specified clinical trial, and that the agency will not collect other data from the trials. For the CAS SOR, we understand that CMS plans to collect data on patients' risk factors from the carotid stent registry, and that the agency does not intend to ask physicians to provide additional data. We appreciate this clarification, but we are concerned that these facts were not explained in the notices, where they would be announced to all stakeholders. We urge CMS to reissue these notices with detailed descriptions of the agency's plans for these SORs, as described above. To the extent that CMS plans to derive data from "clinics, institutions, hospitals, and group practices performing the procedures, and outside registries and professional interest groups," in addition to CMS' contractors' claims files,[9] the agency also must explain how data not included in Medicare claims will be collected from health care providers in compliance with the Health Insurance Portability and Accountability Act privacy regulations and institutional review board (IRB) requirements.

Second, we are concerned that the routine use disclosures could allow entities that do not need the data to access it, while denying manufacturers access to data on their own products. In all of the notices, CMS provides a long list of "routine use disclosures," including disclosures to other federal or state agencies, researchers, members of Congress, and to the Department of Justice. Some of these entities, such as state agencies, appear to have no connection to CMS' purpose for collecting the data. Manufacturers, who need the data for their own

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8 70 Fed. Reg. at 53670, 55134, 55141.
9 70 Fed. Reg. at 53672, 55137, 55142.

research and to assist CMS with its analysis, are not included in the list, however. We believe that manufacturers must have the same access to the data as other researchers. Because manufacturers have the most knowledge about their products, they are the best source of information and assistance for CMS' efforts to study their products. Manufacturers are uniquely able to help CMS identify relevant issues for research, interpret the data, and answer CMS' questions about their products. This input is critical to the appropriate and effective design, implementation, and analysis of evidence development activities, and is possible only if manufacturers have the same access to CMS' data as other researchers. Additionally, having access to the data could help manufacturers identify and respond to regulatory compliance issues as they arise. We therefore urge CMS to allow manufacturers to access data on their own products through routine use disclosures. We also recommend that CMS reissue the notices with greater detail about routine use disclosures so beneficiaries can be informed meaningfully about the data in the SORs and be reassured that their data will be disclosed only when necessary and appropriate.

Third, we are concerned that the SOR notices do not adequately explain why these data are being collected or how CMS will use them. In these notices, CMS states that the purpose of these collections is to collect and maintain data on patients to review determinations of "reasonable and necessary" with respect to CAS and other therapies.[10] The SOR notice for CRC states that its purpose is to "provide reimbursement for CRCs and assist in the collection of data on patients receiving CRC as a new or emerging cancer treatment regimen" and "to assure patient safety and protection and to determine that the CRC is reasonable and necessary."[11] CMS does not describe why these data are needed to determine whether an item or service is reasonable or necessary, however, or how it plans to use the data to make such a determination. CMS also does not address whether it intends to use these data for outcomes research, even though claims data lack the accuracy, consistency, and specificity needed to reach valid conclusions about health outcomes. We understand from conversations with CMS staff that the agency plans to use only baseline data describing patients' conditions at the time they received a therapy to verify that each patient meets the coverage criteria for that therapy, but the agency does not plan to use the data for longer-term research on outcomes. If this is so, CMS should describe its plans in greater detail in the

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10 70 Fed. Reg. at 53671, 55141.
11 70 Fed. Reg. at 55136.

notices themselves so beneficiaries and other stakeholders can be informed and comment on them.

Fourth, and most important, we believe that too many questions about CED remain unanswered for CMS to proceed with these SORs. CMS' vague descriptions of these SORs only reinforce our concerns about CMS' policies regarding CED. We are pleased that CMS plans to release a second draft of the guidance document for public comment and will hold an additional Open Door Forum on CED.[12] The comment period on this draft and the Open Door Forum—not the SOR notices—are the appropriate forums for developing CMS' policy regarding CED. We believe that CMS must first issue the next draft of the guidance document, with a clear explanation of how it intends to use data collected through CED, before it can begin to consider collecting data. We urge CMS to reissue these SOR notices after finalizing the guidance document.

We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Jayson Slotnik at (202) 962-9200 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jim Greenwood
President and CEO
Biotechnology Industry Organization

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[12] Fact Sheet: CMS Responds To Stakeholder Feedback Regarding Coverage With Evidence Development, at 3, available at http://www.cms.hhs.gov/coverage/download/guidfactsheet.pdf.