



December 12, 2005

Office of Inspector General
Department of Health & Human Services
Attention: OIG – 405- P
Room 5246, Cohen Building
330 Independence Ave., S.W.
Washington, DC 20201

Re: Medicare and State Healthcare Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute

Dear Sirs:

The Biotechnology Industry Organization (“BIO”) appreciates this opportunity to comment on the Office of Inspector General’s proposed Rule on the establishment of a new Safe Harbor under the Federal Anti-Kickback Statute for certain arrangements involving the provision of electronic prescribing (“e-prescribing”) technology and a separate Safe Harbor for certain electronic health records, software and directly related training services. We note that the e-prescribing Safe Harbor is specifically intended to address certain arrangements involving hospitals, group practices, prescription drug plan (“PDP”) sponsors and Medicare Advantage (“MA”) organizations that provide certain designated Recipients with non-monetary

remuneration consisting of hardware, software, and training services that are both “necessary” and are used exclusively to receive and transmit e-prescribing drug information.

This proposed Rule was published in the Federal Register on October 11, 2005, 70 FR at 59015.

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 healthcare, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO is highly supportive of the benefits that can be achieved in improving health quality, reducing prescription errors, and lowering costs through the broad adoption and effective implementation of e-prescribing and electronic healthcare records. BIO believes that these components of the adoption of healthcare information technology will result in significant reduction of healthcare costs over the long-term, improved patient safety and better health outcomes through greater availability of the information that is necessary in order to optimize healthcare decisions.

BIO also believes that a robust e-prescribing and electronic health records infrastructure will have a number of benefits for the healthcare system. Patient safety will be enhanced by the provision of accurate drug prescription information, leading to a reduction in the number of adverse experiences arising from mistakes in prescribing. Additionally, BIO believes that patient compliance and persistency with medication therapy also will be improved as a result of the electronic linkage between the physician’s office and retail pharmacy outlets. Finally, an inter-operable system that integrates information about biopharmaceutical therapies into electronic health records will enhance the ability of decision-makers to evaluate the impact of therapies on patient health outcomes and to objectively measure the overall value of biopharmaceutical therapies to the healthcare system.

This demonstration of value will particularly benefit from the availability of longitudinal patient healthcare information, permitting outcomes studies underpinned by reliance on “real-world” data.

BIO also supports the overall development of a health information technology infrastructure that continues to emphasize the primacy of the informed judgment of physicians and individual patients. Such e-prescribing and electronic healthcare records systems should not be employed in a way that unduly focuses attention on the narrow issue of ingredient unit costs, and, therefore, becomes merely a mechanism for inappropriate cost containment, rather than a system to support improved quality healthcare.

In assessing any healthcare information technology infrastructure, BIO believes that there are four broad areas of strategic focus that are inherent in the successful adoption of an inter-connected national healthcare information infrastructure. These are:

1. **Safe Harbors.** BIO supports the OIG’s initiative to begin the discussion of legal Safe Harbors in the context of providing financial support for the adoption of a healthcare information technology infrastructure. While BIO supports Safe Harbors under both the Stark Anti-Referral Act and the Anti-Kickback Statute, we believe that it will be important to address the issue whether the biopharmaceutical industry may also benefit from a Safe Harbor in order that members of the biopharmaceutical industry can provide appropriate support for the adoption of healthcare information technology.

In addition to the issue of providing appropriate safe harbors, we also believe that the other critical success factors include incentives and financing, privacy and security, and the development of appropriate interoperability standards.

2. **Incentives and Financing.** BIO believes that it is important to identify the incentives and financing necessary to facilitate the adoption of technology in clinical settings, especially among single and small group practices. This is especially important in light of the possibility that a very significant percentage of the benefit derived by the adoption of a physician practice of an information technology system actually redounds to the benefit of other health system stakeholders,

such as health plans. Indeed, it has been estimated that physicians typically only derive 11% of the benefits of their investment in this technology. *Assessing IT Value: Ambulatory Care Order Entry, Center for Information Technology Leadership, 2003.*

BIO, therefore, believes that the treatment of Safe Harbors for the provision of electronic prescribing technology and electronic health records software and directly related training services should be viewed in the context of the overall financial incentives that are available to physicians for adopting electronic health records and using technology to improve patient care. BIO believes that there also is a potential role for grants, tax credits and revolving loans to physicians and other providers to purchase inter-operable electronic health record or other technologies that could be used to benefit treatment decisions. The scope of the Safe Harbor should be evaluated in the overall context of the other financing or government-supported incentives that may become available, particularly to sole practitioners and small practice groups.

3. Privacy and Security. BIO believes that patients will need to be convinced that any system of electronic prescribing and electronic healthcare records provides appropriate protections for healthcare-related information.
4. Standards for Inter-operability. Ultimately, the success of any system will depend upon the development of technical and data standards that permit inter-operability. The lack of clinical data standardization has resulted in the continued fragmentation of the United States healthcare system, and BIO applauds efforts by the National Committee on Vital and Health Statistics to help develop accepted standards that will accelerate adoption of e-prescribing technology. We would note again, however, that it remains critically important that the adoption of such standards focus on the improvement of the quality of the provision of healthcare and not inappropriately focus on narrow and short-term cost containment-related issues.

Within the framework of this overall perspective on the appropriate goals and critical success factors of national support for an interconnected national healthcare information infrastructure, BIO would like to offer the following comments and suggestions regarding the draft Rule:

1. Protected Non-Monetary Remuneration

First, BIO categorically supports OIG’s efforts to distinguish between “innocuous or beneficial arrangements that would eliminate perceived barriers to the adoption of e-prescribing” while at the same time, guarding against the creation of “undue risk that the arrangement might be used to induce or reward the generation of federal healthcare program business.” 70 FR at 59016.

Additionally, BIO also supports the OIG’s conclusion that there are a number of existing Safe Harbors that are generally germane to arrangements involving the provision of e-prescribing items and services. *Id.* As noted, the fair market value arrangements that are negotiated at arms’ length and are not premised on, or take into account, the volume or value of federal healthcare program referrals would not raise concerns under the Federal Anti-Kickback Statute. Indeed, as noted in *United States v. McClatchey*, 217 F. 3d 823 (10th Circuit 2000), it is not a violation of the Anti-kickback laws for a party to “hope”, “respect” or “believe” that referrals of business may ensue from remuneration that was designated wholly for other purposes. *Id.* at 834. Thus, a “collateral hope” of referrals alone does not violate the law. *Id.* As to the requisite mental state required to violate the Act, BIO also believes that the law as charged to the jury in *United States v. MacKenzie et al. (Tap Pharmaceuticals)* is an accurate rendering of the current state of the law in this regard. Regardless of which formulation is more appropriate, it is clear that there are a wide variety of arrangements that could involve the provision of e-prescribing items and services that would neither violate the anti-kickback statute nor the physician self-referral law.

BIO also endorses the OIG’s efforts to assure consistency between the OIG Safe Harbor and the corresponding exemption proposed by CMS with regard to what is commonly referred to as ‘the physician self-referral law.’ 70 FR at 59017.

BIO does have some concern regarding the proposed application of the “necessary and used solely” criteria for the provision of items and services that are used to receive and transmit e-prescribing drug information. 70 FR at 59018.

While we understand the basis for fraud and abuse-related concerns in the context of the provision of Donors to Recipients of items or services that are technically or functionally equivalent to items or services presently received by a Recipient, we do have a concern about limiting the provision of improved equipment to upgrades for equipment or software that “significantly enhance the functionality of the item or service.” 70 FR at 59018.

There have been repeated examples in the field of information technology where advances in functionality may be deemed incremental. The value of any one incremental change may vary from user to user. BIO believes it could inject an unnecessary level of uncertainty for stakeholders encompassed by the Safe Harbor to evaluate whether a particular enhancement would be deemed subsequently by the OIG to be sufficiently “significant” to warrant the protection of the Safe Harbor.

Instead, BIO believes that it would be preferable to permit the marketplace to determine whether an improvement in hardware or software provides a beneficial improvement and not to limit or restrict the scope of the Safe Harbor by reference to the inherently ambiguous standard of “significance”. One benefit of a Safe Harbor is its capacity to be applied by stakeholders with a reasonable degree of certainty and with a minimum of administrative burden. Conditioning the Safe Harbor on the degree of improvement could significantly undermine those goals.

BIO also believes that the required certification by the Recipient that the new hardware or software is not functionally equivalent to items already in their possession could be susceptible to the same ambiguities of technological assessment and could undermine incremental improvement in the field of healthcare information technology. It also will impose a further burden on healthcare information technology adoption and, as the OIG itself recognizes, will not necessarily protect the system from the abuses of fraud and abuse in any event. Id.

BIO would like to suggest an alternate approach. The Donor and the Recipient should each certify to the value of the item provided. (In this regard, BIO believes that the recitation of a fair market value would be the appropriate valuation methodology.) This recitation could be combined with a written acknowledgement that the item or service provided is not being used as a vehicle to confer an unlawful payment for referrals for federal

healthcare program business and do not constitute financial incentives offered, paid, solicited or received in exchange for such business. These two representations will minimize the risk and provide a sufficient deterrent of inappropriate conduct without creating unnecessary burdens on the healthcare system.

2. Donors and Recipients Protected by the Proposed Safe Harbor

The OIG's rule specifically limits the protection afforded by the Safe Harbor to:

1. Hospitals with respect to members of their medical staffs;
2. Group practices with respect to prescribing healthcare professionals who are members of the group practice;
3. PDP Sponsors and MA organizations with respect to participating pharmacists and prescribing healthcare professionals.

70 FR at 59019.

We appreciate the OIG's solicitation of comments on whether to protect other categories of Donors or Recipients beyond those specifically identified. Id. at 59019-59020.

BIO believes that there are significant reasons why the research-based biopharmaceutical industry should be able to avail itself of a specific Safe Harbor in this regard. We believe that the OIG guidance that currently restrict research-based biopharmaceutical companies from, among other things, providing assistance to healthcare professionals for the cost of adopting healthcare information technology does not optimize the appropriate level of support that can facilitate the adoption of such technologies and, in fact, hinders the provision of appropriate support for the adoption of these technologies.

In this regard, BIO believes that it is important for OIG to understand that the deployment of healthcare information technology infrastructure brings a number of benefits to the biopharmaceutical industry that are entirely independent of, and separate from, the types of concerns that the OIG has identified in the context of the fraud and abuse rules.

For example, BIO believes that the adoption of a health information technology system may well improve the overall efficiency of interactive communications regarding the benefits and risks of pharmaceuticals and can create powerful new channels of communication among healthcare providers, payors and patients. Additionally, the widespread adoption of electronic healthcare records may well improve the overall clinical trial system that is utilized to evaluate the safety and effectiveness of biopharmaceutical therapies and may well permit a significant reduction in the cost of drug development. For example, the widespread adoption of electronic health records may reduce the need for the research-based biopharmaceutical industry to create expensive proprietary systems that are used solely for the purposes of clinical trial programs.

Additionally, physician adoption of electronic healthcare records should improve the identification of adverse events or other health risks associated with the use of biopharmaceutical therapies by linking the results of laboratory tests and other diagnostic procedures. Electronic health records would thus improve overall drug safety by enhancing post-marketing pharmacovigilance and might also help contribute to the enhanced use of observational studies to assess additional significant benefits that may be derived from utilization of marketed biopharmaceuticals. Additionally, the widespread adoption of health information technology infrastructure will, as noted above, permit the adoption of longitudinal databases that will help evaluate the underlying value of biopharmaceutical therapies in the healthcare system.

Thus, biopharmaceutical companies have a strong and independent motivation to support and facilitate the widespread adoption of e-prescribing and electronic healthcare records in the United States. These independent benefits for BIO's members align the interests of the biopharmaceutical industry with the overall societal goals in achieving an inter-connected healthcare infrastructure and, BIO suggests, should be facilitated by the OIG through the inclusion of biopharmaceutical companies in any final Safe Harbor.

3. Laboratory Services

BIO also expresses its appreciation to the OIG for soliciting comments on whether "the Safe Harbor should protect qualifying electronic prescription technology that is used for the transmission of prescription

information regarding items and services that are not drugs (e.g., supplies and laboratory tests).” 70 FR at 59020. BIO believes that for the full benefit of an inter-connected healthcare information technology infrastructure to be achieved in the United States, it would be optimum to include the ability to provide laboratory and other diagnostic information as part of the integrated healthcare technology infrastructure. Many of the benefits that society will derive from such a system will arise out of the potential linkage of all of these facets of relevant healthcare information into a comprehensive and integrated whole.

4. Additional Conditions on the Provision of Qualifying E-Prescribing Technology, Promoting Compatibility and Inter-operability

BIO strongly agrees with the OIG that inter-operability will serve as an important safeguard against the risks of fraud and abuse. 70 FR at 59020. BIO agrees with the OIG that with an inter-operable system, Recipients will be able to transmit prescriptions, for example, to any appropriate pharmacy. Therefore, BIO supports regulations that would “prohibit Donors or their agents from taking any actions to disable or limit that inter-operability or otherwise impose barriers to compatibility.” *Id.* BIO agrees with the OIG that such a regulation will prevent Donors from using the provision of e-prescribing technology to tie Recipients to the Donor.

5. Monetary Cap

The OIG has also raised the possibility that they will limit the aggregate value of the qualifying e-prescribing technology that a Donor can provide to the Recipient under the Safe Harbor, and that the OIG is considering whether to limit the aggregate fair market value of all items and services provided to a Recipient from a single Donor. *Id.*

The OIG is also soliciting public comment on the amount of a cap that would adequately protect the program against abuse, the methodology that could be used to determine the cap, whether the same cap would be adequate if there were protection for the donation of multi-functional hardware and connectivity services, whether the cap should be reduced over time, and whether the cap places a disadvantage on smaller entities that do not have the financial resources of larger chains or organizations. The OIG has also asked for comment regarding whether retail or non-retail costs should be used. *Id.*

In considering the issue of a cap, BIO suggests that the OIG consider three relevant factors:

1. First, to create an inter-connected national healthcare information infrastructure and to achieve the goals set forth in President Bush's 2004 and 2005 State of the Union Addresses will require a very significant expenditure of resources. Although BIO does not have an independent estimate of the costs for fully "wiring" the United States healthcare system, it has been suggested that the costs may be as much as \$10,000 per physician. Over a five year period, the framework, standards and necessary hardware and software for a national system medical Internet and electronic health records system may cost \$150 billion. Absent a massive infusion of federal funding to help support private investment, there are many healthcare stakeholders who will be significantly challenged to fund such systems on their own.
2. Additionally, the hardware and software industries are especially dynamic and upgrades to both hardware and software have been constant. BIO would anticipate that the healthcare infrastructure also will be dynamic.
3. Moreover, as noted previously, there is at least a widespread perception that the physician does not derive anything close to the majority of the benefit generated by wiring a physician's practice into other system stakeholders. If, as noted previously, physicians only derive as benefit 11% of the total investment, BIO believes that it is appropriate to evaluate a cap based upon the actual benefit that accrues to the Recipient, as distinct from the myriad legitimate benefits that may be obtained from other stakeholders in the healthcare system.

Thus, from a fraud and abuse perspective, BIO suggests that it would be appropriate to contemplate any appropriate caps in the context of the benefit that might genuinely be attributable to the Recipient, as distinct from the legitimate benefit that may accrue to the Donor. Thus, while the provision of \$10,000 worth of hardware and software may be an objective cap in order to facilitate the conversion of a physician to an electronic infrastructure, the realistic value to that physician may be significantly less,

and therefore, the risks of inducement stemming from the monetary value of the item provided, should arguably be significantly less than the face value of the item provided.

The OIG has also suggested setting an initial cap “...which would be lowered after a certain period of time sufficient to promote the adoption of the technology. This would have the effect of encouraging investments in the desired technology, while also ensuring that, once the technology has been widely adopted and its costs have come down, the Safe Harbor cannot be used to disguise referrals.” 70 FR at 59020.

While BIO does not disagree with the underlying premise of the OIG’s comments, BIO would urge caution in establishing today any formula for a reduction of a cap in the future until the pace of technological innovation, resulting cost reductions (if any), and the reaction of the marketplace to the adoption of an electronic healthcare infrastructure are better understood.

6. Selection Criteria

BIO endorses the OIG’s proposal that Recipients “...may not make the donation of qualifying electronic prescribing technology from Donors a condition of doing business with the Donor.” *Id.* Additionally, we agree that the eligibility “...of a Recipient to receive items and services from a protected Donor, nor the amount nor the nature of the item or services received, may be determined in a manner that takes into account the volume or value of the Recipient’s referrals or other business generated between the parties.” 70 FR at 59020-59021. BIO also endorses the OIG proposal that relevant selection criteria could be based upon “the total number of prescriptions written by a Recipient...” 70 FR at 59021.

BIO also appreciates the opportunity to comment “...with respect to other potential criteria for selecting [Recipients] of donated technology.” 70 FR at 59021. In this regard, were the OIG to expand the Safe Harbor to encompass appropriate support by members of the biopharmaceutical industry for the adoption of an interconnected national healthcare information infrastructure, BIO suggests that there are additional appropriate selection criteria that should permit members of the biopharmaceutical industry to select Recipients. These would include benefits that otherwise

would accrue to the biopharmaceutical industry from the adoption of such a system – including:

- the reduced costs of drug development,
- improved pharmacovigilance,
- improved risk management,
- the enhanced measurement of the benefits in patient health outcomes and
- the improved efficiency of communication of benefits and risks of biopharmaceuticals with healthcare providers, payors and patients.

All of these are significant benefits to society that will arise out of, and be derived from, the adoption of e-prescribing and electronic healthcare records. BIO suggests that all of these should be the basis of objectively neutral and appropriate criteria for designating Recipients. All of these criteria help achieve long-term benefits for the United States healthcare infrastructure and most importantly, for the quality of patient healthcare.

In conclusion, BIO appreciates this opportunity to comment on the proposed Rule, and express concerns and offer suggestions. We look forward to working with the OIG on this critically important issue of creating a healthcare information technology infrastructure in the United States. We hope that BIO's suggestions will help the OIG address these important issues in the final rule. Please contact Jayson Slotnik at 202-312-9273 if you have any questions or comments. Thank you for your attention to this very important matter.

Sincerely,

/s/

James C. Greenwood
President & CEO
Biotechnology Industry Organization