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September 13, 2010

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: HITECH Privacy and Security Rule Modifications
Hubert H. Humphrey Building
Room 509 F
200 Independence Avenue, SW
Washington, DC 20201

**Re: Comments on the Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act (HITECH Act) – RIN 0991-AB57.**[1]

Dear Secretary Sebelius:

The International Pharmaceutical Privacy Consortium (IPPC) is an organization formed in 2002 and comprised of chief privacy officers and other data privacy and security professionals from research-based, global pharmaceutical companies. The IPPC is committed to the promotion of sound policies for the protection of patient privacy and advancement of drug development and treatment.[2] The IPPC appreciates this opportunity to comment on the proposed modifications to the HIPAA Privacy and Security Rules under the HITECH Act (the "Proposed Rule").

## I. Research-Related Proposals

In its December 2000 rulemaking concerning standards for the privacy of individually identifiable health information,[3] the Department of Health and Human Services ("the Department" or "HHS") commented on the need to create a balance between the needs and rights of individuals and the needs of society as a whole. Quoting medical historian Paul Starr, the Department noted that "Patients have a strong interest in preserving the privacy of their personal health information but they also have an interest in medical research and other efforts by health care organizations to improve the medical care they receive."[4] HHS emphasized its efforts to balance the needs of scientific researchers with individual privacy interests. The IPPC believes that this philosophy must continue to guide the Department's efforts in this area. The

[1] 75 Fed. Reg. 40,868 (July 14, 2010)

[2] For further information concerning the IPPC, please see our website at www.pharmaprivacy.org.

[3] 65 Fed. Reg. 82,462 (December 28, 2000).

[4] Id. At 82,468.

IPPC has previously commented on some of the challenges in implementing the Privacy Rule in the context of health research and has called on policy makers to fundamentally rethink how to protect patient privacy in this context.[5] We encourage HHS to review those prior comments.

A. Proposed 45 CFR § 164.508(a)(4) – Authorization required for sale of PHI

Proposed 45 CFR § 164.508(a)(4) states that "Notwithstanding any provision of this subpart, a covered entity must obtain an authorization for any disclosure of [PHI] for which the disclosure is in exchange for direct or indirect remuneration from or on behalf of the recipient of the [PHI]. Such authorization must state that the disclosure will result in remuneration to the covered entity." This restriction would not apply to disclosures of PHI "for research purposes . . . where the only remuneration received by the covered entity is a reasonable cost-based fee to cover the cost to prepare and transmit the [PHI] for such purposes." The IPPC has several concerns with this proposal.

*1. Impact on availability of limited data sets for research purposes*

As constructed, the proposed limitation may have a significant impact on the availability of limited data sets for research purposes. The proposal would appear to eliminate any financial incentive a covered entity may have in making a limited data set available to third parties for research purposes. Indeed, because it is not clear whether the proposal would allow recovery of "opportunity costs" associated with the use of resources in the preparation and transmittal of the data, covered entities would have the incentive to allocate any available capital in other, more financially productive ways.

The IPPC believes that it was not the intent of Congress to place further restrictions on the availability of limited data sets for research purposes. We understand that Section 13405(d) of the HITECH Act ("Prohibition on Sale of Electronic Health Records or Protected Health Information") grew out of a concern by certain members of Congress, that existing law permitted a hospital or physician to make a profit by selling people's identified medical data, without restriction, to among others, pharmaceutical companies.[6] This could be viewed as a violation of the ethical principle of respect for persons, impinging both a healthcare provider's duty of fidelity and respect for patient autonomy. While the IPPC would be interested in further dialogue on the ethical and practical implications of more broadly allowing covered entities to disclose PHI for bona fide scientific research purposes, such disclosures have under the Privacy Rule been permitted only (i) pursuant to patient authorization, (ii) pursuant to an Institutional Review Board (IRB) or privacy board waiver of authorization, (iii) to a researcher for purposes

[5] *See, e.g.,* IPPC Comments to the US Federal Trade Commission in Relation to the Exploring Privacy Roundtable Series (April 2010), *available at* http://www.pharmaprivacy.org/activities.html; IPPC Comments to the Committee on Health Research and the Privacy of Health Information of the Institute of Medicine (May 2008), *available at* http://www.pharmaprivacy.org/activities.html.

[6] See Ellen Nakashima, *Lobbying War Ensues Over Digital Health Data*, WASH. POST, Feb. 10, 2009, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2009/02/09/AR2009020903263.html.

preparatory to research, or (iv) in the form of a limited data set, pursuant to a limited data set agreement.

Bioethical norms apply the principle of respect for autonomy to personal health information with the aim of protecting individual dignity, however, such norms generally do not extend to anonymous or anonymized information.[7] Indeed, the law adopts this position to the extent of permitting the use and disclosure of de-identified information *for any purpose whatsoever*. This reflects the general view that even though respect for autonomy and individual privacy rights is important, these interests must be balanced with other societial needs for access to health information, such as public health and research purposes.[8]

In this regard, it is important to recall that "protected health information" under the HIPAA rules includes not just *identified* information but *identifiable* information as well. The breadth of the definition of PHI stems not from the view that identifiable information raises ethical considerations of respect for persons to the same extent as identified information, but rather from the practical data security consideration that unless limitations are placed on identifiable health information, "identifiable" can become "identified." Concern over the possibility of re-identification of health information led to the adoption of a de-identification safe harbor that requires the removal of data elements that traditionally have been regarded as neither "identified" nor "identifiable" but which computer scientists have shown could be used to re-identify data subjects.

It was in this context that the Department determined in 2002 that a "middle road" was needed with respect to data that contains no direct identifiers when it is for use in socially beneficial ways. This led to the adoption of § 164.514(e) concerning uses and disclosures of a limited data set for research and certain other limited purposes. As the Department noted at the time:

> One of the reasons for establishing the limited data set provisions is that the concept of ''personally identifiable information'' that triggers IRB review of research that is subject to the Common Rule does not coincide with the definition of ''individually identifiable health information'' in the Privacy Rule. The Department believes that the limited data set comes closer to the type of information not requiring IRB approval under the Common Rule than does the de-identified data set of the Privacy Rule.[9]

To ensure the security and confidentiality of a limited data set, the Privacy Rule requires the execution of a data use agreement between the covered entity and the limited data set recipient. The agreement must, inter alia, establish the permitted uses of the information and prohibit re-identification of data subjects or attempts to contact the data subjects.

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[7] James G. Hodge and Lawrence O. Gostin, *Confidentiality, in* THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS ch.61 (E.J. Emanuel et al. eds., 2008).

[8] TOM L. BEAUCHAMP AND JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 295 (2008).

[9] 67 Fed. Reg. at 53,237.

The application of § 164.508(a)(4) equally to limited data sets as to fully identified information would mark a significant departure from the Department's stated philosophy of attempting to balance privacy interests with the needs of researchers. The privacy interest individuals enjoy with respect to *indirectly identifiable* data relates to the potential for such information to be re-identified and *directly identify* the data subjects. With respect to disclosure of a limited data set, the risk of re-identification is already addressed by the requirement for a data use agreement between the covered entity and the limited data set recipient. When there is no such risk of re-identification, the individuals' privacy interest in information that only indirectly identifies them is far more questionable. We therefore believe that the objective HHS wishes to achieve in regulating the amount of remuneration that can be provided to a covered entity in exchange for the disclosure of a limited data set for research purposes is unclear.

The HITECH Act does not obligate the Department to treat limited data sets in the same manner as more fully identified data. In fact, Congress granted HHS broad authority to create exceptions to the prohibition on sale of PHI whenever the Secretary deems an exception to be "similarly necessary and appropriate" as the exceptions Congress specifically delineated.[10] Thus, the exemptions Congress enacted were exemplary, not finite. Indeed, the Department has already recognized this fact by proposing additional exemptions.[11] We therefore urge HHS to consider a separate exception under § 164.508(a)(4) for disclosure of limited data sets subject to a valid data use agreement.

*2. Need for clarification of application in context of fees for research services*

A broader concern the IPPC has with proposed § 164.508(a)(4) is that absent further clarification from HHS, a covered entity may need to obtain authorizations in compliance with that section whenever it is paid by a third party to perform research services (excluding the service of preparation and transmittal of the data), and identifiable health information is generated and disclosed in the performance of those services. For example, as sponsors of clinical research, pharmaceutical companies pay clinical investigators to conduct clinical studies, and identifiable health information is reported by those investigators back to the study sponsors via case report forms. Remuneration paid in exchange for the performance of such services should not be deemed "indirect" remuneration in exchange for PHI, and such remuneration should not be included in the calculation of remuneration provided in exchange for PHI.

If HHS deems protected health information generated from the performance of research services to be subject to § 164.508(a)(4), the IPPC urges HHS to distinguish the remuneration paid for performance of the services from the remuneration paid for the protected health information. Traditionally it has not been necessary to stipulate in service agreements that monies are paid in exchange for the provision of *the research services* that generate new data versus paying for the cost of transmitting *that data*. To the extent §

[10] HITECH Act § 13405(d)(2)(G).

[11] The Proposed Rule would exempt any otherwise permitted use or disclosure where the only remuneration received by the covered entity is a reasonable cost-based fee to cover the cost to prepare and transmit the data. Proposed 45 CFR § 164.508(a)(4)(i)(H).

164.508(a)(4) would now require such remuneration to be specifically allocated in contracts to one or the other category, HHS should allow covered entities and those contracting with them broad discretion to determine the appropriate allocation, provided the result is reasonable in accordance with fair market values.

*3. Calculation of "cost to prepare and transmit the [PHI]"*

In order to avoid the risk of disincentivizing covered entities from sharing health information with third parties for scientific research purposes, a broad interpretation of "cost to prepare and transmit the [PHI]" is necessary and appropriate. Such costs should include:

- supplies used in the preparation and transmittal of the data, including hardware (e.g., computers, CDs, tapes) and software (e.g., encryption software);
- labor involved in searching for and retrieving PHI meeting the defined set of criteria as specified by the third party researcher;
- labor involved in the preparation of the data, including the removal of data elements not permitted in a limited data set (to the extent the disclosure is of a limited data set);
- labor, including attorney fees and other contractual costs, involved in the preparation and execution of any disclosure agreements (e.g., in the case of a limited data set, a data use agreement); and
- costs associated with assessing compliance with this section of the Privacy Rule, including attorney fees and costs associated with the maintenance of required records.

To the extent that HHS ultimately decides to support a narrower interpretation, the IPPC requests that HHS provide a clear explanation of the objectives it is trying to achieve and how a further narrowing would better achieve those objectives.

B. Proposed 45 CFR § 164.508(b)(3) – Compound authorizations

The Proposed Rule would relax current requirements concerning the combining of authorizations related to separate research activities. As proposed, an authorization for the use or disclosure of PHI could be combined with any other type of written permission for the same or another research study. However, where a covered health care provider has conditioned the provision of research-related treatment on the provision of one of the authorizations, a compound authorization would need to differentiate between the conditioned and unconditioned components and "provide the individual with the opportunity to opt in to the research activities described in the unconditioned authorization."

The IPPC generally supports this proposal as it would provide researchers with greater flexibility to determine the most efficient and effective way of communicating privacy choices to individual patients based on the proposed research activities. Clinical researchers face a difficult though tremendously important task in conveying to prospective subjects all information relevant to a decision as to whether to participate. Well-intentioned requirements as to how to structure authorization and informed consent documents in order to promote clarity can backfire, leading to greater patient confusion as to, for example, why multiple signatures are necessary. In some cases, this can lead to overall desensitization by patients of the importance of the consent process. In others, it can result in distortions as to the importance of certain

types of risks in relation to other types of risks. The IPPC believes that covered health care providers are in the best position to determine how to structure research permissions to promote patient comprehension.

The IPPC does not agree, however, with the proposed requirement that the unconditioned component of a compound authorization must be "opt in." Our understanding of this proposal is that in order for a compound authorization involving both a conditioned and unconditioned component to be valid, the unconditioned component must require some form of active choice in order to be triggered and evidenced, above and beyond the individual's execution of the compound authorization as a whole. To the extent this is not what HHS intended, we ask that HHS clarify this point in the final rule.

Our concern with the unconditioned component opt in requirement (which is effectively a double opt in requirement as the individual must execute the compound authorization (i.e., "opt in") as a whole) is that this introduces the risk of selection bias and may result in a lower research study participation rate overall. Researchers have documented the negative effects of framing choices as opt in versus opt out.[12] The requirement for an opt in within what is already an opt in simply exacerbates these risks. Researchers should therefore be given the flexibility to structure the unconditioned component of a compound authorization as either opt in or opt out as long as the choice of the patient to participate in the unconditioned component of the research is clear. More broadly, policy makers should recognize that despite the clear importance of the ethical principles of respect for persons and autonomy, which serve as the basis for informed consent and authorization requirements, these principles are not absolutes and must be balanced with other principles of biomedical ethics, such as beneficence. The bioethical principle of beneficence establishes a moral obligation to act for the benefit of others, so that when appropriately balanced with the risks to the individual, the highest net benefit is achieved for all members of society, such as advancements in biomedical knowledge that result in novel, improved and often lifesaving treatments.[13] Indeed, the principle of beneficence is a primary consideration in decisions about pediatric research, where the research participants are not able to provide informed consent. [14]

C. Proposed commentary concerning authorizations for future research

The IPPC supports the Department's proposal to permit authorizations for future research to the extent such purposes are adequately described in the authorization such that it would be reasonable for the individual to expect that his or her PHI could be used or disclosed for such future research. We appreciate the Department's desire to enable individuals to

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[12] *See, e.g.,* Belinda Stanley et al., "Uptake of HIV screening in genitourinary medicine after change to 'opt-out' consent," 326 Brit. Med. J. 1174 (May 29, 2003). *See also* Cornelia Junghans et al., "Recruiting patients to medical research: double blind randomized trial of 'opt-in' versus 'opt-out' strategies," 331 Brit. Med. J. 940 (Sept. 12, 2005); Michelle E. Kho et al., "Written informed consent and selection bias in observation studies using medical records: systematic review," 338 Brit. Med. J. 866 (March 12, 2009).

[13] *Supra*, note 7 at 166.

[14] Alan R. Fleischman and Lauren K. Collogan, *Research With Children, in* THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS ch.42 (E.J. Emanuel et al. eds., 2008).

exercise autonomy with respect to whether to allow personal data to be used for future research while also protecting such individuals from involvement in unanticipated research activities which they may find objectionable.

It is impossible to anticipate all the different sensitivities that individuals may have to different types of research. Nevertheless, we believe that it is possible to identify very broadly certain more common research sensitivities such that it would be prudent to inform individuals of the potential for these types of research activities to be conducted, as applicable. First, an authorization for future research could as a matter of best practice indicate whether the future research to be conducted may include biomedical research, social sciences research, or other types of research. Second, if research involving genetic analyses or mental health research is to be conducted pursuant to an authorization for future research, the potential for such types of research activities could be explained generally in the authorization. We believe it is important to clarify, however, that not all genetic research is linked to clinical information or will yield results that will put subjects at additional risk for stigmatization or discrimination beyond the risks associated other types of medical information or biomedical research results. We recommend that the known or probable risks to research subjects of a particular type of research be emphasized over the categorization or use of labels for particular types of analyses as such an approach can overemphasize the risk of such research to subjects and may impede important research in the future.

We caution against inclusion of any further required elements or statements as such requirements inevitably increase the length and complexity of the authorization. Moreover, we encourage the Department to frame these recommendations as best practices, as we have done above, rather than as requirements. If the Department wishes to impose any additional elements or statements as legal requirements, definitions of each relevant term (e.g., "genetic analysis" and "mental health research") will be necessary to facilitate compliance.

Finally, the Department has requested comment on how a revocation of an authorization for future research would operate with respect to future downstream research studies. The IPPC believes that any information that has already been used or disclosed prior to revocation in reliance on the authorization, including any information derived from the initial use or disclosure, should continue to be usable following revocation. However, no new uses, disclosures, or analyses could be made following revocation.

D. Proposed 45 CFR 164.502(f) – Period of protection for decedent information

HHS proposes to amend Section 164.502(f) to shorten the period during which a covered entity is required to comply with the requirements of the Privacy Rule with regard to the PHI of a deceased individual. HHS would shorten this to a period of 50 years following the date of the individual's death. The Department also proposes to modify the definition of ''protected health information'' at Section 160.103 to provide that the individually identifiable health information of a person who has been deceased for more than 50 years is no longer PHI under the Privacy Rule.

The IPPC generally supports this proposal as it will facilitate records research. However, we believe that this period could be shortened even further without impacting the privacy interests of living individuals directly connected to the deceased. The IPPC believes that this period of protection should be shortened to 25 years.

## II. Subsidized Patient Communication Programs

Pharmaceutical companies collaborate with health care providers and health plans to provide information to patients on treatment options and disease management. For example, pharmaceutical companies sponsor pharmacy programs designed to promote patient adherence to physician-prescribed treatments. Companies also have sponsored programs that communicate information about adjunctive, new or alternative treatments that might be appropriate for patients. These communications can serve a variety of useful purposes, including:

- to help patients recognize disease symptoms and understand treatment options, so that they can more effectively seek appropriate care and make better-informed health decisions;
- to encourage patients to communicate with health care providers about their conditions to determine what treatment options are available;
- to decrease patient inhibitions in addressing sensitive conditions; and
- to promote improved medication compliance by encouraging patients to take their medicine regularly and refill prescriptions as necessary.

### A. Proposed 45 CFR § 164.514(f)(2) – Uses and disclosures for remunerated treatment communications

The Proposed Rule would modify current requirements applicable to treatment communications made by a covered health care provider to a patient when the covered provider receives financial remuneration in exchange for making the communication. Specifically, the Proposed Rule would stipulate that such communications are not "marketing" and do not require prior patient authorization only if the following requirements are met: (i) the provider has included notice of the fact that it may send remunerated treatment communications and information as to how to opt out in its notice of privacy practices; and (ii) the communications disclose the fact that the covered provider is receiving financial remuneration in exchange for making the communication and provide the recipient with a clear and conspicuous opportunity to elect not to receive any further such communications. The method for a recipient to opt out of further such communications may not cause the individual undue burden or more than minimal cost.

The IPPC supports the Department's proposal to distinguish requirements applicable to treatment communications (as summarized above) from requirements applicable to health care operation communications (discussed below). The proposed requirements applicable to treatment communications appear similar to those the Department initially adopted in December 2000.[15] We note that the Department's thinking and approach to these types of

[15] See 65 Fed. Reg. at 82,546.

communications has evolved over the years[16], and we appreciate the policy challenge of trying to address patient privacy interests without unduly interfering in the patient-provider relationship. Nevertheless, we also note that notwithstanding policy makers different views on whether remunerated treatment communications are correctly classified as "treatment" or as "marketing," there has been remarkable consistency in views (despite widely divergent philosophical approaches of senior level policy makers) as to the importance of allowing such communications to be made without the additional burden on covered entities, and potential barrier to such communication programs, of having to obtain prior patient authorization.

*1. Distinction between treatment and health care operation communications*

It is the IPPC's understanding that the distinction in the proposed rule between what constitutes a treatment communication versus a health care operations communication rests on whether the communication has been targeted to individuals based on their health status or condition or instead has been made in a "population-based" fashion. A treatment communication would require the covered health care provider to make a determination that the product or service may be beneficial to the health of the type of class of individuals targeted to receive the communication. However, we note that the term "population-based" in the definition of health care operations can itself create some confusion. We, therefore, request HHS to clarify that a communication that is for the treatment of an individual is a "treatment" communication regardless of whether the covered entity uses population-based criteria to determine the recipients of the communication. For example, a communication sent to patients with diabetes uses population-based criteria (i.e., patients with diabetes), but the communication may nevertheless be made in furtherance of the treatment of individual recipients. Population-based criteria can be particularly relevant to treatment communications regarding important public health issues, such as vaccinations recommended by the Centers for Disease Control and Prevention of HHS. The IPPC believes that subsidized communications by health care providers regarding the availability of vaccines for eligible patients should be considered treatment communications. When communications that a covered health care provider has determined may be beneficial to the health of a defined population are sent to that population, such communications are appropriately categorized as "treatment."

[16] In commentary to the August 2002 Final Rule modifying the Privacy Rule, HHS stated "The Department does not agree that the simple receipt of remuneration should transform a treatment communication into a commercial promotion of a product or service. For example, health care providers should be able to, and can, send patients prescription refill reminders regardless of whether a third party pays or subsidizes the communication." 67 Fed. Reg. at 53,187. Later in the rulemaking HHS stated, "[T]he Department believes that the provision in the December 2000 Rule that transformed a treatment communication into a marketing communication if it was in writing and paid for by a third party blurred the line between treatment and marketing in ways that would have made the Privacy Rule difficult to implement. The Department believes that certain health care communications, such as refill reminders or informing patients about existing or new health care products or services, are appropriate, whether or not the covered entity receives remuneration from third parties to pay for them." Id. At 53,188.

*2. Opt out requirements*

The IPPC supports providing individuals with the ability to choose whether to opt out of all future subsidized treatment communications sent by a health care provider or just a subset of such communications concerning a particular company's products/services or just those products/services described in the communication. Because health care providers will differ in their ability to manage opt out requests, we suggest providing them with the flexibility to determine whether they wish to only provide the option of opting out of all future subsidized treatment communications sent by that provider or to provide a menu or list by which the patient can choose those specific types of communications that he or she no longer wishes to receive from that provider. A similar approach has worked successfully under the Federal Trade Commission (FTC) rules relating to commercial email messages under the CAN-SPAM Act.

Nevertheless, it may prove challenging for covered entities to provide an opt out opportunity to individuals prior to sending the first communication. This is because the communications as well as the opt out process may be frequently managed by a third-party vendor who has been engaged to operate a specific communication program. The vendor receives and processes opt out requests and maintains a list that can then be communicated back to the covered provider. Covered providers may not in the past have independently maintained opt out processes and thus would either need to internally build such capacity or alternatively hire a vendor to provide such services if they were required to provide an opt out opportunity to individuals prior to sending the first subsidized communication.

Finally, the IPPC asks HHS, in consultation with the Federal Trade Commission (FTC), to clarify the application of the CAN-SPAM Act to subsidized treatment communications sent electronically that encourage the purchase or use of a product or service. To the extent such communications are deemed to require the provision of an opt-out option under the CAN-SPAM Act, the IPPC requests that any opt out requirements be made consistent under the two laws.

B. Proposed definition of marketing at 45 CFR § 164.501

In accordance with Section 13406(a) of the HITECH Act, HHS proposes to define a communication about a product or service that encourages recipients of the communication to purchase or use the product or service as "marketing" if it is made for health care operation purposes and the covered entity receives financial remuneration in exchange for making the communication. HHS also proposes to exclude from the definition of marketing a communication made "to provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, only if any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication."

The statutory language concerning a communication describing a drug or biologic currently prescribed to the recipient of the communication is structured as an exception to the general rule requiring covered entities to obtain authorization prior to sending remunerated health care operation communications. The proposed regulation is structured differently – i.e., the exception related to a currently prescribed drug or biologic is structured as a stand-alone

exception to the general definition of marketing. This proposed structure has the potential to generate confusion. Therefore, the IPPC recommends that HHS conform its regulation to the structure of the statute, thereby adding the prescribed drug or biologic provision as an exception to current subparagraph (2)(iii) concerning health care operation communications instead of leaving it as a stand-alone exception.

*1. Restriction on level of remuneration under prescribed drug or biologic exception*

The IPPC has concerns regarding the Department's proposal to limit the remuneration that can be provided under the exception for prescribed drugs or biologics to costs that are "reasonably related" to the costs of making the communication. This proposal may lack the specificity needed to ensure consistent, predictable and appropriate application, and may introduce unwarranted complexity to an area that is already subject to existing federal regulation. The statutory exception for communications about prescribed drugs or biologics appears crafted to ensure that certain health care operation communications could continue to be sent without impediment, regardless of whether the covered entity was paid to make the communication so long as the payment is "reasonable in amount." [17] The reasonableness of these types of payments is currently addressed by existing federal regulatory standards, including the fair market value standard applied under federal anti-kickback law. To the extent that the proposed "reasonably related" standard may be interpreted to impose additional, undefined requirements for calculation of value in connection with subsidized health care operation communications, it has the potential for inconsistent application and to unduly burden beneficial communications.

The IPPC believes that the Department should define "reasonable in amount" in a manner no more complex or restrictive than existing federal law concerning valuation standards. Application of existing standards would effectively serve the purpose of assessing the propriety of a covered entity's motives when it sends or has sent subsidized health care operation communications.

Regardless of which standard HHS ultimately adopts for assessing what is "reasonable in amount," that standard should permit, at a minimum, remuneration for the following costs that are integral to the efficient functioning of such communications programs:

- supplies for the hard copies of the communications, including the cost of paper and the prorated cost of toner and wear and tear on the covered entity's printer;

[17] Indeed, the exception originated in an amendment proposed by Senator Tom Harkin (D-Iowa). The Harkin amendment, which was adopted and incorporated into the Senate version of the bill, was broader than the final exception to make it through the House and the Senate in that it would have allowed communications to be sent concerning any health care item or service previously prescribed to the recipient or a family member of the recipient regardless of whether or how much the covered entity was paid by a third party to make the communication. In conference, this exception was narrowed. Nevertheless, the agreement reached was that an exception should be made that allows covered entities to be paid reasonable fees to make a communication to their patients about a drug or biologic that the patient is currently prescribed. *See* Conference Report to Accompany H.R. 1 (111th Congress) at 497-498.

- supplies used in creating such communications, including the hardware (computers) and software that is used in generating such communications;
- labor involved in searching for and retrieving PHI meeting the defined set of criteria for the communications;
- labor involved in the preparation of the communications, including creative development, physical production, and associated mailing;
- postage associated with mailing the communications; and
- analytics associated with measuring the effectiveness of the communication program and designing improvements, including reporting de-identified metrics to the financial supporter of the communication program.

*2. Scope of exemption for a currently prescribed drug or biologic*

The Department has requested comment on the scope of the exemption for a currently prescribed drug or biologic, including, for example, whether the exemption should cover communications regarding new formulations of the drug.[18] The IPPC believes the exemption should include alternative formulations of the drug, alternative delivery mechanisms of the drug, combination drug products that include components currently prescribed to recipients, and adjunct therapies. The exemption reflects the legislative determination that certain communications are beneficial to health and should be permitted without authorization. A health plan should be able to send to its enrollees a subsidized communication encouraging compliance with a prescribed course of therapy without first having to seek authorization. Similarly, a health plan ought to be able to inform enrollees that an injectable medication has recently become available in inhalation form, for example.

The language of the exemption suggests that Congress was concerned that communications about alternative treatment options could create patient confusion. The IPPC believes that whenever a communication is sent to a patient concerning a new or different treatment option to the prescribed drug or biologic, the communication should clearly indicate that it relates to an alternative treatment option and that the patient should speak with his or her health care provider before making any changes to his or her prescribed treatment program.

*3. Meaning of "currently being prescribed"*

The IPPC believes that the period during which a drug or biologic is "currently being prescribed" should be no less than one year from the most recent request by the patient for a prescription for a non-controlled substance to be filled or refilled, or the time during which any direction to prescribe or administer a controlled or non-controlled substance as issued under applicable state law remains valid under that law, whichever is longer. In addition, the IPPC requests that HHS clarify that the phrase includes a reasonable period after the expiration of the prescription or in order for communications to be sent to remind patients to contact their prescriber to obtain a new prescription.

[18] 75 Fed. Reg. at 40,885.

**III. Adverse Event Reporting**

In the Proposed Rule, HHS solicits comments on what aspects of the minimum necessary standard it would be most helpful to have the Department address in its forthcoming guidance on this topic. The IPPC believes that it is important for such guidance to highlight to covered entities those data elements that are requested in the FDA MedWatch form and the fact that pharmaceutical companies require the most complete set possible of clinically-relevant data so as to be able to analyze causality and understand drug-adverse event relationships. The guidance should also highlight the fact that restricting reported data to a limited data set would (i) reduce FDA and the drug manufacturer's ability to identify duplicate reports, (ii) eliminate the ability of FDA and/or the manufacturer to contact the patient to further investigate the report, and (iii) reduce the ability to assess and describe potential drug-adverse event relationships in terms of unique populations that could benefit or be at higher risk from a given drug.

Thank you again for the consideration of our comments. Please do not hesitate to contact us with any questions or should you require further information.

Sincerely,

Peter Blenkinsop
Secretariat and Legal Counsel

DC01/ 2557162.5