August 1, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Georgina C. Verdugo
Director
Office for Civil Rights
U.S. Department of Health & Human Services
Attention: HIPAA Privacy Rule Accounting of Disclosures
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

RE: HIPAA Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health Act; RIN: 0991-AB62

Dear Secretary Sebelius and Director Verdugo:

The undersigned organizations are pleased to submit the following comments in response to the proposed Health Insurance Portability and Accountability Act (HIPAA) Rule on Accounting of Disclosures. The Department of Health and Human Services' Office for Civil Rights (OCR) is proposing to revise the Privacy Rule by dividing it into two separate rights for patients: a new right to an access report and a revised right to an accounting of disclosures report. The right to an access report would provide information on who has accessed electronic protected health information (PHI) in a patient's designated record set (including access for purposes of treatment, payment, and health care operations), while the right to an accounting of disclosures would provide information about the disclosure of a patient's designated record set of information (both hard-copy and electronic) for certain purposes other than for treatment, payment, and health care operations.

We urge OCR to withdraw the proposed access report requirement and make modifications to the proposed accounting of disclosures report requirement given that these proposed requirements would be costly and overly burdensome to implement, difficult to achieve by physician practices and their business associates, and very few patients have requested or expressed a need for these reports. The proposed access report requirement is also in direct conflict with the rule-making guidance specified in the "Health Information Technology for Economic and Clinical Health Act (HITECH) of the "American Recovery and Reinvestment Act of 2009" (ARRA-Pub. L. 111–5). HITECH specifically limited the reporting requirement to an accounting of disclosures and a requirement that the report only include information collected through an electronic health record (EHR) in a manner that takes into account the interests of the individuals in learning the circumstances under which their PHI is being disclosed and takes into account the administrative burden on physicians, other HIPAA covered entities, and their business associates. The proposed access report requirement would require the collection of information from multiple data sources (within the physician's practice and from external sources), not just information collected through the physician's EHR. This would create excessive financial and administrative burdens on physician practices. Yet, there is no demonstrated need for such a report. The access report requirement also runs counter to President

Obama's January 18, 2011, Executive Order aimed at reforming the regulatory process through simplifying standards and reducing unnecessary burdens on physician practices and other health care stakeholders, and could have the unintended effect of discouraging adoption of EHRs.

We urge the withdrawal of the proposed access report requirement and recommend that the following modifications be made to the proposed accounting of disclosures report:

- **Physicians and other HIPAA covered entities should only be required to produce accounting of disclosures reports based off of information maintained in an EHR that has the functionality to readily produce reports that are not burdensome to create and are meaningful to the patient. Physicians should not be required to produce information from other non-EHR systems that contain PHI, including but not limited to practice management and billing systems.**
- **Physicians should have the option to furnish an accounting of disclosures report on behalf of their business associates or the option to furnish an accounting of disclosures report limited to information from the physician's EHR and provide the patient with a list of the physician's business associates (with contact information for each business associate) so that the patient can directly contact the business associates for a report.**
- **The thirty-day time limit to provide an accounting of disclosures report to a patient, with an additional thirty days upon notice to the patient, should be expanded to sixty days, with an additional thirty days upon notice to the patient.**
- **Physicians should be allowed to provide their patients with a copy of the accounting of disclosures report in an electronic format determined by the practice or on paper.**
- **The compliance enforcement deadline for the new HIPAA accounting of disclosures requirement should be extended and be no sooner than 2016, to provide adequate time for the development of appropriate EHR software, the pursuit of educational outreach, and preparation by physicians and others to ensure compliance with the new HIPAA requirements.**
- **Physicians should only be required to produce information necessary to satisfy the new accounting of disclosures report that is dated on or after the compliance effective date.**

We also urge OCR to immediately convene relevant stakeholders, including physicians and other HIPAA covered entities, consumers, as well as EHR and practice management system vendors, to discuss efforts that must be pursued in order to ensure that systems have the necessary capabilities to produce reports that are not burdensome to create. OCR should conduct pilot testing to determine the ability of physician practices of all sizes and specialties to generate reports from varying levels and types of EHR technology. Moreover, if requests end up causing the production of voluminous reports, the requirements should be modified so as not to impose significant administrative and financial burdens on physicians, including compliance challenges. Physicians, other covered entities, business associates, and patients must be fully educated on the new HIPAA requirements and the technology that will enable the production of these reports well in advance of the compliance deadline. In addition, physicians and patients must be educated on the value of requesting reports that are limited in time and scope given that a report that covers three years worth of information from multiple data sources could be thousands of pages in length, end up requiring significant resources to produce, and be of minimal to no value to the patient.

Overview of the proposed right to an access report

Although HITECH limits reports to disclosures and only disclosures from EHRs, OCR is proposing requirements that go clearly beyond what is required under HITECH, including the creation of a new required report, an access report, that would include information on any time a patient record was accessed and would cover all systems that collect and store PHI, not just EHRs. Our specific comments below on the proposed access report requirement further justify our urging that OCR withdraw the proposed access report requirement.

We strongly oppose the proposed unreasonable expansion of the HITECH requirements to include systems other than EHRs that lack the capabilities to readily produce these proposed reports. In many practices, physicians use multiple systems, including practice management and billing systems, that are separated by function and, in some organizations, by physical location. Compiling records that utilize administrative patient data goes beyond the statutory requirements and would be extremely difficult and time consuming. Practice management and billing systems typically do not have the capabilities to produce the proposed reports. **The only systems that should be considered for reports are EHRs.**

OCR is proposing that the new access report requirements not be extended to cover paper records. The HIPAA Security Rule currently does not require the furnishing of a report based off of PHI contained in paper records. There are inherent difficulties in tracking uses and disclosures in paper records due to the massive manual work that it would entail. HITECH specifically limits the new report requirements to information collected through the EHR. **We agree that requiring a report to also cover paper records would be a significant administrative burden on and compliance challenge for physician practices. We also believe that extending the reporting requirements to cover paper records would be an unreasonable expansion of the requirement specified in HITECH that limits the report to information collected through an EHR.**

OCR is also proposing that physician practices be required to furnish access reports on behalf of their business associates that maintain a designated record set of patient information. HITECH specifically provides an option to physicians: they can produce a report on behalf of themselves and their business associates or they can give patients a list of the business associates and direct patients to request a report directly from the business associates. Physician practices, especially small ones, may not have the resources to contact every business associate, collect information from each and every business associate, prepare and produce a report in a timely manner. In addition, physicians should not be responsible for collecting health information that is transmitted to other health care providers or covered entities for the report. Patients should be responsible for reaching out to each and every health care provider and covered entity to request separate reports. Physicians have no control over another health care provider's/covered entity's handling of PHI. **Congress recognized the potential burdensome nature of requiring physicians and other HIPAA covered entities to collect information from all of their business associates and specifically authorized covered entities to have a choice. As specified in HITECH, physicians should be given the option to furnish reports on behalf of their business associates or a report limited to information from the physician's EHR and provide the patient with a list of the physician's business associates (with contact information for each business associate) so that the patient can directly contact the business associates for a report.**

Implementation specifications/content of the access report

OCR is proposing that the access report set forth: (a) the date of access; (b) the time of access; (c) the name of the natural person, if available, otherwise the name of the entity accessing the electronic designated record set of information; (d) a description of what information was accessed, if available; and (e) a description of the action by the user, if available (e.g., "create," "modify," "access," or "delete").

Date	Time	Name	Action
10/10/2011	02:30 p.m.	John, Andrew	Viewed

For circumstances when information from an EHR is exchanged with an organization outside of the physician's practice, OCR is proposing the production of the name of the organization receiving the information be captured in the report. In such cases, when the name of a natural person is unavailable, OCR is proposing to allow the listing of the name of an entity that is outside of the physician's practice or a business associate. In cases where an electronic designated record set system may exchange data with another electronic system within the organization, OCR is proposing to permit the access log to identify such access by the name of the physician in order to reflect that the patient's information was accessed by one of the physician's systems. Physicians and their office staff and business associates regularly and routinely use and disclose PHI for treatment, payment, and health care operations purposes. PHI access for the purposes of treatment, payment, and health care operations is so integral to the daily activities of physicians, their office staff and business associates that identifying and tracking each and every access becomes extremely difficult. Tracking all of these authorized uses and disclosures in a report is not only burdensome, but will also result in the generation of lengthy reports that will be confusing to and of no benefit to the patient. These lengthy reports would also not provide any information on whether or not a person has appropriately accessed the patient's health record. As required by HIPAA, physicians and other covered entities already have policies and procedures in place to handle inappropriate staff and business associate access to patients' health records. In addition, HIPAA permits patients to request restrictions on who has access to their PHI within the practice. **We do not believe there is a need for requiring a report that duplicates existing oversight and compliance protocols.**

We strongly recommend that the report not include names of individuals or the time of the access. We have serious safety concerns over the proposed requirement to identify the name of the individual who accessed the patient record and strongly believe that the name of the individual should not be included. Disclosing such information could be harmful to the patient and/or physician practice and therefore could have the unintended consequence of causing clinicians and their staff to avoid viewing records out of concern that their names may appear in a report (e.g., the record of a violent patient). **Physicians should have the right to comply with the report request by providing the patient with a report that includes the date of the creation of the patient's record in the physician's EHR system and a total count of actions taken on the patient's record such as the number of EHR record creation(s), modification(s), viewing(s), and printing(s) within a specified period of time.**

30-day production requirement for access report

OCR is proposing that a physician would have thirty days to provide the access report to a patient, including the logs of business associates that create, receive, maintain, or transmit an electronic designated record set of information. The physician may extend the time by thirty days when necessary, as long as the physician provides the patient with a written statement that includes the reason for the delay and the date by which the physician will provide the report. The physician would only be permitted one extension of time per request. The new HIPAA requirements are an example of another unfunded mandate that physicians will have to incorporate into their practices. These unfunded mandates are especially difficult for smaller practices that face the greatest financial, operational, and technological challenges. **The thirty-day production requirement is unreasonable and should be expanded to a minimum of sixty days with an additional thirty days permitted with written notice to the patient so that physicians have a reasonable amount of time to comply with new HIPAA report requirements.**

Form/Format requirement for access report

OCR is also proposing that the physician provide the access report in the machine readable or other electronic form and format (e.g., compatibility with a specific software application) requested by the patient, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the physician and the patient. If the patient does not agree to accept the readable electronic format that is readily producible by the physician, the physician is allowed to provide a readable hard copy. **It is important to provide as much flexibility as possible to allow physicians and their patients the opportunity to determine the form and format for the report. In addition, we strongly recommend that physicians be given the right to provide a hard copy paper form of the report.**

Fees for an access report

OCR is also proposing that the physician may not charge for providing the first access report to a patient in any twelve month period, but may charge a reasonable, cost-based amount for each additional access report that is requested within the twelve month period (which may include the reasonable costs of including access report information of business associates). The current HIPAA rule allows physicians to charge a reasonable fee for providing patients with access to their health information. The production of reports takes time and resources to produce. It is unreasonable to not allow physicians to charge for every report, including the initial report. Physicians should be able to charge a fee that covers the fair market value of labor, office supplies, retrieval, and copying costs associated with preparing, copying, and transmitting the report in an electronic or paper format. **We strongly recommend that physicians be allowed to charge patients for each report.**

Requiring a written request from a patient for an access report is permitted

OCR is also proposing that the physician be allowed to require patients to make requests for an access report in writing provided that the physician informs the patient of such a requirement. Physicians should be able to create forms for patients to request a report that provides information about the information the patient will receive and allows the patient to narrow the request based on the patient's interests. **It is in both the physician's and patient's best interests to permit requiring written requests, which would allow the opportunity to narrow reports in order to minimize the administrative and financial burdens on physician practices while ensuring that the report is helpful to the patient.**

Documentation retention limit on access reports

In addition, OCR is proposing that a physician or business associate would be required to retain the documentation needed to produce an access report for three years from the date of the use or disclosure. We agree that a time limit should be placed on retaining documentation needed to produce reports. We are concerned, however, about whether systems are able to keep three years worth of access data and the size of audit files and logs that would ultimately "power" reports will over time become very large and consume substantial storage. Moreover, the sheer volume of data will require additional storage over time, hardware upgrades, and will slow down data back up processes, which will be costly to and unworkable for physician practices. **It is also important to keep in mind that patients who request a report are interested in learning about more recent information. We strongly recommend limiting the request period to twelve months, which is more appropriate given the above-raised concerns. We also recommend that the documentation retention requirement be no more than twelve months.**

OCR is also proposing to require the physician to retain copies of access reports for a minimum of six years from the date that were provided to patients, and maintain a designation of the persons or offices responsible for receiving and processing requests for access reports for six years from the last date the designation was in effect. **A six year retention requirement is excessive.** It would also be very burdensome to keep track of all employees, departments, or offices involved in the production of a report. Employees depart or move into different positions, and departments may be restructured or eliminated so keeping track of all of these individuals, departments, and offices would require significant resources. This is yet another proposed requirement in which the administrative and financial burdens to the physician practice for complying with the retention requirements for a period of six years far outweigh the benefits to the patient. **We urge OCR to limit the retention requirement of this information to two years.**

Compliance deadline for access report requirements

OCR is proposing to require physicians and their business associates to produce an access report upon request beginning with requests made by patients on or after January 1, 2013, for any electronic designated record set systems that were acquired after January 1, 2009. In addition, OCR is proposing to require physicians and their business associates to produce an access report upon request beginning with requests made by patients on or after January 1, 2014, for electronic designated record set systems that were acquired on or before January 1, 2009. Today, physicians are being overwhelmed by regulatory requirements. Physicians are currently grappling with implementing the requirements for the HIPAA 5010 transactions, ICD-10, meaningful use criteria for the Medicare/Medicaid EHR incentive programs, e-prescribing, and the Physician Quality Reporting System (PQRS) program, among others. They will also be impacted by the implementation of the forthcoming health plan identifier (HPID), operating rules for each HIPAA transaction, electronic funds transfer (EFT) standard, and the claims attachment standard—all of which are required to be implemented in the next five years. Physicians who fail to meet these requirements face decreased reimbursement and/or fines. In addition, given that electronic designated records sets are contained in many systems that have been acquired over time, separate compliance effective dates for systems will be confusing and unmanageable. It will also take significant resources for physician practices to train their office staff and business associates and adjust workflows to ensure compliance with the new requirements. **Given that HITECH allows the Secretary of HHS to extend the deadline for compliance with the reporting requirements, we strongly urge OCR to extend the compliance enforcement deadline to 2016. The compliance deadline for the new HIPAA requirements needs to be extended so**

that: the appropriate EHR software is developed to facilitate the manageable production of reports that are meaningful to patients; pilot tests are pursued to ensure EHR and covered entity readiness to comply, and physician practices and other covered entities are well-educated and prepared to comply with the new HIPAA requirements.

EHR adoption itself is creating a tremendous challenge for vendors in terms of being able to provide the requisite functionality. Currently, EHR vendors are faced with ensuring that EHRs are compliant with Stages 1, 2, and 3 of the meaningful use Medicare/Medicaid EHR incentive programs along with multiple data interfaces requirements. Given that EHR technology as well as other electronic systems do not have the capabilities to facilitate the manageable production of the proposed reports, **we strongly oppose OCR's proposal to back-date the compliance date to cover requests for records that pre-date the compliance effective date of the new HIPAA requirements, and recommend that physicians only be required to produce information to satisfy the report request with EHR patient records that are created on or after the compliance effective date of the new HIPAA rule.**

Overview of the proposed revised right to an accounting of disclosures report

Under current HIPAA requirements, physicians, or their business associates, are already required to provide an individual an accounting of disclosures if requested, but the proposed rule would include a number of changes to this right. OCR has proposed that the accounting of disclosures requirement would continue to cover PHI maintained electronically and hard copy/paper PHI. In addition, OCR is proposing that the accounting of disclosures report would only cover disclosures made outside of the physician's practice and would not include disclosures for treatment, payment, or health care operations purposes. OCR also explicitly lists the types of disclosures that are subject to the accounting requirement: impermissible disclosures under the HIPAA Privacy Rule; public health activities (except those involving reports of child abuse or neglect); judicial and administrative proceedings; law enforcement activities; averting a serious threat to health or safety; military and veterans activities; the Department of State's medical suitability determinations; government programs providing public benefits; and workers' compensation. Providing a list of disclosures that are required for the report is helpful. **We strongly agree that the proposed accounting of disclosures report should not include PHI access, uses, and/or disclosures that occur within a physician's office that involve treatment, payment, or health care operations.**

In addition, OCR is proposing to exempt from the accounting of disclosures requirement impermissible disclosures in which the physician (directly or through a business associate) has provided a breach notice to the affected patient(s). It is not necessary to require the physician or his/her business associates to account for such disclosures since the physician has already made the patient aware of the impermissible disclosure through the notification letter required by the Breach Notification Rule. **We strongly agree with OCR's proposal and believe that requiring the physician to repeat production of a notice of an impermissible disclosure in the accounting of disclosures report is duplicative and unnecessary.**

In addition, OCR is proposing to exempt categories of disclosures that are currently subject to the accounting requirement. In particular, OCR is proposing to exclude disclosures about victims of abuse, neglect, or domestic violence; disclosures for health oversight activities; disclosures for research purposes, which includes research where an Institutional Review Board (IRB) or Privacy Board has waived the requirement for patient authorization because, among other reasons, it determined that the study poses no more than a minimal risk to the privacy of patients and the waiver is needed to conduct the research; disclosures about decedents to coroners and medical

examiners, funeral directors, and for cadaveric organ, eye, or tissue donation purposes; disclosures for protective services for the President and others; and most disclosures that are required by law (including disclosures to the Secretary of HHS to enforce the HIPAA administrative simplification rules). **We agree with OCR's proposal to exempt categories of disclosures in order to minimize the reporting burdens to physician practices as well as other covered entities and their business associates.**

OCR is also proposing that physicians be exempt from having to provide an accounting of disclosures for research, including through a protocol listing. The patient already receives notice through the notice of privacy practices that PHI may be used or disclosed for research, and that the physician would only be able to disclose the patient's PHI for research under limited circumstances (such as based on the patient's authorization or an IRB/Privacy Board finding that the research poses no more than a minimal risk to the patient's privacy). **We agree with OCR's proposal to exempt physicians from having to provide an accounting of disclosures for research, including through a protocol listing.**

OCR is also proposing to exempt disclosures for health oversight activities. Such disclosures primarily are population-based or event triggered and thus relate to the physician practice, rather than the patient. These disclosures are also often routine to a government agency, and required by law. **We strongly agree that disclosures of health oversight activities should be exempt from the reporting requirements.**

OCR is also proposing to exclude from an accounting of disclosures or an access report any information that meets the definition of patient safety work product. We strongly agree. **It is absolutely necessary that patent safety work product be excluded from an accounting/access report. The Patient Safety and Quality Improvement Act of 2005 clearly indicated that the confidentiality and legal protections of patient safety work product must remain intact in order to encourage the voluntary reporting of patient safety events.** Without legal and confidentiality protections, the ultimate goal of the Patient Safety and Quality Improvement Act—to advance culture, process, and system changes that ultimately enhance patient safety in the delivery of quality health care—would completely unravel.

OCR is also proposing to retain the requirement that physicians have the ability to delay the accounting of disclosures based on an ongoing law enforcement investigation. OCR is further proposing that the physician be required to include accounting information for all disclosures by the physician's business associates that create, receive, maintain, or transmit a designated record set of information. OCR is also proposing to limit the information held by business associates that is subject to the accounting to information within a designated record set. For example, if a business associate is a third party administrator and maintains a copy of a patient's billing information, the physician must coordinate with the business associate to provide an accounting of the disclosures of this information. Similarly, OCR is proposing that if a business associate maintains a copy of a patient's medical record, then the physician would be required to account for the business associate's disclosure of this information. However, a physician would not be required to account for a business associate's disclosure of information outside of a designated record set. We do not support OCR's proposal to require physician practices to furnish accounting of disclosures reports on behalf of their business associates that maintain a designated record set of patient information. Physician practices, especially small practices, may not have the resources to contact every business associate, collect information from each and every business associate, prepare and produce an accounting of disclosures report in a timely manner. In addition, physicians should not be responsible for collecting health information that is transmitted to other health care providers or covered entities for the accounting of disclosures

report. Patients should be responsible for reaching out to each and every health care provider and covered entity to request separate reports. Physicians have no control over another health care provider's/covered entity's handling of PHI. **Congress recognized the potential burdensome nature of requiring physicians and other covered entities to collect information from all of their business associates and specifically authorized physicians and other covered entities to have a choice. As specified in HITECH, physicians should be given the option to furnish an accounting of disclosures report on behalf of their business associates or an accounting of disclosures report limited to information from the physician's EHR and provide the patient with a list of the physician's business associates (with contact information for each business associate) so that the patient can directly contact the business associates for an accounting of disclosures report.**

Implementation specifications/content of the accounting of disclosures report

OCR is proposing that physicians be required to provide an approximate date or period of time for each disclosure, if the actual date is not known. At a minimum, the approximate date must include a month and year or a description of when the disclosure occurred from which a patient can readily determine the month and year of the disclosure. For example, the accounting may include the specific date of a disclosure (e.g., December 1, 2010), a month and year (e.g., December 2010), or an approximate time range (e.g., between December 1, 2010 and December 15, 2010). In addition, OCR is proposing that for multiple disclosures to the same person or entity for the same purpose listing the approximate period of time would be sufficient (e.g., for numerous disclosures, "December 2010 through August 2011," or "monthly between December 2010 and present"). Therefore, an exact start date and end date would not be required. OCR further clarifies that the date of disclosure may be descriptive, rather than a specific date. For example, the accounting may provide that a disclosure to a public health authority was "within 15 days of discharge" or "the fifth day of the month following discharge." **We support providing physicians with the flexibility to provide the date, period of time, or a description of the time period.**

As for identifying the name, OCR is proposing that the accounting include the name of the entity or natural person who received the PHI and, if known, their address. OCR is however, proposing an exception for when providing the name of the recipient would itself represent a disclosure of PHI about another patient. For example, if a physician's office mistakenly sends an appointment reminder to the wrong patient (and determines that the impermissible disclosure does not require breach notification because it does not compromise the privacy or security of the information), then the accounting may indicate that the disclosure was to "another patient." We agree that physicians should not disclose the name of the recipient if the recipient is another patient who mistakenly received information. **We do not support the production of the names of individuals. We have serious safety concerns over the requirement to identify the name of the individual who received the patient record and strongly believe that the name of individuals should not be included in the report. Disclosure of the name of the recipient of the disclosure could interfere with patient care or pose other potential harm(s) to the patient, the recipient, and/or the physician practice. We also urge OCR to allow physicians and other HIPAA covered entities the latitude to limit the production of disclosures, especially when the disclosures are inadvertent and do not rise to the level of a breach of PHI.**

As for the brief description of the PHI that was disclosed, OCR is proposing only that a minimum description is required if it reasonably informs the patient of the purpose. For example, "for public health" or "in response to law enforcement request" is sufficient for a description. No

detailed information on the reason for the disclosure should be required given that too much information could interfere with patient care, adversely affect the quality of care, or pose other potential harms. **We agree that only a minimal description be required.**

OCR is also proposing to require physicians to provide patients with the option to limit the accounting of disclosures report to a specific time period, type of disclosure, or recipient. **We agree with OCR's proposal to leave it up to the patient to determine the length of time.** Physicians using EHR technology should be able to provide patients the option of limiting the accounting to a particular time period or type of disclosure. We agree that such options are in the best interests of both the patient and the physician. Most often, patients are only interested in learning of disclosures that occurred over a limited period of time, such as a particular episode of care or within the past few months. In such cases, the patient is not well served by receiving an accounting that covers three years. Similarly, if a patient is only interested in learning of whether certain types of disclosures have been made (such as for treatment) or if a particular entity received the patient's information, then it is in both the patient's and physician's interests to limit the accounting to the relevant information. Physicians should be permitted to also offer other options to patients for how to limit an accounting request. OCR is proposing that a physician would be permitted to provide the patient with the option to limit the accounting of disclosures to disclosures by a specific organization, such as disclosures by the physician or disclosures by a particular business associate of the physician. **We support OCR's proposal to provide as much flexibility as possible to allow physicians to provide their patients with an option to limit the accounting of disclosures.**

OCR is also proposing not to require a full accounting of treatment, payment, and health care operations disclosures through an EHR when such disclosures are made through electronic health information exchanges (e.g., disclosures that originate from an EHR that are received by another electronic system). **We strongly agree that accounting of such disclosures at this time would be overly burdensome and unworkable given the lack of appropriate interfaces amongst health IT systems and significant burdens associated with the collection of these types of disclosures.**

30-day production requirement for accounting of disclosures report

OCR is proposing to reduce the timeframe for physicians to respond to an accounting request from sixty to thirty days. The physician may extend the time by thirty days when necessary, as long as the physician provides the patient with a written statement that includes the reason for the delay and the date by which the physician will provide the accounting of disclosures report. The physician would only be permitted one extension of time per request. The new HIPAA requirements are an example of another unfunded mandate that physicians will have to incorporate into their administrative processes. **The thirty-day production requirement is unreasonable and should be expanded to a minimum of sixty days with an additional thirty days permitted with written notice to the patient so that physicians have a reasonable amount of time to comply with new HIPAA requirements.**

Form/Format requirement for accounting of disclosures report

OCR is proposing that the physician be required to provide patients with the accounting in the form (e.g., paper or electronic) and format (e.g., compatibility with a specific software application) requested by the patient if readily producible in such form and format. If the requested form and format is not readily producible, then OCR is proposing to allow a physician to provide a hard copy of the accounting or the parties may try to determine if another form and

format is acceptable. **Generating an accounting of disclosures report is still a very manual, time-consuming process. We strongly recommend that physicians be given the right to provide a hard copy paper form of the accounting of disclosures report.**

OCR further proposes that if the patient asks for an electronic copy of the accounting but does not want the file to be encrypted or password protected, then the physician should provide the electronic copy without such protections. **OCR should make it clear that physicians will not be held responsible or liable for the information once the file that lacks encryption or password protection is in the patient's possession.**

Fees for an accounting of disclosures report

OCR is proposing that the physician is not allowed to charge for the first request for an accounting in a twelve month period, but may charge a reasonable and cost-based fee for providing an accounting in response to subsequent requests in the twelve month period (which may include the reasonable costs of including disclosures by business associates). The current HIPAA rule allows physicians to charge a reasonable fee for providing patients with access to their health information. The production of accounting of disclosures reports takes time and resources to produce. It is unreasonable to not allow physicians to charge for every accounting of disclosures report, including an initial report. Physicians should be able to charge a fee that covers the fair market value of labor, office supplies, retrieval, and copying costs associated with preparing, copying, and transmitting the accounting of disclosures report in an electronic or paper format. **We strongly recommend that physicians be allowed to charge patients for each accounting of disclosures report.**

Requiring a written request from a patient for an accounting of disclosures is permitted

OCR is proposing to allow physicians to require patients to make a request for an accounting in writing (which includes electronic requests) provided that the physician informs patients of such a requirement. Physicians should have the option to request a written request from their patients. Physicians should be able to create forms for patients to request an accounting of disclosures report that provides information about the information the patient will receive and allows the patient to narrow the request based on the patient's interests. **We agree that it is in both the physician's and patient's best interests to permit requiring written requests, which would allow the opportunity to narrow the accounting of disclosures report in order to minimize the administrative and financial burdens on physician practices while ensuring that the report is helpful to the patient.**

Documentation retention limit on accounting of disclosures reports

OCR is proposing that a physician or business associate would be required to retain the documentation necessary to generate an accounting of disclosures for three years (rather than for six years) and must retain a copy of any accounting that was provided to a patient for six years from the date the accounting was provided, and must retain documentation of the designation of who is responsible for handling accounting requests for six years from the last date the designation was in effect. We believe that requiring **the retaining of documentation for up to three years from the date of disclosure is both overly burdensome and unnecessary.** We are concerned about whether systems are able to keep three years worth of data and the size of audit files and logs that would ultimately "power" accounting of disclosures reports will over time become very large and consume substantial storage. Moreover, the sheer volume of data will require additional storage over time, hardware upgrades, and will slow down data back up

processes. **It would be a significant burden on physicians and their business associates to retain up to three years worth of documentation.** Practical experience from physicians and other health care providers suggests that there are extremely few requests for these types of disclosure reports and when there are requests, the patients overwhelmingly are seeking information on disclosures that occurred in the past year. **We recommend that the requirement for retaining documentation necessary to generate an accounting of disclosures report be reduced to twelve months.**

OCR is requiring the physician to retain for six years copies of accounting of disclosures reports that were provided to patients, and maintain a designation of the persons or offices responsible for receiving and processing requests for accounting of disclosures reports for six years from the last date the designation was in effect. **A six year retention requirement is excessive.** It would also be very burdensome to keep track of all employees, departments, or offices involved in the production of an accounting of disclosures report. Employees depart or move into different positions, and departments may be restructured or eliminated so keeping track of all of these individuals, departments, and offices would require significant resources. This is yet another proposed requirement in which the administrative and financial burdens to the physician practice for complying with the retention requirements for a period of six years far outweigh the benefits to the patient. **We urge OCR to limit the retention requirement of this information to two years.**

Compliance deadline for accounting of disclosures report requirements

The proposed rule indicates that physicians and their business associates would have to comply with the modifications to the accounting of disclosures requirement beginning 180 days after the effective date of the final regulation (240 days after the publication date).

We support the proposed compliance deadline for the proposed revisions that would result in exempting a number of disclosures from the current HIPAA requirements for the accounting of disclosures report. Given that HITECH allows the Secretary of HHS to extend the deadline for compliance with the new HIPAA requirements, we strongly urge OCR to extend the compliance enforcement deadline to 2016. Congress provided the Secretary of HHS with the authority to extend the compliance deadline to ensure that EHR technology would enable physicians and other covered entities to comply with the proposed new HIPAA requirements. The compliance deadline needs to be extended so that: the appropriate EHR software is developed to facilitate the manageable creation of helpful reports; pilot tests are pursued to ensure EHR and covered entity readiness to comply: and physician practices and other covered entities are well-educated and prepared to comply with the new HIPAA requirements.

Definition for a designated record set

OCR is proposing that the designated record set include medical and health care payment records maintained by or for a physician, and other records used by or for the physician to make decisions about patients. Most EHRs today do not have inherent intelligence to discern information needed for the proposed reports so users would need to "set up" a table or algorithm for this. A more clear definition is needed for a designated record set and should only cover EHRs, not non-EHR systems like practice management or billing systems. We strongly support OCR's decision that peer review files and transcripts of customer calls that are used only for purposes of customer service review rather than to make decisions about the patient are examples of information that is not within the scope of a designated record set and is therefore not discloseable. **We further**

urge OCR to limit the information that is required for the report to information available through an EHR.

Notice of privacy practices update required

Although the notice of privacy practices already requires a statement of the patient's right to receive an accounting of disclosures, OCR is proposing requiring physicians to amend the notice by including a statement on a patient's right to receive an access report. **We urge OCR to withdraw the proposed access report requirement and to develop and disseminate a revised model Notice that includes language covering all changes as a result of the final regulation.**

Compliance and EHR Vendor Support

The Office of the National Coordinator's (ONC) standard and certification criterion provide that certified EHR technology must have the capability to record the date, time, patient identification, user identification, and a description of the disclosure, for disclosures made for treatment, payment, and health care operations. ONC published a final rule on July 28, 2010, which retained this standard but made the certification criterion optional. Therefore, EHR technology is not required to have the capability to account for treatment, payment, and health care operations disclosures as a condition of certification for meaningful use Stage 1 under the Medicare and Medicaid EHR incentive payment programs. Without the functionality to enable physicians to readily produce reports from their EHRs to comply with the new HIPAA reporting requirements, the process for tracking reportable activity will be manual and extremely burdensome. In addition, a manual process will generate less information than an automated process. **We urge OCR to work with ONC, EHR and practice management system vendors, as well as other key stakeholders to ensure that EHRs and practice management systems have the technological capabilities to generate manageable reports required by HIPAA and are affordable and readily available in the market.**

Conclusion

The proposed access report requirements would be costly and overly burdensome to implement and difficult to achieve by physician practices and their business associates. HITECH only requires that information be collected through EHRs. Excessively expanding the HITECH requirements to apply to non-EHR systems that lack the capabilities to aid physicians with compliance may make compliance difficult if not impossible. This proposed rule includes unworkable requirements that contradict President Obama's commitment to improving the implementation of new rules and easing regulatory burdens on physician practices. Because there is no demonstrated need for the proposed access report and such a report would be extremely burdensome to create, **we urge OCR to withdraw the proposed access report requirement. We also urge OCR to make modifications to the proposed accounting of disclosures requirements that we recommend above to ease production burdens.** We further recommend that OCR immediately convene relevant stakeholders including physicians and other covered entities, consumers, as well as EHR and practice management system vendors to discuss

efforts that must be pursued in order to ensure that systems have the capabilities to produce a meaningful report that is easy and inexpensive to create and maintain. Should you have any questions, please contact Margaret Garikes, American Medical Association's Director of Federal Affairs, at (202) 789-7409 or margaret.garikes@ama-assn.org.

Sincerely,

American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Ophthalmology
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American College of Cardiology
American College of Emergency Physicians
American College of Osteopathic Surgeons
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Medical Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
American Urological Association
Congress of Neurological Surgeons
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
Society for Vascular Surgery