

WEDI Final Comments to Privacy Rule 3/27/2001

March 27, 2001

Department of Health & Human Services
Attn: Privacy-P
Room G-322A
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Privacy-P

Dear Secretary Thompson,

The following represent the comments of the Workgroup on Electronic Data Interchange (WEDI) on the final rule on the Standards for Privacy of Individually Identifiable health Information which is mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This final rule is referred to in the Federal Register as 45CFR Parts 160 through 164.

Following its publication in the Federal Register of December 28, 2000 the final rule was posted to the WEDI web site. Shortly thereafter, WEDI announced that a 2-day Privacy Policy Advisory Group (PAG) forum was to be held in Washington, DC on February 26 and 27, 2001. Members of Privacy PAG and other industry representatives reviewed and discussed the final rule and developed a series of recommendations to modify the final rule in order to enhance the ability of industry to implement its standards and implementation specifications. The forum was open to both WEDI members and non-members and was well attended by representatives from the payer, provider and vendor communities.

The recommendations and comments to the proposed rule received at the forum were presented to WEDI's Board of Directors. On March 27, 2001, the Board met to review those recommendations. The following comments are the product of the Board's deliberations and represent WEDI's official positions on these issues. However, there may be individual organizations represented by members of the WEDI board that will be submitting separate comments that may differ from the comments included herein. The discussion held during the forum made it clear that certain segments of the industry have unique, but nevertheless significant issues with specific provisions of the final rule. We believe that the comments set forth in this letter represent the views of a broad coalition in the health care industry. We encourage the Department of Health and Human Services (DHHS) to carefully consider these suggestions and recommended modifications the final rule on Privacy.

Executive Summary

In regards to the final Privacy rule, the following Executive Summary represents the majority position of the WEDI board of directors with respect to identified critical issues contained in the final Privacy rule.

1. WEDI first wants to re-state that all comments contained herein should be assessed by DHHS with the knowledge that the WEDI board unanimously, strongly supports the protection of individual health information and the rights of the individual to the

privacy of that information. Furthermore, individuals deserve protections of their right to privacy of their health information.

2. WEDI expresses thanks and praises the efforts of the DHHS staff working on the final Privacy rule. It is readily apparent that DHHS was responsive and gave a great deal of consideration to WEDI and other industry comments during the preparation of the final Privacy rule. This responsiveness and willingness to work with the industry is especially reflected by comparison of the February 11, 2000 WEDI comments to DHHS regarding the Privacy NPRM with the final Privacy rule. DHHS addressed and made revisions to the final Privacy rule that positively addressed almost all of those comments. WEDI thanks DHHS for its hard work and efforts made to address the concerns of industry. The volume and complexity of the final rule coupled with the comparatively small number of comments set forth in this letter reflect the high quality of work and responsiveness of DHHS.
3. WEDI supports DHHS publicly stated position of working with covered entities to enforce the Privacy rule through voluntary efforts, to work with covered entities and assist them in their compliance efforts, and to apply penalties and sanctions only as a last resort.
4. WEDI re-states its position communicated to DHHS on February 11, 2000 that WEDI agrees with the DHHS position that all entities that store or use protected health information should be subject to privacy rules and is concerned that DHHS does not have the authority to cover entities outside of providers, clearinghouses and payers. WEDI does agree that, in the absence of DHHS rules covering all entities, a Business Associate Contract that protects covered information consistent with this final Privacy Rule should be required for a covered entity to share protected health information. However, this should be presented as a concept and particular language should not be mandated by the regulations. The specific business partner contractual arrangements and the contract terms should be left up to the individual entities.

WEDI is concerned about the ability of covered entities to manage their contract negotiations within the two-year compliance period. There may be times that covered entities could have existing contracts that would be in effect for a period that exceeded the two year compliance date and would not have the opportunity to renegotiate the required Business Associate Contract terms prior to the compliance date. In those cases where existing contracts that a covered may have with their business associates may not terminate prior to six months before the two-year compliance date, WEDI recommends that DHHS extend the compliance period for covered entities to comply with the business associate contract provision of the Privacy rule to three years.

WEDI notes that we appreciate and support the removal of the third beneficiary provision in the final Privacy rule.

5. In regards to pre-emption of State law and regulation, WEDI still feels that this issue is extremely critical, a significant obstacle to compliance, and re-states the position it communicated to DHHS in August of 1999, which is included in the detailed comments following the executive summary. Accordingly, WEDI encourages the Secretary to support Congressional action that will provide for full pre-emption over state privacy laws that relate to protected health information in order to provide for consistency in application and enforcement. In addition, DHHS should take a leadership role to work with states on this issue to encourage cooperation and collaboration so as to avoid duplicative and unnecessary regulation and work towards uniformity of privacy standards. WEDI recommends that DHHS undertake and

maintain a survey of all state privacy laws related to health information and assess areas where such laws may conflict with the final privacy rule.

6. WEDI believes that the provisions related to patient's rights to access their records must be balanced with reasonable measures that will prevent the process for obtaining access from being unnecessarily burdensome or expensive. Covered entities should be allowed to charge and collect reasonable costs related to retrieval and preparation of reports specifically requested by and provided to an individual. In addition, in the absence of a good reason to receive information sooner, patient requests for such reports should be limited to one request every 90 days so as to encourage consolidation of requests for information and to discourage requests made to harass the covered entity rather than a sincere desire or need for information.
7. The prolonged process to document contested requests to amend the record is unduly complicated. WEDI recommends simplifying the four-step approach outlined in the final rule and the generation of additional documentation that does not appear to have any discernable benefit or purpose. WEDI believes that amendments and documentation of amendment requests should only be linked to the "outcome determinative" portions of the designated record set that will be used for purposes of medical treatment, payment, or determination of health benefits.
8. WEDI believes that the minimum necessary requirement should not apply to uses or disclosures for treatment, payment or health care operations. The final rule already provides sufficient protections to prohibit and otherwise track unauthorized uses and disclosures of protected health information by those who appropriately have access to such information for purposes of treatment, payment, or health care operations. These protections are typically enhanced by policies already adopted by many covered entities that require such information to be kept confidential. The imposition of additional efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use or disclosure creates additional steps to process information that unnecessarily restrict administrative operations. WEDI therefore recommends that minimum use limitations be excluded from uses and disclosures for purposes related to payment and health care operations as well as treatment.
9. WEDI is sensitive to the need to have appropriate limitations on oral communications. We recommend that covered entities create and maintain policies and procedures that support sensitivity to inappropriate oral communications regarding personal health information. These policies and procedures should be included in the privacy training and education programs.

However, for example, there are patient care areas that are intentionally designed to be open so that access to the patient, by provider or equipment, is not hindered and that there is free and open communication between providers. WEDI is concerned that there may be an unreasonable interpretation of the Privacy rule such that hospitals and other providers would have to turn their ward and semi-private accommodations into private accommodations to comply with Privacy rule's coverage of oral communication.

WEDI recommends that DHHS exempt oral communication of protected health information in patient care areas from protection under the Privacy rule. WEDI recommends that DHHS clarify that policy, procedure and education would suffice in non-private patient accommodations and there would be no requirement for providers to turn wards and semi-private patient rooms into private rooms.

Additionally, WEDI expresses concern regarding administrative areas, such as registration, billing and scheduling, in hospitals, clinics, and medical offices that are

designed to facilitate oral communications between patients and office administration staff. WEDI does not believe that providers should be required to undertake major modifications in their facilities to comply with the Privacy rule. WEDI therefore recommends that DHHS provide clarification in the final Privacy rule that it is not reasonable to expect that these administrative areas of a facility be redesigned and rebuilt, but rather that reasonable policies and procedures be instituted to protect health information orally communicated in those environments

10. WEDI restates its position in our February 11, 2000 letter to DHHS in which WEDI supported the Privacy NPRM not requiring individual consent or authorization for the purpose of treatment, payment or health care operations. WEDI believes that the rationale that DHHS used in the Privacy NPRM is valid today and recommends that DHHS modify the final Privacy rule to state that consent or authorization are not required for the purpose of treatment, payment and health care operations.

In the event DHHS does not amend the Privacy rule to state that consent or authorization is not required for the purpose of treatment, payment or health care operations, WEDI has identified a number of concerns in the consent provision of the final rule that require modifications. These concerns are further laid out in the Detailed Comment section below. Even if the recommendations detailed below are adopted by DHHS, WEDI is concerned that other issues may surface during the implementation that could introduce barriers to patient care.

Detailed Comments

For ease of reference, each comment referenced to the citation of the rule.

1. Definition of Protected Health Information (Oral Communication) - 164.501

WEDI is concerned that there are many cases in which the Privacy Rule requirements for protecting oral communication of protected health information may not be clear and could be burdensome, especially for providers. There are patient care areas that are intentionally designed to be open so as not to restrict provider or equipment access and to the patient and allow free-flowing communication during patient crisis situations. It is essential that these areas, including but not limited to examination rooms, emergency rooms, trauma units, recovery rooms, operating rooms, intensive care units, coronary care units and burn treatment units, be able to maintain their open design and not restrict provider access or communication. WEDI recommends that DHHS exempt oral communication of protected health information in patient care areas from protection under the Privacy rule.

WEDI is concerned about areas such as ward and semi-private rooms where provider-patient-family communications with a patient in bed "A" takes place within earshot of the patient in bed "B". While covered Entities should be sensitive to where and how oral communication takes place in a semi-private or ward environment and should have protective policies and procedures in place, it is not reasonable to expect perfect compliance in oral communication in these environments. WEDI is concerned that the rule could be interpreted to expect hospitals to essentially turn those areas into private accommodations. The cost of that type of facility modification would be extremely burdensome and WEDI does not believe it is in the individual's best interest for the industry to incur and pass on these costs. WEDI recommends that DHHS clarify that it is not reasonable to expect hospitals to turn semi-private or ward accommodations into private rooms and that reasonable policy and procedure to protect the privacy of orally communicated protected health information in these areas

oral would suffice.

Additionally, WEDI expresses concern regarding areas in hospitals, clinics, and medical offices that are designed to facilitate oral communications between patients and office administration staff. Some examples are registration, billing, and scheduling. Again, WEDI is concerned that the rule could be interpreted to expect facilities to undertake major modifications of those areas in order to comply with the Privacy rule. While WEDI recognizes that covered entities should be sensitive to where and how oral communication takes place, WEDI does not believe that providers should be required to undertake major modifications in their facilities to comply with the Privacy rule. WEDI therefore recommends that DHHS provide clarification in the final Privacy rule that it is not reasonable to expect that these administrative areas of a facility be redesigned and rebuilt, but rather that reasonable policies and procedures be instituted to protect health information orally communicated in those environments

2. Business Associate Contract – 164.504(e)

The Business Associate Contract provision in final Privacy rule makes some significant changes such as removal of the third party beneficiary provision in contracts and clarification that the covered entity is not responsible for proactive monitoring of their Business Associate. However, WEDI still has significant concerns on the burden to the industry that will result in having to comply with this provision. Each covered entity has dozens of existing vendor relationships that would be subject to the Business Associate Contract provision. Even though vendors and/or vendor types (e.g. practice management vendor) may have the same products or services provided to covered entities, each relationship is unique and varies from covered entity to covered entity and from vendor to vendor. Under the final Privacy rule each of these relationships will still require a separate Business Associate Contract. The outcome under the final Privacy rule is that the complexity and uniqueness of these relationships will result in the industry having to negotiate or renegotiate millions of these relationships to conform to the requirements of Business Associate Contract provision in the final Privacy rule. The redeployment of executive resources and associated legal costs will outstrip the industries ability to respond; at the risk of diverting already depleted funds and resources from other critical areas, such as patient care.

Therefore, while WEDI does agree that, in the absence of DHHS rules covering all entities, a Business Associate Contract that protects covered information consistent with this final Privacy rule should be required for a covered entity to share protected health information. However, WEDI recommends that the mandated terms of the Business Associate Contract should be removed from the final Privacy rule and the Business Associate Contract should be presented as a concept and particular language should not be mandated by the regulations. The specific business partner contractual arrangements and the contract terms should be left up to the individual entities.

WEDI is concerned about the ability of covered entities to manage their contract negotiations within the two-year compliance period. There may be times that covered entities could have existing contracts that would be in effect for a period that exceeded the two year compliance date. WEDI recommends that DHHS extend the compliance period for covered entities to comply with the business associate contract provision of the Privacy rule to three years for those existing contracts that a covered may have with their business associates that may not terminate within the two-year compliance time limit.

3. Consent – 164.506

Understanding that it is not DHHS's intention for the Privacy rule to provide any obstacles to patient care, WEDI has a few concerns regarding the consent provision in the final rule as it is currently constructed. First, as WEDI communicated to DHHS in its letter of February 11, 2000, WEDI would like to clarify that it supports the initial DHHS position in the Privacy NPRM that consent or authorization should not be required for using or disclosing protected health information for the purpose of treatment, payment and health care operations. WEDI believes that the current crafting of the Privacy rule's consent requirements may have issues that are yet to be discovered that could interfere with patient care. Therefore, WEDI recommends that DHHS modify the final Privacy rule to state that would be no consent or authorization requirements for use or disclosure of protected health information for the purpose of treatment, payment and health care operations.

In the event that DHHS retains the consent provision, WEDI has identified the following concerns.

- A. In the process of providing a continuum of care, there are circumstances that, prior to seeing an individual, there is a need for some covered provider entities that have direct treatment relationships, to receive and use protected health information. Although required to obtain consent because of their direct treatment relationship, prior to having an opportunity to obtain that consent, these providers have a need to receive the protected health information, use it internally for the purpose of treatment preparation and may need to share it for the purpose of payment and/or health care operations. The requirement of consent prior to use or disclosure presents a dilemma for those providers in these circumstances. Although the provision of single consent and notice for an Organized Health Care Arrangement covers some cases, that provision does not cover all the examples and is predicated on having such an established arrangement. WEDI recommends that, in the interest of patient care, that DHHS modify the final Privacy rule to accommodate these and similar circumstances. Following are two examples that WEDI has included for clarification. These are included for the purpose of concept and WEDI's concerns are not limited to these specific examples. They are:
 1. Pre-registration of individuals and initial appointment scheduling. These activities require receiving protected health information either directly from the patient over the phone in the case of an appointment, or from a provider scheduling an operating room or hospital admission. Protected health information needs to be used to prepare charts, inform staff of conditions, prepare and equip operating rooms, order lab tests, schedule personnel, etc. Also, protected health information would need to be shared for the purpose of payment for eligibility requests and pre-certification.
 2. Discharge planning. With this activity there is a need for a hospital to share protected health information with one or more entities that would not have an opportunity to obtain consent prior to having to prepare to receive and care for an individual. These include, but are not limited to, assisted living units, nursing homes, skilled nursing facilities, hospice care, home health care, long term acute care, etc. These facilities need to use protected health information in advance in order to prepare for receiving the individual, prepare for providing care and may have a need to share the information for eligibility and preauthorization.

- B. There is a concern in the industry that the Privacy rule is not clear on revocation of consent by the individual or the individual's estate may prevent a provider from billing for health services rendered prior to the revocation or prevent them from using the protected health information obtained prior to the revocation for quality assurance purposes such as peer review, morbidity and mortality, etc. With this in mind, WEDI recommends that DHHS modify the Privacy rule to clarify that the Privacy rule allows such uses of protected health information.
- C. The industry showed concern that the final Privacy rule was not clear that consents and authorizations obtained under state statutes would be recognized as valid after the compliance date of the until the provider had an opportunity to obtain an updated consent. WEDI therefore recommends that DHHS modify the final Privacy rule to clarify that the Privacy rule recognizes consents and authorizations obtained under state statutes as valid after the compliance date, until the provider has an opportunity to obtain an updated consent.
- D. In regards to telemedicine, WEDI is concerned that although it may be considered a direct treatment relationship that obtaining a written consent is not practical and should not be required for telemedicine encounters.
- E. WEDI is concerned that final Privacy rule may prevent an individual from having a family member or friend deliver for filling or pick up a prescription, DME or other similar provider if the pharmacy DME or other similar provider does not already have a consent on file. In the pharmacy example;
 - 1. As the rule is currently constructed, a pharmacy has a direct treatment relationship with an individual and must obtain consent prior to use or disclosure of protected health information for the purpose of treatment, payment or health care operations. There is also a provision that the provider can use their professional judgment to infer permission, based on circumstance, from an individual to share their protected health information with the individual's spouse, friends or family for the purpose of patient care. Therefore, if the pharmacy already has the consent on file, if someone other than the individual attempts to pick up the individual's prescription, the pharmacist could reasonably infer permission from the individual and give them the individual's prescription and instructions on usage of the drug.
 - 2. However, unless the pharmacy has a consent already on file, the ability to infer permission from the individual to share their protected health information with another person would not apply since the pharmacy would not have the consent which forms the foundation to give the pharmacist permission to share the protected health information for the purpose of treatment.
 - 3. Therefore, if the pharmacy does not already have a consent on file and someone other than the individual is attempting to pick up the prescription, there would be an unreasonable requirement that the individual, for whom it may be detrimental to their well being to do so, personally appear and sign a consent.
- F. WEDI recommends that DHHS modify the final rule such that even if the individual does not have a consent on file, to accommodate and allow persons other than the individual to act on the individual's behalf for purposes of delivering the prescription to be filled and for picking up prescriptions, DME or other similar circumstances.

- G. WEDI recommends that clinical labs also be considered indirect providers in all circumstances where the provider orders the tests and the results are reported directly to the provider. This includes circumstances where the individuals present themselves directly to the clinical lab for blood draw, obtaining specimens, etc.

4. Pre-emption – Subpart B, Sections 160.201 through 160.205

WEDI's continued position is that federal privacy legislation related to health information should be passed with the power and authority to preempt all state law. In other words, federal law should serve as both a floor and a ceiling with respect to privacy standards and enforcement. Competing and inconsistent regulatory schemes to protect privacy threaten to impede the enhanced commerce promoted through the use of electronic transactions as provided under the Administrative Simplification Provisions of HIPAA. For that purpose, WEDI included its recommendation presented to DHHS August 16, 1999 in regards to preemption of State laws. The exact text of that recommendation is as follows:

Preemption of State Law:

WEDI recognizes that DHHS is not empowered under HIPAA legislation to write regulations that pre-empt state law. However, WEDI determined that it was important to formally state and present WEDI's strong position that to be practically effective and not cost prohibitive, any privacy legislation and/or rules must preempt all existing and future state laws and regulations. It is WEDI's position that non-preemptive privacy regulations will result in the stifling of the use of electronic technology thereby increasing the administrative costs and reducing the quality of patient care. All of which is contrary to the intent and purpose of the Administrative Simplification portion of HIPAA.

There are two primary and compelling reasons for this position:

A) Jurisdiction Confusion:

The confusion generated by multiple state regulations would serve to limit the use of electronic interstate communication of protected health care information. Since there is no defined methodology to resolve the jurisdictional issues that individual state laws represent, health care entities would not know which laws may impact them and in order to reduce risk would reduce or eliminate their use of electronic interstate communication of protected health care data.

There has been a natural evolution of the interstate transmission of protected health care information that has resulted in a natural and beneficial integration and communication between health care entities. This communication is a necessary component of both improved patient care and administrative cost reduction. For the common good of the U.S. health care system, the growth of interstate communication of protected health care data should be fostered and preserved.

Health care data is currently communicated interstate for patient care/treatment (e.g. laboratory samples, reports and consultations), payment (e.g. insurance claims, remittance and eligibility requests) and health care operations (e.g. utilization review aggregating and analyzing data for the purpose of improving patient care). All sizes and manner of health care entities are currently involved in these transactions including

small and large clearinghouses, laboratories, single practitioners, multi-state clinics, employers, regional and national insurance carriers, etc.

One fairly common example of such a transaction would be a Florida resident, insured through their employer in Alabama by a carrier in Connecticut presenting to a California clinic for treatment. Prior to treating the patient, the clinic could electronically request eligibility information through a local California clearinghouse, which may route the request to another clearinghouse in New York who would route it again to yet another clearinghouse in Georgia who finally routes it to the carrier's eligibility contractor in Tennessee. The eligibility contractor's system then generates a response that reverses the path and is delivered back to the clinic, all within 30 seconds of the clinic generating the initial request. After treating the patient, the clinic would generate an electronic claim that is transmitted to a clearinghouse in Illinois that sends it to another clearinghouse in Ohio that routes it to the insurance carrier in Connecticut. After processing the claim, the insurance carrier could then deliver the EFT and electronic remittance advice to a clearinghouse in Indiana that routes it to the clinic's bank in Nebraska who, after balancing with the ERA deposits the EFT and forwards the ERA on to the clinic for posting.

In the above hypothetical example, which is not extreme, these transactions pass through eleven states and none of the trading partners involved in the transactions would be aware of all of the states through which these transactions passed. This does not take into account the complexities and variables of dial-up, frame relay and other wide area routing through public telephony and data carriers. Routing these transactions through the fabric of multiple telephony and data carriers that represent the wide area and PSTN (public switched telephone network) could easily add 10 more states to the path that the transaction could follow. There is no way for the health care entities to know which State laws are applicable to their transactions.

B) Cost of Compliance:

The cost of monitoring various state laws and establishing different administrative and technical procedures for each state that a health care entity sends or receives protected health care information would impose an extreme burden to all of the health care entities. Even small provider offices that use clearinghouses would be sending protected health information through multiple states and would have the same issues and costs of compliance as large clinics.

Assuming that there was a methodology to establish jurisdiction, without preemption there is nothing in place to prevent states from enacting conflicting laws. As a result, a health care entity implementing processes and technologies to comply with State A's law could create non-compliance with State B's law. Therefore, the architecture of health care entities systems and processes would have to be extremely complex and cumbersome to allow the kind of diversity that would enable a health care entity the ability to deploy multiple concurrent processes and systems on a state by state basis. The cost of re-engineering to enable this level of diversity would be prohibitive and if forced on the health care system would raise the cost of every entity in the chain of care and payment. This would obviously be contrary to the

*intent of the Administrative Simplification portion of the HIPAA
legislation.*

5. Patient Access – 164.524

- A. WEDI is concerned that the final rule does not sufficiently clarify the obligation of a Business Associate in its written contract with a Covered Entity to “make available protected health information in accordance with § 164.524.” Portions of the Preamble suggest that a Business Associate of a Covered Entity is not required to give the individual making a request direct access to protected health information. For example, at page 82554, the Preamble indicates that the access rules apply to the three classifications of covered entities “other than as a business associate of another covered entity.” Where a Business Associate is obligated under its contract to make protected health information maintained by the Business Associate available to Covered Entity for purposes of responding to such requests; there is no purpose to require the Business Associate to give the individual direct access to the same information. WEDI recommends that DHHS modify the final rule to clarify that Business Associate can fully satisfy its obligation under the provision of its contract described in § 164.504(e)(2)(E) where it makes available to the Covered Entity the requested portion of the designated record so that the Covered Entity may make such information available to the individual as provided under § 164.524.
- B. WEDI suggests that DHHS permit a Covered Entity to charge a fee for retrieval and processing of information in circumstances where a request requires the segregation/manipulation of data or preparation of a special report not otherwise available to or commonly utilized by the Covered Entity. Health plans, in particular, may have portions of the designated record stored in various electronic databases that may not be individually accessible or accessible in the aggregate so as to be responsive to an individual’s request. Even if the individual does specifically request an explanation or summary, preparation of such documentation may be the only reasonable means for a Covered Entity to respond. In these circumstances, the Covered Entity should be permitted to recover its reasonable costs for retrieval and processing where the individual consents in advance to pay such costs or to deny the request.
- C. WEDI is concerned that a few individuals may utilize their right to access their protected health information as a means to harass the covered entity by imposing unnecessary administrative burdens as a result of repetitive or duplicative requests. To prevent potential abuses, WEDI recommends that DHHS create a new basis for denial of access without a right of review where an individual has made a request to the same Covered Entity for access to their information within the past ninety (90) days in the absence of a good cause explanation by the individual as to why the second request should be processed sooner. Examples of good cause may include where the individual has reason to believe that additional information has been added since the date of their last request, where the reason or need to obtain the information arose subsequent to the date of their last request, or where the request is important for purposes related to their current care and treatment or the eligibility of benefits for their current care or treatment. We expect that most Covered Entities will respond in a timely manner to all reasonable requests, even when requests are made more frequently than once every 90 days. However, there is nothing in the existing final rule that limits an individual from making the same request each and every day or that encourages that individual to consolidate requests for separate portions of their record into one request. Requests that are intended to be abusive or punitive to the Covered Entity receiving them needlessly add to the administrative burden and costs for complying with this standard. As a result,

there may be delays in responding to requests by other individuals as well as the pass through of additional costs to administer the patient access implementation specifications.

6. Patient Amendment – 164.526

- A. WEDI believes that DHHS should simplify the extended process and additional documentation set out in § 164.526(d) related to situations where a Covered Entity denies an individual's request to amend his or her record. The primary purpose of allowing individuals the ability to amend their protected health information is to correct errors where there are inaccuracies or where the record is incomplete. We do not believe that the rule or this purpose is furthered by allowing an individual to prepare and file a Statement of Disagreement or by allowing the Covered Entity to prepare and file a Rebuttal Statement. WEDI therefore recommends that DHHS simplify the denial process by removing the reference to these two documents and thereby limit the record keeping requirements to the original request and denial.
- B. WEDI believes that the requirement set forth in § 164.526(c)(1) that requires the Covered Entity to append or provide a link to the location of any amendment is unnecessary and potentially confusing in situations where records are stored in multiple places and subject to permitted uses for health care operations rather than treatment or payment. For example, if a provider stores dictation tapes apart from the medical record utilized for treatment and /or billing purposes that includes a transcript of the same tape, then the amendment should only need to be referenced in the medical record and not in the location where the tapes are archived. Similarly, information obtained from the designated record, such as age, that is used for compiling aggregate data necessary for health care operations should not require amendment. WEDI therefore recommends that DHHS modify this section of the rule to only apply to outcome determinative portions of the designated record set will be utilized and relied upon for that individual's treatment, payment, or healthcare benefits.

7. Minimum Necessary – 164.502

WEDI believes that DHHS should reconsider the Department's conclusion in the preamble of the final rule that the minimum necessary standard should be applied to uses and disclosures for payment or health care operations. The steps for extracting necessary information (or redacting unnecessary information) may be significant and lead to additional costs and disruptions in the flow of information needed for payment and health care operations. Rather than place somewhat subjective limits on what information can be disclosed, privacy protections should focus on preventing uses and disclosures not otherwise permitted or authorized under the rule. Individuals understand that a number of persons who work for their health care provider or health plan will have access to protected health information. Limiting access of their information to the amount reasonably necessary does not further this expectation because these persons will nevertheless have access to at least some amount of protected information that an individual would not want further disclosed. For this reason, the minimum necessary requirements do not protect the privacy of such, but instead limit the damage or effect of an improper use or disclosure. WEDI believes that the privacy rule along with the policies and procedures adopted by covered entities should concentrate on prevention of unauthorized uses and disclosures rather than damage control through the segregation of the type of information used or disclosed for treatment, payment, and health care operations. WEDI therefore

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Assistant Secretary for Planning & Evaluation
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recommends that payment and health care operations be exempted from the minimum necessary requirement.

WEDI reiterates the recommendation made to Secretary Thompson in its letter dated February 28, 2001. The specific recommendation asks that the enforcement date for the final privacy regulation be set the same as the enforcement date for the yet-to-be published final security regulation.

We thank you for your careful consideration of these comments and invite you and members of your staff to contact us to discuss these comments in more detail.

Very truly yours,

Steven S. Lazarus, Ph.D.
FHIMSS
Chair, WEDI Board of Directors