

February 17, 2000

**BY HAND DELIVERY**

Secretary Donna Shalala  
U.S. Department of Health and Human Services  
Room 442E  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: Proposed Rule on *Standards for Privacy of Individually  
Identifiable Health Information* (RIN 0991-AB08)

Dear Secretary Shalala:

The American Health Care Association (AHCA) submits the following comments in response to the proposed rule regarding *Standards for Privacy of Individually Identifiable Health Information* issued by the U.S. Department of Health and Human Services (HHS) on November 3, 1999 (64 *Fed. Reg.* 59917).

AHCA is a federation of 50 affiliated long-term care provider associations representing more than 12, 000 nonprofit and for-profit nursing facilities, skilled nursing facilities, assisted living and residential care facilities, subacute providers and intermediate care facilities for the mentally retarded. The vast majority of AHCA's member providers participate in the Medicare and/or Medicaid programs, which require providers to electronically submit individual resident assessment instruments, including the minimum data set (MDS), to their respective responsible state agency. This information includes key characteristics about facility residents, which is used throughout the resident's stay at the facility and discharge planning to other health care providers. Thus, as a practical matter, under the proposed rule, virtually every piece of resident information will be "protected health information" (PHI) subject to the rule. Accordingly, AHCA and its members have a direct interest in HHS's efforts to develop and mandate privacy standards that are applicable to the electronic storage, transmission and subsequent use of health care information. The proposed regulations contain numerous requirements for the privacy of health information, many of which would mandate fundamental changes in the way long-term health care (LTC) organizations operate. We appreciate the opportunity to comment on the proposal *Standards for Privacy of Individually Identifiable Health Information*.

## **GENERAL COMMENTS:**

### **I. Scope of the Regulation**

AHCA believes that the Secretary's authorization to adopt confidentiality regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is limited. According to the statute, the Secretary is limited to promulgating regulations that apply only to the HIPAA transactions and the data elements for such transactions. The purported purpose of these standards is to facilitate the electronic exchange of health information. Despite this limitation, the proposed rule takes an overly broad interpretation of the statutory intent, and attempts to establish requirements for every single use and disclosure of PHI, requiring HHS to anticipate every use and disclosure and make a determination as to the appropriateness of such uses. Any HHS failure to anticipate certain information needs could have the unintended consequence of prohibiting providers from using information for necessary and legitimate functions or creating significant barriers to providers' current information uses. AHCA does not believe that the proposed rule, with its expanded coverage, could ever address all of the possible legitimate and necessary uses of information.

One of the intended purposes of the HIPAA Administrative Simplification provisions is to improve the "efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain information." In the proposed rule, however, the Secretary would create impossible barriers to the continuous and smooth flows of information that is already difficult enough to achieve. Furthermore, AHCA believes that HHS's proposal would impede the appropriate sharing of PHI between and among health care providers that could ultimately result in harm to LTC residents and add unnecessary and costly administrative burdens for providers.

AHCA strongly urges HHS to revise the proposed rule to apply privacy standards only to individually identifiable information used in connection with the transactions as outlined in the HIPAA statute. If HHS decides not to limit the applicability of these regulations, AHCA believes the Secretary must provide a legitimate rationale for the expansion, including how the costs of implementing the regulations, in terms of resident care and resources, are consistent with the HIPAA goal of reducing cost.

### **II. Preemption**

The proposed rule allows a state that already has contrary and more stringent privacy laws on the books to override the new federal regulations. Yet, at the same time, the proposed rule gives covered entities no assistance in determining how or if their state laws match up with the complex and lengthy federal requirements, and no process for seeking guidance if the state is confused about how to best comply with the federal standards. The proposed rule's only suggested process is that states ask for such guidance whenever a state law is

considered contrary to and more stringent than the federal requirements. Further, there is no process for individual covered entities to seek an opinion or the application of federal or state law.

AHCA agrees that national rules may be necessary to establish stronger and more uniform privacy protection across the country. However, the proposed rule's current preemption provisions would complicate providers' ability to develop clear and consistent privacy policies and procedures. If the proposed rules are finalized, providers not only will have to comply with multiple state requirements, but also must understand exactly how the complex and confusing federal rules overlay on state requirements. Consequently, providers will have to carry out a five-part inquiry to determine what rules apply. The provider will have to ask which state laws are: 1) carved out from the preemption; 2) privacy laws; 3) "related to" the individual provisions in the federal regulation; 4) contrary to the federal regulation; and 5) more stringent than the federal regulation. HHS should not expect any regulated party to undertake such a complex analysis in order to determine its basic compliance obligations.

AHCA recommends that HHS first perform a state-by-state analysis to enable the Secretary to provide specific guidance to individual states on what privacy laws apply. This analysis and guidance should be completed so that providers will have an opportunity to know the rules and to accurately assess what they need to do to come into compliance before they are required to comply. AHCA also recommends that HHS allow providers to seek advisory opinions in certain circumstances, or at least establish an informal process to answer questions. In addition, AHCA recommends that the Secretary work with the providers to create implementation guidelines.

### III. Cost

AHCA believes the Secretary's financial impact statement seriously underestimates the cost of the proposed rule's implementation. For example, several very significant sections of the regulation are not provided with a cost. While other sections are primarily identified as one-time costs. Yet, many of these new systems would require considerable financial resources to initiate, maintain and update on an on-going basis.

When estimating the cost of implementing the privacy standards, AHCA believes that the requirements whose costs must be considered include, but are not limited to: 1) sophisticated analysis of which state or federal laws apply and under what circumstances; 2) comprehensive assessment of all of a provider's departments to determine how privacy is protected and whether new policies and procedures or information system software would be the most efficient way to comply with the new requirements; 3) initial and on-going training for every employee and practitioner; 4) new disclosure policies; 5) new procedures allowing residents to request information from a variety of new sources beyond medical records; 6) new procedures for amending records; 7) development of

new notices of policies; 8) determination of what new authorizations may need to be required; 9) new contracts to be written with “business partners;” 10) recognition of the new liability contained in the “third party beneficiary” clause of the business partner provisions; 11) designation of a privacy official and a privacy review committee for research or development of policies on monitoring current research partners; 12) development of a system for ensuring that directory information reaches the directory adequately and timely; 13) provider assurance that employees discontinue the use of current authorization forms; 14) new employee and practitioner policies to ensure that information is not inappropriately leaked to law enforcement officials; 15) new policies to ensure that practitioners do not withhold information necessary to provide care through the right to request restrictions on uses and disclosures; 16) establishment of an internal complaint process; and 17) development of a system to account for disclosures of information. AHCA believes that the resources necessary to ensure compliance with the proposed rule are much more than the Secretary’s estimated five-year price tag of \$3.8 billion.

AHCA has obtained information from the Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University that indicate that HHS’s proposed rule cost estimates are entirely too low. For example, look at the analysis of the different cost estimates for one time or start-up costs as prepared by RSP and HHS: 1) analysis of the significance of the federal regulations on covered entity operations (RSP-\$686,000,000; HHS-Combines 1) and 2) at \$1,295,900,000); 2) development and documentation of policies and procedures (RSP-\$609,900,000; HHS-Combines 1) and 2) at \$1,295,900,000); 3) dissemination of such policies and procedures both inside and outside the organization (over five-year period)(RSP-\$139,000,000; HHS-\$231,000,000); 4) changing existing records management systems or developing new systems (RSP-\$792,000,000; HHS-\$90,000,000); 5) training personnel on new policies and systems changes (RSP-\$116,800,000; HHS-\$22,000,000); and 6) business partner contract review (RSP-\$459,800,000; HHS-No cost estimate). HHS estimates that the one-time costs of the proposed rule are roughly \$738,000,000. RSP’s estimates by comparison place this burden at \$2,732,400,000. HHS estimates a weighted average per provider cost of \$375. RSP’s estimates by contrast place the average burden at \$2,700.

AHCA also believes that HHS must consider the on-going costs of the proposed privacy rule. A partial list of the on-going costs of implementing the proposed rule includes, but is not limited to: 1) patient requests for access and copying of their own records; 2) patient requests to amend or correct records; 3) the need for covered entities to obtain patient authorization for uses of PHI that had not previously required an authorization; 4) dissemination and implementation both internally and externally of changes in privacy policies and system changes; 5) continual training and re-training of personnel on policies in light of the very high (85-100%) staff turnover rates in long-term care organizations ; and 6) periodic review and oversight of business partners.

AHCA recommends that HHS reconsider the financial implications of requiring providers to develop so many new systems. The proposed rule mandates complex and resource-intensive efforts on the part of all health care providers. Even entities with sophisticated security protocols would need to conduct audits and reviews to ensure compliance with the proposed HHS standards. AHCA urges HHS to recommend to Congress that it allocate an appropriate, specific amount of money, as determined by more realistic and relevant cost impact analysis, to ensure that affected providers have the capacity to comply with the new regulation.

**SPECIFIC COMMENTS:**

AHCA's specific comments are intended to address only the most significant elements of the proposed rule that would, if adopted, dramatically impact long-term care providers.

I. Disclosures for Judicial and Law Enforcement Purposes

AHCA does not believe that law enforcement officials should have the great latitude the proposed rule affords them in obtaining an individual's PHI. Furthermore, the proposed rule's blanket exception allowing law enforcement officials access to medical records may be at odds with other statutes specifically protecting information regarding patient alcohol and drug abuse treatment. The proposed rule places the provider as the information gatekeeper between competing governmental interests and with substantial penalty for exercising that function less than perfectly.

AHCA also believes that providers are often in the middle of conflicts between law enforcement, legal counsel, "next of kin," and residents about access to PHI. For example, the proposed rule makes it relatively impossible to avoid showing the local police specific information about an Alzheimer's resident when the family has reported that the resident may have been assaulted or hurt. HHS must acknowledge that providers already have well-established rules and procedures, in these types of situations, about when and how information is released.

**Recommendation:** Delete § 164.510(d)(3)(ii). This section makes it too easy for legal counsel to obtain PHI on any party to litigation by simply stating that the information requested concerns the litigant and that the litigant's health condition is at stake. It should not be this simple for any party to litigation to obtain information about the other party so easily. These sorts of evidentiary rules are ruled by state law and should not be preempted.

**Recommendation:** Delete § 164.510(l). This section is ambiguous. There is no clear definition of "next of kin" under most state laws, and the provision in the subparagraph at (i) is completely unworkable. Under most state laws, the permission to disclose must be in writing to protect both the resident and the facility. Otherwise, the facility is faced with different family members with

competing interests who will hold the facility accountable for not disclosing when the resident allegedly gave “verbal” permission to disclose.

## II. Business Partners

AHCA is concerned about the scope of the proposed rule and its applicability to business partners, such as attorneys, who may, in the course of representing facilities, be in receipt of PHI. In this regard, we are concerned that the provisions in the proposed rule requiring written agreements with business partners (to include attorneys and accountants, for example) and business partners being subject to third party liability would conflict with state procedures and rules of the state Supreme Courts governing the practice of law. Lawyers are under specific ethical requirements to keep confidential information disclosed to them. These laws and ethical rules should not be preempted by federal law. We note that the proposed exception for disclosures and uses for judicial and administrative proceedings (§ 164.510(d)) is not helpful since attorneys often become involved defending facilities during licensure, survey, employment, labor and other matters before final decisions are announced and before there is a proceeding or order of a court or administrative tribunal or where it is known that a particular individual is a party to the proceedings. It simply is unworkable to subject the facility to disclose to the resident its attorney-client communications or even the fact that it is consulting an attorney, especially in those situations where the identity of the resident involved in the matter may not be immediately known.

AHCA also is concerned about the scope of the proposed rule and its applicability to business partners, such as attending physicians and medical directors. AHCA believes that the proposed rule should clearly state that these physicians are not considered business partners. Long-term care providers cannot possibly monitor all practitioners who use the facility. They may not even have contracts with some of them.

**Recommendation:** Delete from the definition of business partners attorneys engaged by covered entities seeking legal advice. Alternatively, amend § 164.510(d) to permit a covered entity to disclose PHI to its attorneys in the course of seeking legal advice.

**Recommendation:** Clarify § 164.504 to clearly state that attending physicians and medical directors are not considered business partners.

## III. Treatment, Payment or Health Care Operations Exceptions

AHCA is concerned that the proposed rule fails to address many practical situations that arise daily in our member’s facilities. For example, the proposed rule is unclear about whether or not a transfer of PHI between two or more facilities in order to evaluate a possible admission (e.g., a transfer from a nursing facility (NF) to an assisted living facility (ALF)) is covered under any of the exceptions. While transfer of information between two or more facilities would

appear not to be covered under the health care operations exception, it is not entirely clear whether HHS would view such an exchange under the treatment exception or the business partner provision. In fact, HHS may have simply neglected to consider this type of exchange when it drafted the proposed rule, since it does not seem to fit neatly under any exception despite its obvious role in the provision of health care.

#### A. Treatment Exception

Under the proposed rule, treatment is defined as:

the provision of health care by, or the coordination of health care among, health care providers; the referral of a patient from one provider to another; or the coordination of health care or other services among health care providers and third parties authorized by the health plan or the individual.” (*Id.* p. 60053, emphasis added.)

Under this definition, an evaluation for admission is related to treatment and, therefore, could be considered exempt from the otherwise required individual authorization. Moreover, construing such an exchange of information between two health care providers as related to treatment directly fits within HHS’s purported purpose for the exclusion:

Our proposal is intended to make the exchange of protected health information relatively easy for health care purposes and more difficult for purposes other than health care . . . We therefore propose that covered entities be permitted to use and disclose protected health information without individual authorization for treatment and payment purposes, and for related purposes that we have defined as health care operations. For example, health care providers could . . . disclose information to other providers or persons as necessary for consultation about diagnosis or treatment, and disclose information as part of referrals to other providers. (*Id.* p. 59940, emphasis added.)

However, some uncertainty exists concerning whether a prospective patient—who may not yet have actually received services from the provider—would be regarded as a “patient” under the proposed rule and, therefore, whether the treatment exception would, in fact, apply. Therefore, AHCA seeks clarification from HHS that this exchange of information falls under the treatment exception and, therefore, exempts the provider from the individual authorization requirement.

#### B. Business Partner Exception

If HHS does not provide such clarification, a question remains whether such exchanges of information to evaluate a possible admission could be covered under the business partner provision. The proposed rule provides that:

Except for disclosures of protected health information by a covered entity that is a health care provider to another health care provider for consultation or referral purposes, a covered entity may not disclose PHI to a business partner without satisfactory assurance from the business partner that it will appropriately safeguard the information. (*Id.* p. 60054, emphasis added.)

The proposed rule is ambiguous as to whether the provider receiving the PHI for consultation or referral meets the definition of business partner since the definition includes only entities that carry out, assist with the performance of or perform on behalf of, a function or activity for the covered entity. It also is unclear whether this definition applies where the resident being referred has not yet been treated by either provider. In the preamble, HHS provides its rationale for allowing business partners to exchange PHI for referral purposes without receiving satisfactory assurances (i.e., without entering into a contract):

Unlike most business partner relationships, which involve the systematic sharing of PHI under a business relationship, consultation and referrals for treatment occur on a more informal basis among peers, and are specific to a particular individual. Such exchanges of information for treatment also appear to be less likely to raise concerns about further impermissible use or disclosure, because health care providers receiving such information are unlikely to have a commercial or other interest in using or disclosing the information. (*Id.* p. 59949.)

This rationale comports with the intended use and purpose of providers exchanging information—such exchanges occur regularly in the current environment (one without privacy regulations) between both types of providers in order to decide the best course of treatment for an individual. In addition, in our example, the ALF receiving such information is unlikely to have a commercial or other interest in using or disclosing the information regardless of whether it meets the definition of business partner. This type of exchange is simply to advance the course of treatment for an individual.

**Recommendation:** Given the inconsistencies and gaps in coverage for the exchange of PHI between health care providers for referral purposes, HHS should clarify this matter within the various sections that explain the treatment, payment or health care operation exceptions. AHCA suggests that either the treatment or business partner provision, should specifically exempt the transfer of information between two or more facilities in the long-term care continuum to evaluate a possible admission matter.



#### IV. Uses and Disclosures of PHI

The proposed rule outlines the contract requirements between the covered entity and the business partner and establishes the permitted and required uses and disclosures of PHI by the partner. Among the various requirements, the proposed rule states that the contract must:

State that the individuals whose protected health information is disclosed under the contract are intended third party beneficiaries of the contract. (*Id.* p. 60055.)

This provision creates a third-party-beneficiary contract, which means that the third party or the individual whose PHI is disclosed under the contract, has a right to file a suit for breach of contract by either of the original parties to the contract. This provision should not be expanded to include a private right of action by a third party beneficiary. Instead, HHS should limit inappropriate disclosures of PHI to those explicitly provided in the regulation.

**Recommendation:** Delete § 164.506(I)(ii)(A).

#### V. Minimum Necessary Use and Disclosures

The proposed rule also establishes a principle of the “minimum necessary” uses and disclosures to apply to uses within the covered entity, and to other entities. According to the proposed rule, only the minimum necessary information may be used or disclosed, measured by the purpose of the use or disclosure. Covered entities also would be required to designate personnel to perform and police this function, and adopt policies and procedures for implementation. HHS acknowledges that this requirement is probably the most burdensome of all of its proposals. According to the agency, each time PHI is disclosed to any individual, including internal disclosures for the resident’s treatment or for internal health care operations such as quality assurance or quality improvement activities, only the minimum necessary information may be disclosed, consistent with the purpose. AHCA believes that this requirement, as currently structured in the proposed rule, is unworkable and would impose significant and costly administrative burdens on long-term care providers.

We can see numerous areas where this limitation could pose significant obstacles to the care and treatment of our residents and for appropriate billing for their services. For example, for quality assurance and quality improvement activities, a nurse may decide certain information (e.g., family history) should not be disclosed to the reviewing committee because it may not be critical to the key issue that they are reviewing (e.g., resident falls). It may turn out, however, that the family history is extremely relevant to the resident’s condition, the propensity for attempting to ambulate unassisted and related falls. As a general matter, it

would be impossible for a facility to redact or modify patient records based upon the purpose of review by each care provider that accesses the record on a daily basis. In short, these limitations ultimately could be detrimental to residents because they undermine the interdisciplinary approach to resident care.

Another area where implementing this minimum necessary requirement would be extremely difficult is with respect to claims processing. Increasingly, fiscal intermediaries and Medicare carriers are requiring additional information to substantiate the medical necessity of services provided. If providers were to disclose only what they believe to be the “minimum necessary” information, the intermediary or carrier may regard this as insufficient, and reject the claim. Providers, or providers on behalf of beneficiaries, would then be required to pursue an extensive appeal provision to ensure that the payor has the appropriate information. It is possible that HHS intended that the provision allowing disclosure of PHI to health plans for “audit and related purposes” means that the “minimum necessary” requirement does not apply to support for payment claims, but this is not clear in the proposed regulation. If this is HHS’ intent, it needs to be clarified.

**Recommendation:** AHCA proposes that the “minimum necessary” requirement be deleted in its entirety and replaced with a principle for consideration in facility privacy policies. Alternatively, the minimum necessary requirement should only apply to disclosures (not uses) of PHI in limited circumstances, such as for purposes other than treatment and health care operations. In other words, the requirement would only apply to disclosures by covered entities to individuals outside of the organization and not to disclosures related to claims processing. This would mean, for example, that the minimum necessary requirement would apply to disclosures to business partners, but would not apply to internal uses of the information within the covered entity or to components of the same covered entity using the information for treatment or health care operations.

#### VI. Whistleblower Provisions

The proposed rule has two separate provisions that would establish new whistleblower requirements. The first section, § 164.518(c)(4) allows a “member of the workforce,” if they believe any law has been violated to give an oversight or law enforcement agency or legal counsel individually identifiable health information with absolutely no process parameters. While technically a protection from liability for covered entities, placed in a regulation on privacy it establishes a *de facto* standard on the circumstances under which disclosure of PHI is appropriate. As such it is very disturbing. While painstakingly creating numerous barriers to use of identifiable information for the purposes for which it was created—treatment—the provisions would allow patient identifiable information to be disclosed externally with absolutely no strings attached simply if an individual believes a law has been violated. This process directly contradicts not only the basic premise of the proposed rule, but also the standards

that outline procedures for law enforcement officials to obtain the individually identifiable information.

The second provision, § 164.522(d)(4), also is unnecessary. If an employee believes a law has been broken, there is nothing to stop him or her from going directly to a law enforcement official or legal counsel and describing the situation. The law enforcement or oversight official or legal counsel is then free to pursue the case through the other parameters established by these regulations. If this type of provision is left in the regulation, it should require nothing less of the employee than it would the covered entity (who also could be an individual) and require that they strip the information of all identifiers.

**Recommendation:** Delete § 164.518(c)(4). Employees already have adequate mechanisms for informing law enforcement, oversight and legal counsel of possible violations without patient identifiable information.

**Recommendation:** Section 164.522(d)(4) attempts to protect employees from recrimination if they assist law enforcement in an investigation into whether a covered entity violated the act, however, this provision in its current form makes it very difficult for covered entities to enforce their own internal privacy policies.

**CONCLUSION:**

The proposed rule in its current form offers limited tangible benefits in the area of medical privacy protection, and in fact erodes the few protections that do exist, while at the same time it significantly raise health care costs in the U.S. AHCA urges HHS to modify the proposed rules with an eye toward reducing their cost impact, and constraining law enforcement access to private health information without violating due process. AHCA also urges HHS to revise the proposed rule to apply privacy standards only to the transactions outlined in the HIPAA statute and to provide some type of guidance to individual states on the applicability of the new standards. In addition, AHCA asks HHS to consider formatting these rules so that there are general provisions which apply to all providers and separate provisions which apply to specific industry segments to allow for the differences within the covered entities.

Sincerely,

Charles H. Roadman II, M.D.  
President and CEO