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DATE: February 2, 2000

TO: Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Attention: Privacy-P
Room G-322A
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

FROM: Delta Dental Plan of New Jersey, Inc.
1639 Rt. 10
Parsippany, NJ 07054

RE: 45 CFR Parts 160 through 164
Standards for Privacy of Individually Identifiable Health Information
Proposed Rule
(Federal Register/Vol. 64, No. 212/Wednesday, November 3, 1999)

Delta Dental Plan of New Jersey Inc., as part of the Delta Dental Plans Association (DDPA), serves more than one million workers and their families in the states of New Jersey and Connecticut. We appreciate the opportunity to comment on the above captioned Notice of Proposed Rulemaking.

Attached is the response from DDPA to your offices. Delta Dental Plan of New Jersey strongly supports the comments and recommendations attached in the letter.

Sincerely,

Bruce D. Silverman
Senior Vice President

encl.

cc: Walt VanBrunt, Resident

Date: January 31, 2000

To: Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Attention: Privacy-P
Room G-322A
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

From: Delta Dental Plans Association
1515 West 22nd Street
Suite 1200
Oak Brook, IL. 60521

Subject: 45 CFR Parts 160 through 164
Standards for Privacy of Individually Identifiable Health Information
Proposed Rule
(Federal Register/Vol. 64, No. 212/Wednesday, November 3, 1999)

Delta Dental Plans collectively form the nation's largest and most experienced dental benefits organization, serving more than 30 million workers and their families through 50,000 employer and labor union groups enrolled in our system. Since its inception in 1954, Delta Dental has held the confidentiality of patient records to be a continuing priority in all of its programs.

Delta Dental Plans Association appreciates the opportunity to submit the following comments on the above captioned Notice of Proposed Rulemaking.

Applicability to dental plans

Delta Dental has undertaken a thorough review of the proposed rule, in large part because we recognize that the maintenance and exchange of patient records represents an integral component of the delivery of quality health care. Individuals who avail themselves of health plan services and share with health care providers detailed information about their personal health do so with the expectation that sensitive information will be protected not only during the course of their treatment, but also as that information is maintained or transmitted to others within the health care system.

Having stated that, we first wish to seek clarification of a very fundamental issue raised by the NPRM: Does the proposed rule apply to limited scope dental plans?

Tide I of the Health Insurance Portability and Accountability Act (HIPAA) specifically exempts "limited scope dental or vision benefits" from meeting its requirements when those benefits are offered separately. Along the same lines, page 59932 of the NPRM's commentary states that "Consistent with the other parts of HIPAA, the provisions of this rule generally would not apply to certain types of insurance entities, such as workers' compensation and automobile insurance carriers, other property and casualty insurers, and certain forms of limited benefits coverage, even when such arrangements provide coverage for health care services." The commentary appears to be based on the language contained in Title I, Sec. 1191 of HIPAA, which includes an exception for limited, excepted benefits "if the benefits are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of the plan."

While it is apparent that dental plans that are offered through federal benefit programs such as Medicaid, CHAMPUS and the Federal Employees' Health Benefits Program are subject to the requirements of the NPRM, this does not appear to be the case for commercial coverage.

Again, we seek clarification on this important point.

Need for privacy standards

Delta Dental acknowledges the importance of safeguarding the confidentiality of sensitive medical information. However, we believe that a reasonable balance must be struck, one that avoids imposing new and costly administrative requirements for the sake of unnecessary restrictions on the use and availability of patient records information. In that regard, for example, we wish to point out that unlike medical care, dental care claims and related information generally are not transmitted electronically. In fact, presently only about 17 percent of practicing dentists file claims electronically, mainly through clearinghouses. While Delta Dental will continue to encourage electronic transmission of dental claims, we wish to point out that many of the requirements proposed in this NPRM could have a chilling effect on any significant expansion in electronic claims submissions. Under the circumstances, we recommend that the Department undertake a cost-benefit analysis to determine whether ancillary services such as dental care should be exempted or phased in over time.

Summary purpose

The NPRM permits covered entities to use or disclose protected information without authorization so long as that use or disclosure is for purposes of treatment, payment or health care operations. We wholeheartedly concur with this approach.

We note that the NPRM calls for passage of additional legislation that would entitle individuals to a right of private action. We disagree. Section 1177 of HIPAA already establishes ample penalties for any person who knowingly obtains or discloses indi-

vidually identifiable health information. To add further penalties runs the risk of increasing costs to all health care consumers without adding any commensurate value.

Under the subheading "Individual Rights," the proposed rule states that the covered entity's uses and disclosures notice to individuals "could be stated in broad terms." In order to avert problems of interpretation, we suggest that the Department further clarify this statement.

Applicability

This section of the NPRM states that once protected information is transmitted or maintained electronically, the protections afforded by this regulation would apply to the information in any form, including information received orally. As a practical matter, it is difficult to envision a system capable of identifying and protecting information gathered during a customer service telephone call. An example would be where information from a telephone call documents responsibility for payment based upon a divorce decree. If subsequently asked to defend that payment on a claim, information would have to be communicated to the employer group.

Definitions

With respect to §164.506(d), the NPRM proposes an approach for de-identifying identifiable information. In essence, this approach presumes that, if specified identifying information is removed and if the holder has no reason to believe that the remaining information can be used by the reasonably anticipated recipients, then the covered entity is presumed to have created de-identified information. We strongly support this approach, as it mirrors a critical element of Delta Dental's efforts to combat fraud and abuse. This enables participating dentists to de-identify non-covered patient records, thereby allowing Delta to review and monitor those records for purposes of claims verification.

In general, we believe that the NPRM defines covered entities too narrowly. Employers, marketing firms and legal entities--each of which have access to individually identifiable information-should bear the same responsibilities to protect medical records privacy as do health plans, providers and clearinghouses. On a related note, the NPRM goes on to exempt clearinghouses from a number of the provisions in this rule that would apply to other covered entities. We believe that exempting clearinghouses from any provision undermines the spirit and intent of the proposed rule and jeopardizes its efficacy. It is quite common, for example, for clearinghouses to siphon off data on patients for purposes of identifying trends that might be used for other commercial purposes. Applying a less rigorous standard to clearinghouses-and then holding insurers responsible for a clearinghouse's actions as a business partner-not only weakens the effectiveness of the NPRM, but unfairly imposes the enforcement

burden on health plans which may not have the means to assure compliance, particularly if clearinghouses decline to accept such responsibility in the contracts.

The NPRM solicits comments on how the Department can best inform covered entities of information on methods they can use to determine whether information is de-identified. We suggest that (1) covered entities that wish to receive this information be encouraged to submit the name and e-mail address of their privacy officer, who would receive the information, and (2) that the Department publish this information on its web site.

The NPRM also solicits comments on whether the enforcement approach it is suggesting and its overall approach relating to the creation of de-identified information would provide sufficient guidance to covered entities. We believe that the approach used is highly subjective, and suggest as an alternative that agreement be reached on listed identifiers which, when removed, result in de-identified information.

Under the subheading "Payment" the Department invites comments on how disclosures to employers should be treated under this rule. (As noted earlier, we recommend that employers be included in the definition of covered entities.) Currently, employers receive claims experience reports on each enrollee and their dependents. This information is used to understand plan expenses or to implement improved benefit structures. Stripping certain information from these reports would serve to hinder the process of making appropriate health care determinations and have a detrimental effect on the group's ability to detect fraud.

Under the subheading "Protected health information" the NPRM extends this definition to include telephone voice response and facsimile transmissions. We wish to point out that while laudable, the added cost of this requirement is likely to be substantial. In Delta Dental's case, for example, an enrollee or provider seeking access to a voice response system simply enters an ID number, usually a social security number. Under the NPRM, insurers would have to issue PIN numbers or similar security ID.

The NPRM invites additional information on the extent to which plans disclose information to employers. Following is the information Delta Dental Plans typically disclose to employers:

Patient Social Security number
Patient name
Relationship to employee
Month and year of payment
Claim tracking number
Amount paid by health plan
Amount to be paid by patient

In addition, it is important to note that the appeal mechanism for claim denials in an ERISA self-funded plan may require the employer or union to be involved in reviewing the disputed claim. In those instances, the employer would likely want to review the records, e.g. interpretation or application of a contractual limitation. Therefore, the final rule should clearly permit the plan, acting as the administrator of the program, to share this information with an employer to resolve claim appeals.

Lastly, we propose that the final rule explicitly state that the following business functions are allowable under the definitions of treatment, payment and health care operations:

- customer service representatives responding verbally to requests for information regarding dental claims payment or dental treatment history from providers, employers and individuals (payment);

- distribution of enrollment information to brokers, groups or third-party administrators (health care operations);

- wellness promotion (treatment);

- paid claims activity information to employers and/or brokers and other health plans, as allowable under state law (health care operations); and

- provision of claim and treatment information, as necessary, to self-insured employers to assist with appeals of claim denials.

Individual authorization

With respect to "Requirements When the Covered Entity Initiates the Authorization," the NPRM proposes a model form for review and signature by individuals. Rather than provide a straightforward vehicle for authorizing disclosure, the proposed form superimposes a negative slant by including statements such as "The released material may no longer be protected by federal privacy regulations." and "You may refuse to sign this authorization." We recommend that the form be cleansed of any subjective "warnings" that might cause an individual to prejudge the use of the information.

Although the NPRM implies that individual authorization would not be required when group information regarding treatment is being provided to a carrier for purposes of rating or making eligibility or enrollment determinations, §164.508(a)(2)(ii)(D) appears to do just that. We seek clarification that this requirement does not apply when the' health plan is providing the individualized information of its participants so as to allow the insurer to properly process claims or to provide an accurate rate proposal to the plan sponsor.

This section would also appear to preclude health plans from sharing individually identifiable information to dentists who frequently request such information for predeterminations. For example, a dentist may now obtain information as to when a patient last received a cleaning. Easy access to that information enables the dentist to establish and schedule the most effective course of treatment for the patient. Similarly, if a dentist wanted to perform a crown procedure, we would not be permitted to tell the dentist whether the patient's plan imposed limits on the frequency of those procedures unless expressly authorized by the patient. If one assumes that a patient has entrusted his or her care to a particular dentist, we see no good reason why that dentist should be precluded from receiving information on prior treatment. At a minimum, the final rule should be more explicit in stating that the treatment process will not be adversely affected or otherwise limited.

Similarly, we would argue that the final NPRM allow a carrier to provide necessary information to the employer, so that the employer can perform audit compliance under its health care contracts.

In order to access payment and/or treatment history, Delta relies on social security numbers and birth dates, which appear to fall within the category of protected health information. And as noted above, Delta is frequently asked to relay payment and/or treatment history over the telephone to providers, covered individuals and/or processing centers. This raises a series of questions which we believe should be clarified in the final rule, including

- Would an insurer be permitted to confirm a social security number, birth date or any other identifiable information over the telephone?

- What steps must be taken to confirm that a caller is either a provider or subscriber, before relaying any information?

- Assuming that a participating provider's contract would satisfy privacy rules, what steps should be taken to ensure privacy when inquiries come from non-participating providers who treated patients?

- As with most insurers, Delta employees must sign a confidentiality statement promising not to release patient information to individuals other than providers, subscribers and/or patients. Would this satisfy the requirements of the NPRM? Should similar restrictions be extended to support and processing staff?

- Does the NPRM apply to requests for information sent to providers through the mail?

Business partners

The NPRM states that a covered entity may not disclose protected health information to a business partner without satisfactory assurance that the information will be appropriately safeguarded. The NPRM further provides that a "covered entity must take reasonable steps to ensure that each business partner complies with the requirements of this subpart with respect to any task or other activity it performs on behalf of the entity." Detailed requirements for implementing these business partner standards are specified by the NPRM.

A question arises as to the authority of the NPRM to regulate a covered entity's relationships with its business partners for a number of reasons. First, the enabling statute (HIPAA) clearly states that any standard adopted under its administrative simplification provisions applies to health plans, health care clearinghouses, and health care providers (i.e. covered entities). No mention is made by HIPAA or HIPAA's legislative history with respect to "business partners." Second, the commentary to the NPRM explicitly acknowledges the Department of Health and Human Services' (HHS) lack of statutory authority to directly apply the NPRM to any entity other than a covered entity. Thus, in apparent reliance upon its statutory authority over covered entities, HHS has opted to make covered entities the enforcer of the NPRM against covered entities' business partners, since I-II-IS cannot be. Such action by HHS appears to be an extension of HIPAA rather than an interpretation of any ambiguity in HIPAA. Only Congress has the authority to extend the law.

Third, the commentary to the NPRM states that the security standard provision of HIPAA is particularly relevant to the NPRM. According to that commentary as well as HIPAA itself, the security standard authority applies both to the transmission and maintenance of health information and requires covered entities to maintain reasonable and appropriate safeguards to, among other things, ensure the confidentiality of information; to protect against any reasonably anticipated unauthorized uses or disclosures of the information; and to ensure compliance with HIPAA's administrative simplification provisions by "the officers and employees" of covered entities. Certainly, had Congress intended to make covered entities responsible for their business partners' compliance with those provisions, it would have so stated just as it stated with respect to officers and employees of covered entities.

Even if one accepts that HI-IS has sufficient statutory authority to regulate a covered entity's relationship with its business partners through the business partner standards, a question arises as to whether those standards violate HIPAA's requirement that any standard adopted under HIPAA's administrative simplification provisions must be consistent with the objective of reducing the administrative cost of providing and paying for health care. Should covered entities be required to comply with the business partner standards, that compliance, at a minimum, would necessitate re-

contracting with its business partners so as to include the required contract provisions in their contracts with business partners. Obviously, such re-contracting--assuming business partners are willing to do so--would add to, rather than subtract from, the administrative cost of providing and paying for health care.

If business partners are to be covered in the final rule, we wish to raise some specific concerns. As we interpret $164.504 of the NPRM, for example, Delta Dental would fall under the category of "business partner" to self-funded plans that contract with Delta Dental. The self-funded plan must obtain a confidentiality agreement from Delta as well as assurances that there will be no use of the information after the contract term expires. Furthermore, the contract must require that the business partner return or destroy all individually identifiable information received from the covered entity, in this case the self-funded plan.

We would argue that payment and treatment data should not be returned for at least five years. Without it, a covered entity would find it difficult to determine the precise procedures performed on patients, and the dates on which those procedures were performed-information that is critical not only from a treatment standpoint but also from the standpoint of preventing fraud and abuse. So long as the individual's history is used and disclosed only for purposes of processing claims, there should be no requirement that the information be deleted. Failure to maintain this information runs the very real risk that claims will be incorrectly processed-either inadvertently or as a result of malfeasance. At a minimum, the final rule should permit those entities which have legal responsibility for processing claims to retain information that is germane to the fulfillment of those responsibilities under prior contracts, and to ensure accurate processing under future contracts. We recommend that health plans be permitted to retain health information for at least five years following termination of administrative contracts with self-funded employers: (1) to process run-off claims and (2) to develop any necessary defense in the event of suit with respect to the performance of contracted functions on behalf of self-funded employers.

Again, while it may be reasonable to expect that business partners take appropriate steps to protect patient record confidentiality, the requirements set forth in §164.506(e) run counter to the principles of administrative simplification by imposing undue and costly administrative burdens on covered entities. For example, each of the 105,000 participating dentists in Delta Dental's network of providers would arguably be considered a business partner. That means Delta Dental is responsible for ensuring that each of those dentists complies with the requirements of the NPRM—a significant administrative burden in and of itself. Moreover, the NPRM sets out mandatory provisions that must be incorporated in contract agreements with business partners. This would force plans to revise and/or renegotiate all existing provider contracts-a time-consuming, costly and very disruptive process. Delta Dental strongly urges that the final rule be amended to clarify that requirements with respect to business partners do not apply when the business partner is a covered entity.

The NPRM requires that the written contract between covered entities and business partners "state that individuals who are the subject of the protected health information disclosed are intended to be third-party beneficiaries of the contract." We submit that this requirement is overly burdensome, especially for multi-state entities, and should be stricken; it is also an alternate means of creating a private cause of action.

The NPRM solicits comments on whether a business partner's mishandling of information should w-t immediate termination in any circumstance. We agree with the NPRM's position that steps should first be taken to end the breach and mitigate its effects. Where repeated or gross violations lead to termination we caution only that it not result in disruption of services to plan enrollees.

Lastly, the NPRM states that a covered entity be held accountable for breaches by a business partner, and that the covered entity be considered in violation of the rule if it "knew or reasonably should have known" of a material breach of the contract. This language seems entirely too subjective to be enforceable.

Treatment, payment and health care operations

This section sets out rules for the disclosure of individually identifiable information without authorization of the identified individual. We strongly recommend that the final rule be amended to permit disclosure without authorization when the information in question relates to the administration of the health care coverage. As it now stands, the NPRM is unclear as to whether "payment" refers only to payment for the covered service or includes the patient's or the patient's employer's payment for the coverage. In this instance, we would argue that "administration" should include both premium and eligibility collection where more than one entity is often involved in the implementation and continuation of coverage with a health plan. The final rule should explicitly state that the reasonable determination should be made by the covered entity, and that disclosure be permitted when other components of a health plan must be consulted to determine contractual coverage.

The NPRM's preamble states that a covered entity is required to create barriers between components so that information is not used inappropriately. However, many components within a health plan may need to be consulted to determine contractual coverage for a requested service, and the final rule should more clearly permit such disclosure. Similarly, multiple divisions within one health plan may provide some or all of the components of the health care coverage offered by an employer. A health plan may enter into arrangements with affiliated companies or other business partners to provide some or all of the coverage. In those instances, individuals are likely to desire the convenience of dealing with only one of the entities. The final rule should permit such disclosure and sharing of information to administer such programs.

Banking and payment processes

The NPRM would not allow covered entities to include any diagnostic or treatment information in the data transmitted to a financial institution. It would seem likely that in the future, financial statements, including credit card statements, will serve as a notification of payment for health services. Under the circumstances, a statement listing the date of service, name of the provider, the charge and a procedure description would enhance the information and better inform the patient of the service charge. In the dental health field this information is "sensitive" in only the rarest of instances.

Notice of information practices

This section discusses how best to facilitate individual understanding of and involvement in the handling of protected health information. More specifically, this section solicits comments as to the how best to obtain acknowledgement from the individual that he or she understands and agrees to the information practices of covered entities. The NPRM suggests, for example, that if a signed acknowledgement were required, it could be incorporated into the enrollment form. Since individuals often do not return signed acknowledgments, this method seems impractical and unnecessarily burdensome.

Since most employers use generic enrollment forms, inclusion of every provider's and carrier's information practices would be extremely cumbersome, and run counter to the goal of administrative simplification. Instead, we would suggest that each carrier be required to provide a statement of its practices to the plan sponsor for distribution to enrollees. Alternatively, each carrier's Notice of Benefits (NOB) or Statement of Eligibility of Benefits (EOB) might include a telephone number to call, or perhaps a website address where enrollee's could obtain a copy of the carrier's practices.

The NPRM invites comments on whether health plans should be required to notify individuals of their privacy rights every three years. We suggest that notices be posted on a web site and that insurers be required to distribute notices to employers, who would then be responsible for distributing the information as they see fit.

Under the subheading "Procedures to effect right of access for inspection and copying," we note that, initially, there are likely to be numerous requests for access to records. We suggest that during the first year of implementation, plans or providers be allowed 60 days to respond to such requests, then 30 days thereafter. As for an extension procedure, we suggest that a process be put in place to handle extenuating circumstances and that plans or providers be required to submit a copy to the Department to ensure that this procedure is not being abused. With regard to copying fees, we suggest that the Department set a reasonable fee, updated annually to account for inflation.

Accounting of disclosures

This section of the NPRM lays out a complex set of procedures for the accounting of disclosures. As a practical matter, this could prove to be one of the most difficult and most expensive requirements in the proposed rule, owing to the fact that most claims and eligibility systems do not have the capability to track individual information of this type. New databases would have to be constructed in order to comply, raising the larger question as to whether this requirement is consistent with the overall administrative simplification goals of HIPAA.

With regard to the denial of a request to amend or correct protected health information, the NPRM requires that an individual's statement of disagreement must be maintained with the disputed information. This would be a manually-intensive procedure, requiring the merging of electronic data with paper. We suggest that health plans only be required to note in the record that a dispute exists, and the outcome of that dispute.

Policies and procedures

This section of the NPRM would require entities with annual receipts greater than five million to maintain a privacy board to review and approve the documentation of policies and procedures. This would seem to be an undue and costly requirement. We recommend that this responsibility reside with the privacy officer.

The NPRM invites comments on whether health plans should be required to acknowledge receipt of requests to inspect or copy patient records. This appears to be unnecessary given the relatively short (30-day) deadline for responding to such requests.

In general, we wish to underscore that this requirement will impose a heavy cost burden on covered entities. For the most part, systems do not currently exist to meet all of the NPRM's requirements, and new data bases will have to be constructed to accomplish all of the required tasks.

Relationship to state laws

The underlying statute sets out a general rule whereby state laws are preempted by the federal requirements, with certain exceptions. One exception provides that state law that is contrary to federal standards will not be preempted if the Secretary determines that the state law is necessary to prevent fraud and abuse or to ensure appropriate regulation of insurance or health plans. Another exception occurs when state law is more stringent than the federal standard.

A number of states are in the process of enacting privacy legislation. In the absence of congressional action, others are likely to follow suit. Not surprisingly, most if not all

state proposals will purport to "ensure appropriate regulation of insurance and health plans." Each of those states can also be expected to assert that its legislation is more stringent than the federal standard. In the absence of further guidance, arguably each health plan would be responsible for determining, on a state-by-state basis, whether it is subject to state law or the federal standard. This presents especially difficult obstacles where multi-state employer health plans are involved.

The NPRM would allow states to seek a determination as to whether HI-IS should grant a provision in state law an exception. We recommend that this process be taken a step further. The final rule should also contain a mechanism for covered entities to receive guidance as to whether or not the federal standard preempts a state law. Furthermore, the final rule should include a process for determining whether certain provisions within a state law are more stringent than the federal standard.

Finally, HHS should establish a mechanism for communicating its determinations in a timely fashion, and as broadly as possible.

On behalf of the Delta Dental Plans Association, I would like to express our appreciation for the opportunity to respond to this NPRM. I trust that our comments will be of assistance during the review and final refinement process.

Sincerely,

Kim Volk
President and Chief Executive Officer
Delta Dental Plans Association