



AMERICAN
PSYCHOLOGICAL
ASSOCIATION

Practice Directorate

January 20, 2000

Secretary Donna E. Shalala
U.S. Department of Health and Human Services
Assistant Secretary for Planning and Evaluation
Attention: Privacy-P, Room G-322A
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Proposed Rule on Standards for Privacy of Individually Identifiable Health Information, as published in 64 Federal Register 59917, November 3, 1999.

Dear Secretary Shalala:

We submit these comments on behalf of the American Psychological Association (APA), the professional organization representing more than 159,000 members and affiliates engaged in the practice, research, and teaching of psychology, regarding the proposed rule on standards for privacy of individually identifiable health information, as published in 64 Federal Register 59917 et seq., November 3, 1999. We recognize that promulgating rules regarding the privacy of individually identifiable patient information is a daunting task and commend Secretary Donna E. Shalala (the Secretary) for proposing a rule with several provisions that proactively protect the privacy of patient records. These include, for example, provisions which require patient authorization for disclosure of psychotherapy notes, ensure that more protective State records' privacy laws are not preempted, and permit patients who do not want any disclosure of their health records to pay privately for services. However, we are concerned that other key provisions of the proposed rule will only weaken the already inadequate patient records privacy protections afforded under current law and focus our comments on these provisions.

Ideally, the Secretary should propose a rule, just as Congress should pass a law, which protects the private relationship between the patient and his or her treating health care provider. A strong patient-provider relationship privacy rule would necessarily protect the privacy associated with the patient's record, **because** a patient's record could not be disclosed in a manner that violated the privacy of the underlying relationship. Such a rule would be very different from that proposed by the Secretary today, which seeks merely to address actual and potential disclosures of the patient record.

The **APA** recognizes that the Secretary is limited in her rule-making authority by the specific statutory requirements imposed by Congress through the Health Insurance

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Portability and Accountability Act (HIPAA). As HIPAA mandates, the Secretary must issue standards to facilitate the electronic exchange of information with respect to financial and administrative transactions carried out by health plans, health providers, and certain other entities. Given this limitation, however, we believe the proposed rule can be substantially improved. We offer the following comments with specific suggestions to improve the proposed rule, particularly as it relates to mental health records.

We note that the proposed rule mainly concerns the protection of patient records in the health care delivery system, as our comments reflect. However, the proposed rule also permits the disclosure of a patient's protected health information for specified public and public policy purposes, including research. Comments on the impact of the proposed rule on the conduct of research will be addressed at a future date in a separate letter by Richard McCarty, Ph.D., the Executive Director of APA's Science Directorate.

APA Comment Summary.

I. Disclosure of individually identifiable records for "treatment, payment, and health care operations" without patient authorization. Patients in our country are facing a privacy crisis regarding their health records. This crisis has been brought on by each patient's loss of control of his or her records, as parties beyond the patient and his or her treating health care professional demand records for a host of reasons not directly related to care.

We believe that allowing patient records to be shared with potentially innumerable other parties for "treatment, payment, and health care operations" without patient authorization, as the proposed rule permits, may exacerbate the crisis. Disclosure of patient records for these mainly health administration functions without meaningful patient authorization validates an unacceptable status quo, which recognizes that many parties beyond the patient and his or her treating health care professional may use and disclose these records for purposes not directly related to treatment. We offer suggestions to the proposed rule to provide patients with some control over their records when disclosed to third parties for "treatment, payment, and health care operations."

Mental health records are particularly sensitive to disclosures beyond the patient and his or her treating psychologist or other health care professional. Therefore, we view (A) the requirement that patients must specifically authorize disclosure of psychotherapy notes for "treatment, payment, and health care operations" purposes, and (B) the **non-**preemption of stronger State mental health privacy laws as central to securing for patients some meaningful privacy for their mental health records.

A. The psychotherapy notes exception from disclosure without authorization for "treatment, payment, and health care operations." We are particularly pleased that the Secretary shares with psychology the recognition of the importance of ensuring the privacy of the psychologist and patient treatment relationship by requiring that "psychotherapy notes" require specific patient authorization before they may be disclosed to third parties for "treatment, payment, and health care operations."

We appreciate the Secretary's reliance on the United States Supreme Court decision of *Jaffee v. Redmond*, 518 US. 1 (1996), to provide for the psychotherapy notes exception. While upholding the existence of the psychotherapist-patient Federal evidentiary privilege, the Supreme Court found in *Jaffee* that the relationship is "rooted in the imperative need for confidentiality and trust" and that the "mere possibility" of disclosure could impede the development of a confidential relationship necessary for successful treatment.

To reflect fully the spirit of the Supreme Court's decision, we suggest that the definition of "psychotherapy notes" be more comprehensively defined to protect the unauthorized disclosure of all particularly sensitive mental health information related to psychotherapeutic treatment, such as assessment results and clinical observations. In so doing, the "psychotherapy notes" exception will more adequately preserve the confidence and trust between the psychotherapist and patient and help eliminate the mere possibility of disclosures that would otherwise hamper treatment.

B. Non-preemption of stronger State patient records' privacy laws. We are also pleased that stronger State laws that protect the confidentiality of patient records are not preempted by this proposed rule. Many States have enacted laws that more stringently protect the privacy of mental health records than the standards provided by the proposed rule. We agree with the Secretary that the proposed rule should "act as a floor, but not a ceiling on privacy protections."¹ We are concerned, however, with the Secretary's interpretation of those States laws which are sufficiently "related to" the privacy of patient records to be saved from Federal preemption. We suggest that the proposed rule's "related to" requirement is unnecessarily restrictive and may be inappropriately interpreted to preempt many State laws that protect the privacy of mental health records.

II. Provisions which particularly impact the privacy of mental health records. The proposed rule is very broad and considers a gamut of issues related to the privacy of individually identifiable patient information. We have focused on three areas of particular pertinence for persons seeking and receiving psychologists' services:

A. Disclosure of individually identifiable patient information for "emergency circumstances." With regard to the provision that permits use and disclosure of patient records without authorization for "emergency circumstances," we believe that this provision is drafted too broadly, permitting any number of persons in health plans or providers to disclose patient information based on a reasonable belief of endangerment. The provisions should be redrafted to ensure that only a licensed mental health care professional exercising his or her reasonable professional judgment should make disclosure determinations in emergency circumstances.

B. Patient inspection of information that may cause psychological harm. The rule does not recognize, as some States have recognized, that patients can be psychologically harmed if permitted to see sensitive information in their mental health records. We urge that the inspection provisions be amended to permit licensed mental health care

¹ 64 Fed. Reg. 59917, 59994 (1999).

professionals to prevent such disclosure upon a determination that such disclosure could cause substantial psychological harm to the patient who is the subject of the record.

C. Law enforcement access to patient records. We raise a number of concerns regarding the unauthorized disclosure of patient records to law enforcement officials. As an overarching concern, assuming that appropriately limited disclosure to a law enforcement official has been made, the proposed rule does not provide for limitations for further use and re-disclosure of the records. We urge that limitations be incorporated into the rule.

We additionally focus on specific permitted disclosures to law enforcement entities. These are disclosures related to: (1) information about the victim of a crime, abuse or other harm, (2) information disclosure pursuant to a legal process, and (3) the investigation of health care fraud. We seek additional regulatory language regarding these provisions to narrow their scope or to clarify their meaning and application.

APA Comments and Suggested Improvements.

I. Allowing individually identifiable health records to be shared with potentially innumerable parties beyond the patient and his or her treating health care professional for “treatment, payment, and health care operations” without authorization exacerbates the current privacy crisis that patients face regarding their health records in our country.

Patients in our country are facing a privacy crisis regarding their health records. The Secretary’s reference to the California **HealthCare** Foundation’s “National Survey: Confidentiality of Medical Records” is appropriate and gives some indication of the concern that patients have in the loss of their health records privacy. As the Secretary states, this survey found that one-fifth of Americans believe that their personal health information has been used inappropriately. Worse, one-sixth indicate that they have taken some form of action to avoid the misuse of their information, including providing inaccurate information, frequently changing health care professionals, or avoiding care.² In fact, more than half of those surveyed are very concerned that even with the use of unique health identifiers, people with mental illnesses, AIDS, or drug or alcohol problems will avoid seeking care for fear of exposure?

Mental health and certain other records are particularly vulnerable to disclosure because they typically contain information that could lead to a patient’s embarrassment or stigmatization. For these patients, the potential loss of records’ privacy can be devastating. To avoid the potential loss of privacy, patients receiving mental health services may make decisions that sacrifice their care and that could jeopardize their health. We agree with the Secretary when she states in her regulatory impact analysis that:

² *Id.* at 59920.

³ California HealthCare Foundation, *National Survey: Confidentiality of Medical Records*, p. 21 (January 1999).

Where patients are concerned about a lack of privacy protections, they might fail to get medical treatment that they would otherwise seek. This failure to get treatment may be especially likely for certain conditions, including mental health, substance abuse, and conditions such as HIV. Similarly, patients who are concerned about lack of privacy protections may report inaccurately to their providers when they do seek treatment. For instance, they might decide not to mention that they are taking prescription drugs that indicate that they have an embarrassing condition. These inaccurate reports may lead to mis-diagnosis and less-than optimal treatment, including inappropriate medications. In short, the lack of privacy safeguards can lead to efficiency losses in the form of foregone or inappropriate treatment.⁴

Our health care system can not deliver appropriate, high quality care to patients with mental health or other sensitive services needs, if the patients have a real or perceived loss in the privacy of their records. Patients must have a clear indication of who will see their records when these records leave the hands of their direct treating provider. Because our delivery system has shifted from a fee-for-service to a managed care system, patients really can not determine who and how many other persons are viewing their records.

The health care delivery shift to a managed care system, where potentially thousands of individuals have access to a patient's record, combined with the increasing use of electronic records within managed care delivery systems have, in large part, caused the current patient records' privacy crisis. As the Secretary mentions, "[t]he number of entities who are maintaining and transmitting individually identifiable health information has increased significantly over the last 10 years."⁵

The problem of managed care access to records is actually twofold. First, once created solely for clinical and treatment purposes, patient records are now also being used for administrative purposes, such as for coverage determinations and payment. Second, the line between clinical use of records and administrative use of records has become blurred. Patients, health care professionals and payers in the health care system no longer can easily distinguish the purposes for which records are being used. Hence, Congress has been grappling for nearly the last decade to address legislatively patient and provider calls to protect the privacy of patient records, and the Secretary today proposes rules for the electronic exchange of records among various entities with an attempt to distinguish records use for "treatment, payment, and health care operations."

For a number of years, the **APA** has pointed out to Congress and the Secretary that access by managed health plan and other third parties to patient records has been causing a patient privacy crisis and that the line between use for treatment purposes and use for

⁴ 64 Fed. Reg. at 60009-60010.

⁵ *Id.* at 59920.

administrative purposes has become blurred.⁶ In **APA** testimony submitted to the Senate Committee on Labor and Human Resources in November 1995, the **APA** wrote:

Rapid changes in the health care delivery system have meant that parties other than health care providers have access to patient records for a host of reasons, including those related to payment for and financial review of services. Technological advances in record-keeping now permit computerized and electronically transferable patient records. While federal and state statutes and case law have generally established the duty of health care providers to protect the confidentiality of patient records, the duty of many third parties must still be legally defined.’

In February 1997, when the **APA** submitted comments to the National Committee on Vital and Health Statistics (NCVHS), the committee with which the Secretary consulted before submitting her comments to Congress regarding the privacy of individually identifiable patient information, we reiterated this underlying problem.* In addition, several commentators on the confidentiality status of patient records have recently discussed the loss of privacy connected with third-party use of patient records brought on by managed health plan access to patient records.’

The Secretary’s suggestion that a lack of national standards has “. . . made the health care industry and the population in general uncomfortable about this primarily financially driven expansion in the use of electronic data. . .” is an understatement. Patients are “uncomfortable” because in this financially driven managed care system they simply do not know who is seeing their records, and they are justifiably concerned with their loss of privacy. The health care industry is “uncomfortable,” because managed health plans have no uniform law that applies across all States, which justifies **and** legalizes their **current use of patient records**.

Unfortunately, in certain provisions of the proposed rule, the Secretary addresses the health care industry’s discomfort with regard to their current use of patient records at patient expense. In this respect, the proposed rule may be viewed as a promulgation by the Secretary of a Federal law that validates the managed health care industry’s current

⁶ We use the term “managed health plan” throughout this comment to indicate managed care organizations’ access to and use of patient records. While we recognize that the proposed rule covers disclosure of records to other entities, such as fee-for-service health plans, health care clearinghouses, and health care providers, we use the term “managed health plans” to stress that these are the entities which primarily use patient records for payment, “health care operations,” and other administrative purposes.

⁷ *Hearing on S. 1360, The Medical Records Confidentiality Act of 1995: Before the Senate Comm. On Labor and Human Resources, 104th Cong., 1st Sess. (1995)* (statement for the record of the American Psychological Association).

⁸ Letter from Marilyn S. Richmond, Assistant Executive Director, Government Relations, Practice Directorate, American Psychological Association, to the National Committee on Vital and Health Statistics (NCVHS), c/o U.S. Department of Health and Human Services (Feb. 14, 1997).

⁹ See, e.g., Health Privacy Project, *Best Principles for Health Privacy: A Report of the Health Privacy Working Group*, Institute for Health Care Research and Policy, Georgetown University (July 1999); Lise Rybowski, *Protecting the Confidentiality of Health Information*, National Health Policy Forum, George Washington University (July 1998).

use and disclosure of patient records, particularly with regard to their use for “treatment, payment, and health care operations.”

In essence, the proposed rule preserves an unacceptable status quo where the managed health care industry uses patient records for a number of purposes not directly related to patient care. In fact, the proposed rule exacerbates the current problem of too much managed health plan access to patient information, because patient consent, through authorization, to such access is not even required for use by managed health plans for purposes of “treatment, payment, and health care operations.”

The Secretary justifies this fundamental shift away from patient authorization by commenting that the current practice of blanket authorization for records’ release provides individuals “with little actual control over their health information,” since such authorization is “often not voluntary because the individual must sign the form as a condition of treatment or payment for treatment.”¹⁰ The Secretary may be correct concerning the current ineffectuality of blanket authorizations. Blanket authorizations, however, are not meaningless. At the very least they allow the patient an opportunity to read and have some idea of the manner in which his or her records will be used, and they may permit a legal cause of action if the plan or provider fails to provide the blanket authorization in the first place.

We suggest further that the many uses of records permitted to managed health plans under the proposed rule for “treatment, payment and health care operations purposes” primarily benefit the administrative functions of plans and have little or no connection to care directly provided to the individual patient. During the last several years, the **APA** has recommended to Congress and the Secretary that higher standards should be imposed when records are released for administrative purposes not directly related to patient care. The Secretary appears to understand this principle. For instance, in proposing this rule the Secretary indicates that:

The purpose of our proposal is to define and limit the circumstances in which an individual’s protected health information may be used or disclosed by others. We are proposing to make the use and exchange of protected health information relatively easy for health care purposes, and more difficult for purposes other than health care.”

We respectfully submit that the Secretary will not accomplish the goal of making the use and exchange of protected health information “more difficult for purposes other than health care” when patient records may be disclosed without authorization for “treatment, payment, and health care operations” purposes as those terms are defined in the proposed rule. A careful reading of the “treatment, payment, and **health** care operations definitions” reveal that much of this access is not directly related to the health care that an individual patient receives. Rather such access is for other purposes, primarily administrative, which benefit managed health plans or other entities.

¹⁰ 64 Fed. Reg. at 59940.

¹¹ *Id.* at 59924.

We are particularly troubled by the Secretary’s assertion that the use and disclosure of patient information without patient authorization for “payment” and “health care operations” is primarily for health care purposes. A summary examination of the definitions of these “payment” and “health care operations” reveals that they define **activities** primarily to fulfill the administrative function of managed health plans:

- The proposed rule defines “payment” to mean the activities undertaken by a **health plan** or its business partner to obtain premiums or to determine coverage, or along with a health care provider, to obtain reimbursement for the provision of care. Payment activities specifically include: determinations of coverage, “improved methods of paying or coverage policies,” adjudication or subrogation of claims, risk adjustment, billing, claims management, medical data processing, medical necessity review, and utilization review, including **precertification and preauthorization services**.¹²
- “Health care operations” are defined as activities undertaken by a health plan or health care provider for the purpose of “carrying out the management functions of such entity necessary for the support of treatment or payment.” These activities specifically include: quality assessment and improvement activities such as outcomes evaluation and development of clinical guidelines, reviewing the competence and qualifications of health care professionals and their performance, training activities, insurance rating and other insurance activities, medical review and auditing, and compiling and analyzing information in anticipation of or for use in a civil or criminal legal proceeding.”

Simply stated, too many of the “payment” and “health care operations” functions are administrative and have little or no connection to direct provision of health care to a patient. These administrative functions, including claims adjustment, billing, development of clinical guidelines, and training activities may serve patients in the aggregate, but they do not have a sufficient nexus to the actual care and treatment of an individual patient.

The purpose of this proposed rule is to protect the privacy of the individual’s identifiable information. An individual’s privacy is lost when his or her individually identifiable information is shared for administrative purposes or for purposes that may benefit patients in general.

The proposed rule’s definition of “treatment” is also troubling for vagueness. The “treatment” definition potentially could be read to permit the unauthorized disclosure of records for purposes that are actually administrative and not related to treatment. In the proposed rule:

¹² *Id.* at 60053 (to be codified at 45 C.F.R. § 164.504).

¹³ *Id.* at 60052 (to be codified at 45 C.F.R. § 164.504).

- Treatment means the provision of health care by, or the coordination of health care (including health care management of the individual through risk assessment, case management, and disease management) 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.¹⁴

Of course, psychologists and other health care professionals and providers need to share information and coordinate patient care to ensure appropriate care and patient safety. Therefore, health care professionals who are directly delivering services to patients must coordinate care and share information as necessary. This situation is properly considered within the “treatment” definition proposed by the rule.

The “treatment” definition, however, would also permit the sharing of patient information by a health plan for “the coordination of health care or other services among health care providers and third parties” as authorized by the plan. This permissible sharing of information could encompass the purely administrative function of a plan’s management or coordination of care and is not necessarily linked to direct treatment of a patient. As we mentioned above, patients should have some control over the sharing of their records by those individuals who are not directly providing care to them. Therefore, the “treatment” definition should be more narrowly tailored to ensure that it considers only those activities related to the direct treatment of the patient. The administrative functions are more properly contained within the “payment” and “health care operations” definitions.

As in our testimony before Congress and in our comments to NVCHS, the **APA** urges the Secretary to afford greater protection for patient records when disclosed for administrative or other purposes not related to direct patient care.” Sharing information not directly related to patient care is at the **crux** of the current patient privacy crisis. Patients can not feel secure, and indeed they should not feel secure in the privacy of their health records, if these records are permitted to be shared with innumerable other persons for a long list of administrative purposes not directly associated with the patient’s care.

Given the limitations implicit in the proposed rule, greater protection of the patient record can and must be afforded when patient records are disclosed for “treatment, payment, and health care operations” purposes. We propose, for example, that:

1. **Blanket authorization.** A blanket patient authorization for all of these administrative activities should be required. Patients have a right to their privacy. Therefore they should be afforded the opportunity to exercise their right to protect their patient record information by signing off on its disclosure. Not permitting patient authorization presumes that patients have no right to the privacy of their records. Since blanket authorizations are standard practice today, such authorizations will cause no more inconvenience or increased expense to managed health plans or other

¹⁴ *Id.* at 60053 (to be codified at 45 C.F.R. § 164.501).

¹⁵ Letter from Marilyn S. Richmond to NCVHS. p. 4.

entities requesting the records, and at the very least such authorization gives patients the opportunity to read or discuss the possible future disclosure of their records.

We agree with the Secretary that the current practice of blanket authorization provides patients with little control over their health records. We suggest, however, that rather than eliminating blanket authorizations, the Secretary and individuals involved in the health care delivery system work together to improve such authorizations. For example, the Secretary could develop and publish a model authorization form so that patients might more readily understand their rights and responsibilities when signing the authorization. Perhaps the Secretary could propose a model blanket authorization to be used by health care providers and payers. The **APA** would welcome the opportunity to assist the Secretary in this endeavor, particularly as it would affect those patients seeking and receiving mental health services.

2. ***Additional patient authorization for disclosures for administrative purposes.*** The Secretary should reexamine the definitions of “treatment, payment, and health care operations,” and particularly those of “treatment” and “health care operations.” These definitions permit very broad administrative activities, some of which could be narrowed or eliminated. Further, we suggest that some of these administrative functions should require specific patient authorization in addition to an initial blanket authorization. For example, we suggest that within the definitions of “payment” or “health care operations” that improvement of payment methodologies for risk adjustment or of clinical guidelines development are isolated activities mainly for administrative purposes, which should require additional patient authorization.
3. ***Enforcement of use and disclosure limitations.*** The Secretary should stress that the general rules that apply to patient records, such as requiring that the minimum amount of the patient record be used for the specific purpose of disclosure and that de-identified information be used where possible, apply to managed health plans for “treatment, payment, and health care operations” purposes. The Secretary should impose a process whereby managed health plans and providers must demonstrate to the Secretary that they have specific procedures in place to accomplish these standards and are meeting these requirements.
4. ***Enforcement of the psychotherapy notes disclosure exception.*** Regarding disclosure of mental health records, the Secretary should ensure that the exception from disclosure without patient authorization for “psychotherapy notes” is strictly enforced and improved. We now offer specific comments on how the “psychotherapy notes” exception may be improved.
 - A. **Requiring that patients must authorize disclosure of psychotherapy notes to managed health plans and other entities for “treatment, payment, and health care operations” purposes is of central importance to preserving the privacy of the psychologist-patient relationship. The APA urges that this provision be included in the final rule and offers**

specific improvements to ensure that it appropriately protects all sensitive mental health information.

We have mentioned above that mental health records are particularly “sensitive” to disclosure. This sensitivity exists for several reasons, many of which are rooted in societal stigmatization of mental disorders, and more intimately to the individual patient, in the fear that disclosure to loved ones, family, friends, business associates, even acquaintances could harm these relationships, perhaps irreparably. We need not discuss the sensitivity of mental health records in depth since the Secretary clearly shares this view. We agree, for example, with the Secretary’s comments that a greater intrusion in privacy occurs when mental health records are disclosed than when records regarding physical health are disclosed:

Many people believe that details about their physical self should not generally be put on display for neighbors, employers, and government officials to see. Informed consent laws place limits on the ability of other persons to intrude physically on a person’s body. Similar concerns apply to intrusions on information about the person. Moving beyond these facts about physical treatment, there is likely a greater intrusion when the medical records reveal details about a person’s mental state, such as during treatment for mental health. If, in Justice Brandeis’ words, the “right to be let alone” means anything, then it likely applies to having outsiders have access to one’s intimate thoughts, words, and emotions.¹⁶

Due to the particular sensitivity of mental health records, we suggest that patients seeking and receiving mental health treatment have different, generally greater, privacy and confidentiality needs than persons receiving general health services. Therefore, greater protection must be afforded mental health records when medical records’ confidentiality legislation or regulation is considered.

State legislatures and governments have long recognized this need for heightened protection of mental health records. The most recent and comprehensive survey of state records confidentiality laws conducted by the Institute for Health Care Research and Policy of Georgetown University concluded that “[b]y far, state legislation concerning mental health is among the most detailed and complex. All states have some statutory provision addressing mental health communications and records.”¹⁷

The Secretary has implemented her recognition that mental health information must be afforded heightened protection through the psychotherapy notes patient authorization requirement. Specifically, the proposed rule will permit records to be disclosed to managed health plans, other health providers, and their agents without patient authorization for “treatment, payment, and health care operations purposes.” Patients

¹⁶ 64 Fed. Reg. at 60008.

¹⁷ Health Privacy Project: *The State of Health Privacy: An Uneven Terrain*. Institute for Health Care Research and Policy, Georgetown University (July 1999). (Seep. 3 of ‘Secondary Findings,’ as available at <http://www.healthprivacy.org/resources/statereports/secondary.html>).

must, however, authorize disclosure of psychotherapy notes to these entities for such purposes.

The APA appreciates the Secretary's reliance on and extensive quotation of the recent United States Supreme Court decision of *Jaffee v. Redmond*, 518 U.S. 1 (1996) to provide for the psychotherapy notes disclosure requirement in the proposed rule. In *Jaffee*, a decision upholding the existence of the psychotherapist-patient evidentiary privilege under the Federal Rules of Evidence, the Supreme Court found that psychotherapist-patient relationship is:

[R]ooted in the imperative need for confidentiality and trust. . . Treatment by a physician for physical ailments can often proceed successfully on the basis of a physical examination, objective information supplied by the patient, and the results of diagnostic tests. Effective psychotherapy, by contrast, depends upon an atmosphere of confidence and trust in which the patient is willing to make a frank and complete disclosure of facts, emotions, memories, and fears. Because of the sensitive nature of the problems for which individuals consult psychotherapists, disclosure of confidential communications made during counseling sessions may cause embarrassment or disgrace. For this reason, the mere possibility of disclosure may impede development of the confidential relationship necessary for successful treatment.*

In recognizing the particular sensitivity of mental health records, the Secretary is right to apply the *Jaffee* decision as the underlying rationale for requiring patient authorization for the disclosure of psychotherapy notes. However, the Secretary's definition of "psychotherapy notes" in the proposed rule encompasses a narrower range of sensitive mental health information than that recognized by the Supreme Court in the *Jaffee* decision.

Psychologists and other mental health professionals typically create and maintain records, in addition and related to psychotherapy notes. The privacy of these records must also be protected to ensure effective psychotherapy and to preserve an atmosphere of confidence and trust so that the patient "is willing to make a frank and complete disclosure of facts, emotions, memories, and fears." A patient can not feel secure in the privacy of his or her relationship with a psychologist if he or she perceives that some records require specific authorization for release, while other records with similar and highly sensitive information do not. As the Supreme Court states, "the mere possibility of disclosure may impede development of the confidential relationship necessary for successful treatment." Patients need to know that all sensitive information related to their psychotherapy and treatment is secure and requires their specific authorization for release.

Therefore, the Secretary should define "psychotherapy notes" to include notes and **all** other records, which contain highly sensitive information related to treatment. These records would include, for example, those clinical observations made by the psychologist

¹⁸ 518 U.S. at 10.

outside of a psychotherapy session, and perhaps most importantly, psychological assessment, responses and assessment results.

An expanded definition of “psychotherapy notes,” as we propose, is appropriate and justified in the context of the **Jaffee** decision upon which the Secretary relies. The Supreme Court’s decision is a carefully tailored examination of the **psychotherapist-patient** relationship in the context of a Federal **evidentiary** privilege. In contrast, the Secretary is proposing a rule with broad application to mental health records and their disclosure to third parties. To fully reflect the spirit of the Supreme Court’s decision-to ensure the preservation of “confidence and trust” in the psychotherapist-patient relationship-the Secretary should apply the disclosure requirement broadly to all particularly sensitive mental health information.

We offer specific suggestions to amend the current “psychotherapy notes” patient authorization requirement to ensure that the provision protects all sensitive mental health records detailing the psychotherapist-patient relationship. We begin with an examination of the proposed rule’s “psychotherapy notes” definition, which states that:

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session. For purposes of this definition, “psychotherapy notes” excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.”

We suggest that the “psychotherapy notes” definition should be improved as follows:

1. The word “conversation” should be replaced with the word “communication.” The **Jaffee** decision more properly recognizes the protection of “communications” between the psychotherapist and patient. Not all communications between psychotherapists and their patients are limited to conversations. For example, during therapy with a child where the child may not be easily able to converse, the psychologist may allow the child to draw pictures or to sand play, creating images, which the psychologist photographs. For example, a disabled patient may have to communicate through means other than vocal conversation, such as through sign language, written notes, and computer-generated or other mechanical means. These are communications in recorded form generated as part of the psychotherapist-patient relationship, and therefore should fall under the psychotherapy notes authorization requirement.
2. Psychotherapy notes are, at times, created through patient contact outside of a “private counseling session or a group, joint, or family counseling session.” These words should be replaced with “psychotherapy, interview, or counseling session.”

¹⁹ 64 Fed. Reg. at 60055 (to be codified at 45 C.F.R. § 164.508(a)(3)(iv)(A)).

For example, a mental health provider may treat a patient with a phobic condition by accompanying him and applying psychotherapeutic techniques while he performs a behavior in the community outside of a “private counseling session.” Specifically, the mental health provider might give relaxation instructions and “expose” a patient with a social phobia to crowds during a treatment session. Typically too, counseling occurs not only in “private counseling sessions,” but also in other settings, such as in rehabilitation settings or in transplantation settings, where highly personal and subjective information about a patient’s emotional and psychological state may be elicited. Our language change ensures that this information requires specific patient authorization before disclosure may occur.

3. Strike the words “results of clinical tests” and insert immediately after the phrase “and any summary of the following items:” the words “assessment results”. Additionally, add the following new sentence at the end of the psychotherapy notes definition: “Test responses, scores, items and forms used in assessment or personal history shall be considered a part of psychotherapy notes, if the mental health professional determines that such assessment or history contains information directly related to psychological treatment.” Psychologists typically utilize psychological tests that require patients to divulge highly sensitive personal information, which is as sensitive as the information contained in psychotherapy notes. To preserve the privacy of the patient-mental health professional relationship, test responses, scores, items and even test forms themselves should require patient authorization for disclosure when such assessment would divulge sensitive information about the patient.

The current wording could be construed to allow the release of responses to psychological test items or scores on particular personality or behavioral dimensions. For example, the Minnesota Multiphasic Personality Inventory (**MMPI-2**), one of the most commonly used clinical tests, contains an item asking the respondent to indicate whether he or she has “indulged in unusual sex practices.” We believe that managed health plans and other third parties have no need for this sort of highly sensitive and embarrassing patient information and are able to make coverage and payment determinations with appropriate summaries of such clinical test results.

4. Move the words “functional status” to immediately precede the words “and progress to date” and insert immediately before “functional status” the phrase “and as related to diagnosis and prognosis,“. In addition, insert after the second sentence, the following new sentence: “Psychotherapy notes include clinical observations or other references in a patient’s record, and summaries of functional status or progress to date, which would otherwise divulge the nature or contents of communication made during a psychotherapy, interview, or counseling session.”

Clinical observations of behavior commonly record extremely sensitive information regarding the personal characteristics and behaviors of a patient in psychotherapy. For example, behavior observations commonly include detailed descriptions of a patient’s strong emotional reactions associated with the content of sessions such as

screaming, crying, or striking an object or herself. While these observations aid the psychotherapist in treatment, a managed health plan or other third party generally has no need for this level of detailed information for purposes of payment or other administrative activities.

Such observations and references are typically central to the psychotherapist's history regarding a patient, may occur during or after sessions, and may be placed in other parts of the patient's record, such as for purposes of treatment in hospitals or in other integrated health care facilities. Therefore, clinical observations and similar references should be considered psychotherapy notes when such information would reveal the nature or the contents of communication made during psychotherapy.

Likewise, summaries of functional status and progress to date can contain extremely sensitive patient information, which if inappropriately released to third parties without patient authorization could impede treatment progress and harm the relationship between the mental health professional and patient. Our amendment recognizes that managed health plans and other third parties may have access to summaries of functional status and progress to date in order to make decisions about care, as related to diagnosis and prognosis. Disclosure of a patient's functional status or progress to date, which would divulge sensitive patient information central to psychotherapeutic treatment, however, would require specific patient authorization.

As we have mentioned, the *Jaffee* decision considers the "mere possibility" of disclosure as impeding the confidential relationship between the patient and his or her psychotherapist. The inclusion of this additional sentence will help prevent the mere possibility that information is disclosed that would otherwise divulge the communications made during psychotherapy. We therefore believe the inclusion of this additional sentence is necessary for the "psychotherapy notes" authorization requirement to accomplish its fundamental goal of shielding highly sensitive information from disclosures beyond the patient and his or her treating provider.

Incorporating these changes into the "psychotherapy notes" definition, we suggest that the definition read as follows with the text of our amendments underlined:

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of communication during a psychotherapy, interview, or counseling session. For purposes of this definition, "psychotherapy notes" excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, and any summary of the following items: assessment results, diagnosis, the treatment plan, symptoms, prognosis, and as related to diagnosis and prognosis, functional status and progress to date. Psychotherapy notes include clinical observations or other references in a patient's record, and summaries of functional status or progress to date, which would otherwise divulge the nature or contents of communication made during a psychotherapy, interview or counseling session. Test responses,

scores, items and forms used in assessment or personal history shall be considered a part of psychotherapy notes, if the mental health professional determines that such assessment or history contains information directly related to usvcholoical treatment.

In addition to amending the definition of “psychotherapy notes” we offer additional suggestions to ensure that the psychotherapy notes authorization requirement works in practice and that it accomplishes the goal of providing patients the ability to determine when their psychotherapy notes may be disclosed to managed health plans and other entities:

1. We believe that covered entities should not be permitted to condition treatment, enrollment in a health plan, or payment on the disclosure of psychotherapy notes relating to the individual. A provision is needed to ensure that the psychotherapy notes authorization requirement can not be circumvented and dismissed as a mere procedural formality by managed health plans. Such a provision was included at proposed section 164.508(a)(3)(iii) before it was eliminated by the “corrections” published on January 5, 2000, 65 Federal Register 427. We urge that this provision be included in the final rule.
2. Psychologists and other psychotherapists must, at times, share portions of psychotherapy notes with other treating health care professionals in integrated health care facilities to ensure coordination of care. For example, psychologists typically include portions of psychotherapy records in the patient’s hospital record for care coordination. The requirement contained in the exception, at section 164.508(a)(3)(I)(A), that only the “creator” of the notes may use the notes without specific patient authorization, is a vitally important provision. It does not, however, permit the sharing of some portions of sensitive patient information needed to ensure coordinated and appropriate care in hospitals or other integrated health care facilities. We suggest that this language be amended to add directly after the word “creator,” the words “or in an integrated health care facility, the creator or other treating health care professional,”.

Relatedly, we note that the Secretary includes in her commentary additional “psychotherapy notes” requirements which are not included in the proposed “psychotherapy notes” definition. These requirements are that to qualify for the exception to disclosure without patient authorization, “such notes could be used only by the therapist who wrote them, would have to be maintained separately from the medical record, and could not be involved in the documentation necessary for health care treatment, payment, or operations”²⁰ As in our example above, psychologists share information with other treating health care professionals in hospitals for coordinated-care and patient safety purposes. We suggest that these additional requirements are unworkable in practice and may harm patient care. We urge the Secretary to continue to exclude these requirements in the language of the final rule.

²⁰ Id. at 59941.

Although including relevant portions of psychotherapy notes in a patient's medical record is a common practice, this does not mean that the patient and his or her psychotherapist relinquish the privacy of the record. Rather, the patient and psychotherapist choose pertinent information relative to assuring appropriate overall treatment for the patient. Psychologists often work in settings, such as in medical units in hospitals, where their treatment notes are used to communicate sensitive information to other treating health care professions to enhance the effectiveness of the patient's overall health care. Disclosure to a core group of treating providers in this situation is necessary and does not expose the record to a substantial loss of privacy, which would be the case in the sharing of such information for payment, health care operations, and other administrative purposes.

3. We suggest that an additional requirement be inserted which states that for purposes of the psychotherapy notes authorization requirement, a health plan may not claim "ownership" of the record and therefore thwart the requirement. A July 1999 National Mental Health Association (NMHA) survey of the current confidentiality protocols under private sector managed care systems found that for purposes of utilization review, every managed health plan policy reviewed "maintains the right to access the full medical record (including detailed psychotherapy notes) of any consumer covered under its benefit plan at its whim."²¹ Worse, at least one of the major managed health plans surveyed considered the patient record to be the property of the health plan and governed by the health plan's policies.^{**}

Clearly, a patient is less likely to be afforded the protection provided by the psychotherapy notes authorization requirement if he or she is enrolled in a plan which states that it owns the patient's psychotherapy notes. Therefore, language should be included in the final rule that specifies that **real** or perceived "ownership" of the mental health record does not negate the requirement that patients must specifically authorize the disclosure of their psychotherapy notes.

B. Many States have laws that more stringently protect the **privacy** of mental health records than those requirements provided in the **proposed rule**. The **APA** believes that the **proposed rule's non-preemption** of these State laws is **vital** important for the preservation of the **psychologist-patient** relationship. We are concerned, however, with the **proposed rule's** and the Secretary's **interpretation** of those States laws that are **sufficiently "related to"** the **privacy** of patient records to be saved from Federal **preemption**. We suggest that the **proposed rule's "related to"** requirement is **unnecessarily restrictive** and may be inappropriately interpreted to **preempt** many State laws that protect the privacy of mental health records.

As we have mentioned, States across the country currently protect the privacy of the psychotherapist-patient relationship and the confidentiality of the records that are created

²¹ National Mental Health Association: *Best (& Worst) Practices in Private Sector Managed Mental Healthcare, Part II: Confidentiality*, p. 13 (July 1999).

²² *Id.* at 13.

as a result of this relationship. The **APA** appreciates that the Secretary acknowledges and accepts the importance of this body of mental health privacy law throughout her commentary and by providing that these laws, when mandating stronger protections, will not be preempted by the proposed rule. We strongly support the non-preemption of these State laws.

We are concerned, however, with the manner in which the Secretary has interpreted and implemented the “related to” requirement. As proposed, only a State mental health law which is sufficiently related to the privacy of individually identifiable health information is saved from preemption. To be sufficiently related, the State law must have “the specific purpose of protecting the privacy of health information or the effect of affecting the privacy of health information in a direct, clear, and substantial way.”²³ While the second part of the requirement—that the law is saved when it has the “effect of affecting the privacy of health information in a direct, clear, and substantial way”—may preserve State laws addressing mental health records, we suggest that the “specific purpose” first part requirement may be unnecessarily restrictive and inappropriately interpreted to preempt these laws,

Many States currently afford a range of patient confidentiality protections for persons receiving mental health services. Some of these laws may not be interpreted as having been created for the “specific purpose of protecting the privacy of health information.” For example, psychologists’ and other professionals’ licensure laws often provide and laws related to a psychotherapist’s duty to warn others of potential harm from his or her dangerous patients provide requirements related to the privacy of health information. These laws, however, were not created for the specific purpose of protecting health information and therefore could be seen as preempted by the proposed rule.

The statutory basis for the proposed rule’s non-preemption of stronger State laws may be found in section 264(c)(2) and section 1178 of the Health Insurance Portability and Accountability Act (HIPAA). The language of these sections together, as the Secretary concludes, provides that State laws relating to the privacy of individually identifiable health information, which are contrary to and more stringent than the Federal requirements are not preempted. No provision of the statute qualifies non-preemption through the additional requirement that the State laws must have the “specific purpose of protecting the privacy of health information.”

The Secretary relies on and cites the House Report language leading to the passage of HIPAA as authority for this additional requirement:

The intent of this section is to ensure that State privacy laws that are more stringent than the requirements and standards contained in the bill are not superseded.

Based on this report language alone, the Secretary concludes State laws that relate to the privacy of individually identifiable health information are “simply those that are

²³ 64 Fed. Reg. 60051 (to be codified at 45 C.F.R. § 160.202).

specifically or explicitly designed to regulate the privacy of personal health information and not ones that might have the incidental effect of doing so.”²⁴ The **APA** does not understand how the Secretary could have reached this conclusion based on House Report language, which merely restates the general non-preemption standard. More importantly, we suggest that the additional “specific purpose” requirement to be implemented in the proposed rule could be interpreted to preempt State laws that Congress intended to save.

For this reason, we suggest that the Secretary amend section 160.202 of the proposed rule to more closely reflect Congressional intent regarding non-preemption of stronger state laws. We suggest, for example, that the words “the specific” be deleted and replaced with the word “a”.

II. Other provisions which particularly impact the privacy of mental health records.

A. In mental health case, the authority to use and disclose patient information in “emergency circumstances” should be restricted to licensed mental health care professionals exercising their professional judgment.

The **APA** is greatly troubled by the breadth of the proposed provision allowing unauthorized use and disclosure of patient information in emergencies, particularly with respect to mental health records. Quite simply, the proposed rule appears to open up the ability to invade patients’ privacy to too many people in too many circumstances. Specifically, the Secretary is proposing that health plans, health care clearinghouses, and providers be permitted to:

[C]onsistent with applicable law and standards of ethical conduct and based on a reasonable belief that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of an individual or the public, use or disclose protected health information to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.²⁵

On its face, this provision would permit virtually anyone working for a health plan or a health care clearinghouse -- even a receptionist or clerk with no mental health training whatsoever -- to breach a patient’s confidentiality if in their lay opinion the circumstances warrant. The **APA** firmly believes and strongly urges the Secretary to propose that, in the case of patients’ mental health records, only licensed mental health care professionals based upon their professional judgment should be authorized to assess whether the circumstances justify invading patients’ privacy. Only if the mental health care professional recommends disclosure, should the individual provider, health plan or health care clearinghouse be permitted to release confidential patient records. This change would ensure that only persons with professional expertise in mental health care would be making these extremely difficult decisions.

²⁴ *Id.* at 59996.

²⁵ *Id.* at 60058 (to be codified at 45 C.F.R. § 164.510(k)(1)).

The Secretary already has proposed that only a licensed health care professional based upon his or her reasonable professional judgment of possible harm to the patient may deny a patient's request to inspect or copy the patient's medical records.²⁶ Health plans that choose to deny patients their right to inspect and copy their records must first consult with a licensed health care professional. The assessment of potential for harm to the patient is precisely the same here. Therefore, requiring that only licensed health care professionals judge whether an emergency of sufficient severity exists to warrant disclosure of a patient's private information would be fully consistent with the Secretary's own proposals for other sections of this rule.

Further, the Secretary's proposal to allow disclosure by simply anyone who believes an emergency exists is a tremendous unprecedented expansion of *Tarasoff v. Regents of the University of California*,²⁷ and similar State laws throughout the country. We understand and agree with the California Supreme Court's finding in *Tarasoff* that "the protective privilege ends where public safety begins." We also understand the Secretary's very practical desire to ensure that health care professionals and law enforcement officials have access to the medical records of an individual who, for example, is injured in an automobile accident and cannot consent to disclosure in order to ensure that proper medical care can be provided. In the context of mental health, however, confidential communications between psychotherapists and their patients deserve greater protection.

As the Supreme Court has stated in *Jaffe*, as the Secretary already has recognized, and as we have commented throughout this letter, communications between patients and their psychotherapists deserve heightened protection due to the records' greater sensitivity and the special need for confidentiality and trust in the psychotherapeutic relationship. The Secretary also has recognized that nearly all States have adopted some form of additional privacy protection for mental health records.²⁸ Under California law, for example, the psychotherapist-patient privilege is considered to be a broader privilege than the physician-patient privilege.²⁹

Moreover, the need to balance the patient's need for confidentiality against the public interest of health and safety is already addressed by many States under their "duty to protect" laws, which impose an obligation on psychotherapists and other providers to protect readily identifiable third parties from potential harm. As the Secretary already has acknowledged, this duty was first established in *Tarasoff*, but has since been adopted in similar form by many States.³⁰ For more than two decades, these States have worked carefully and meticulously to achieve an appropriate balance between the need for confidentiality and the need to protect the health and safety of others. If there is the possibility of danger to a readily identifiable third party, the psychotherapist must take steps to warn and protect that third party. These steps might include warning the potential

²⁶ *Id.* at 60060 (to be codified at 45 C.F.R. § 164.514(b)(1)(i)).

²⁷ 17 Cal. 3d 425 (1976).

²⁸ *Id.* at 60012.

²⁹ California Evid. Code Ann. § 1014 (Deering 1999).

³⁰ *Id.* at 59972.

victim of the danger, notifying the police, or even involuntarily committing the patient to the hospital.

To better balance the need for public safety and patient privacy, the APA strongly urges the Secretary to more narrowly tailor the “emergency circumstances” provision in the manner suggested above. We offer below our recommended revisions to this provision with the following underlined amendments:

A covered entity may, consistent with applicable law and standards of ethical conduct and based on a reasonable belief that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of an individual or the public, use and disclose protected health information to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat. In the case of a serious and imminent threat to the health or safety of an individual or the public resulting from an individual’s mental health condition, a covered entity may, based on a licensed mental health care professional’s exercise of reasonable professional judgment that disclosure is necessary to prevent or lessen the threat and consistent with applicable law and standards of ethical conduct, use and disclose protected health information to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.

B. The proposed rule should provide an exception to the right of patients to inspect and copy their mental health records if, in the opinion of a licensed mental health care professional, disclosure could reasonably be expected to cause substantial psychological harm to the individual who is the subject of the record.

The APA appreciates that the provision protecting patients’ right to inspect, copy, and correct their records is consistent with evolving legal recognition of these rights. However, we strongly urge the Secretary to reverse her decision to remove the exception for psychological harm and include it in the final rule.

As presently drafted, the provision permits health plans, health care clearinghouses and providers to deny patients’ requests for access to their records where licensed health care professionals judge that access is reasonably likely to endanger only “the life or physical safety of the individual or another person.”³¹ The Secretary has made clear that she considered, but declined to include, a similar exception where the information has the potential to cause emotional or psychological harm. The Secretary apparently arrived at this determination after concluding: “in the current age of health care, it is critical that the individual is aware of his or her health information.”³²

The APA agrees that in today’s environment it is important for individuals to have access to their health care information. However, the exception to this principle, **where the** life and safety of the individual are at stake, is no less critical for patients endangered

³¹ Id. at 60060 (to be codified at 45 C.F.R. § 164.514(b)(1)(i)).

³² Id. at 59982.

psychologically than physically. The potential for serious psychological injury in this regard is not the equivalent of just a broken arm, but could be far more serious, even permanent. For example, if a patient suffering from paranoid delusions believes he or she is hearing voices, then inspects and reads in a therapist's record that ~~the therapist~~ believes these voices are auditory hallucinations rather than "real" voices, distrust of the therapist could occur if revealed too early in the treatment. To ignore the possibility of psychological harm in mental health treatment works contrary to the very purpose of the treatment.

In fact, the psychological harm exception to patients' right of access to their records also is consistent with evolving law. For example, legislation proposed in this congressional session by Senator Jeffords, "The Health Care Personal Information Nondisclosure Act of 1999," (S. 578), included a psychological harm exception. Specifically, the bill would permit denial of patient access to their records if "the disclosure of the information could reasonably be expected to endanger the life or physical safety of, or cause *substantial mental harm* to, the individual who is the subject of the record (emphasis added)."

Similarly, as the Secretary herself has acknowledged, a number of States allow an exception for psychological harm including, but not limited to: California, Connecticut, the District of Columbia, Indiana, and Maine.³⁴ In the District of Columbia, for example, the treating mental health care professional may refuse a patient's request to see the patient's records if the professional "reasonably believes that such refusal or limitation on disclosure is necessary to protect the client from a substantial risk of imminent psychological impairment . . ."³⁵

The APA understands that concerns have been raised that the psychological harm exception is often too vague or too broadly worded because it permits the covered entity subjectively to determine whether there is a risk of psychological harm. To ensure greater accuracy in assessing the potential for psychological harm, the APA strongly recommends that the determination whether to deny access be made solely by a licensed mental health care professional, who has the requisite training to assess whether serious psychological harm is likely to occur.

Accordingly, incorporating the above referenced changes into the "harm" exception to patients' right to inspect and copy their records, we suggest that the regulation read as follows with the text of our amendments underlined:

[A] covered entity may deny a request for access under paragraph (a) of this section where (i) a licensed health care professional has determined that, in the exercise of reasonable professional judgment, the inspection and copying requested is reasonably likely to endanger the life or physical safety of the individual or another person; or (ii) a licensed mental health care professional has determined that, in the exercise of reasonable professional judgment, the

³³ S.578, 106th Cong., 1st Sess. §101(b)(1).

³⁴ *Id.* at 59982.

"D.C. Code § 6-2016 (1999).

inspection and copying requested is reasonably likely to cause substantial mental harm to the individual or another person.

In the alternative, because so many State laws already contain exceptions for psychological harm, the **APA** respectfully requests that the Secretary at the very least not preempt State laws governing patients' right to inspect and copy their records.

C. Law enforcement officials should be limited in their use and re-disclosure of patient records. Permissible disclosures under the proposed rule (1) related to victims of crime or abuse, (2) pursuant to legal processes, and (3) related to the investigation of health care fraud should be narrowed in scope or their meaning clarified.

We raise a number of concerns regarding section 164.51 O(f) of the proposed rule, which permits health providers and plans to disclose records to law enforcement officials without patient authorization. Generally, we believe that law enforcement access to patient records should be limited to the absolute minimum disclosure and use necessary in the interest of justice. The law enforcement access provisions of the proposed rule do not provide and therefore should be clarified to meet this burden.

We first discuss an overarching concern with the law enforcement disclosure provision: Assuming that disclosure to a law enforcement official has been made, the proposed rule provides no limitation for further use and re-disclosure of the records. Limitations on law enforcement use and re-disclosure should be included in the final rule.

By not imposing use and re-disclosure safeguards, the Secretary may have assumed that a court, grand jury, or judicial official in an administrative proceeding would impose such limitations. It seems reasonable to believe, however, that various administrative law bodies may not have specific procedures for use and re-disclosure in place. In addition, the proposed rule allows disclosure of patient records in other instances unrelated to legal processes or proceedings. These include release of patient records to a law enforcement entity: (1) to identify as suspect, fugitive, material witness, or missing person, (2) regarding the victim of a crime, abuse, or other harm, or (3) pursuant to an investigation of health care fraud. The proposed rule should specify use and re-disclosure requirements for disclosures to law enforcement in these instances.

Both Senators Jeffords and Leahy specify limitations on law enforcement use and re-disclosure of patient records in their proposed patient records privacy bills (S. 578 and S. 573, respectively). Both the Jeffords and **Leahy** bills, for example, require that a law enforcement entity either destroy the patient information or return it to the disclosing party when the matter or need for which the information was disclosed has concluded. Both bills require redaction of personally identifiable information prior to public disclosure in a judicial or administrative procedure. Senator Leahy's bill additionally requires the court granting law enforcement access to impose appropriate safeguards to ensure the privacy of the information and to protect against unauthorized or improper use

and disclosure.³⁶ The provisions of these bills could serve as starting points for limitations recommended by the Secretary.

In addition to the lack of limitations specified for use and re-disclosure of records by law enforcement officials, we raise three other issues concerning certain permissible disclosures to law enforcement:

1. Unauthorized disclosure of patient records of victims of crime. abuse of other harm. Section 164.5 10(f)(3) permits health care providers and plans to disclose information about an individual who is a “suspected” victim of a crime or abuse, if: (1) such information is needed to determine a law violation by a person other than the victim, and (2) immediate law enforcement activity, depending upon such information, may be necessary. On its face, this provision appears over-broad, potentially giving law enforcement officials broad access to patient records in a number of instances where judicial review is necessary to protect the privacy of the victim’s health record. For example, the provision:

- envisions access to the records of any victim of a crime, even if the victim or public is not endangered by the on-going criminal activity.
- provides no limitation on the amount of information law enforcement may have access to, such as the “minimum necessary” to pursue the law enforcement activity.
- does not define “immediate” law enforcement activity. Urgent pursuit of a criminal suspect seems a reasonable immediate law enforcement activity, but pursuit of a suspect who is “engaged in ongoing criminal activities,” as offered by the commentary, does not give a sense of immediacy.” Such ongoing criminal activities could be taking place over a period of months or years.

Perhaps the Secretary’s most compelling argument for unauthorized records disclosure to law enforcement officials concerns protecting victims of spousal or child abuse from additional violent crimes.³⁸ While we might agree that this a reasonable unauthorized records disclosure, to our knowledge, law enforcement officials currently must pursue judicial review and other requirements to receive access to patient records of victims of crime or abuse. Therefore, this provision would allow significant new law enforcement access to patient records.

As we have mentioned throughout our comments, mental health records are particularly sensitive to disclosure. Disclosure of psychotherapy notes and other mental health records to law enforcement without authorization could have dire consequences for a patient. For example, a victim of spousal or child abuse may no longer trust a mental health provider who relinquished his or her records to law enforcement officials. Further,

³⁶ S. 578, 106th Cong., 1st Sess. § 210; S. 573, 106th Cong., 1st Sess. § 208.

³⁷ 64 Fed. Reg. at 59962.

³⁸ *Id.* at 59962.

the mental health records may contain sensitive information, to which the victim does not want the abuser, in turn, to have access.

Judicial review allows an unbiased judge to weigh the privacy interests of the patient against the public interest of law enforcement's pursuit of criminals. Certainly, the mental health records of victims of crime should be particularly protected from unauthorized disclosure unless a compelling interest justifies such disclosure. Therefore, unauthorized records disclosure to law enforcement, particularly with regard to mental health records, should be confined to narrow circumstances. We urge that the provision be narrowly tailored to recognize the particular sensitivity of mental health records.

2. Disclosure of patient records pursuant to a legal process. Section 164.510(f)(1) would permit unauthorized patient records disclosure pursuant to a law enforcement inquiry authorized by law through: (1) a warrant, subpoena, or order issued by a judicial officer, (2) a grand jury subpoena, or (3) an administrative request. Unlike disclosures made through warrants, subpoenas, and other court orders, disclosures pursuant to administrative requests do not require judicial review. We seek clarification of this provision to assure that law enforcement officials can not thwart the current warrant, subpoena, and court-ordered processes by accessing patient records through administrative requests.

We assume that law enforcement officials would seek disclosure of records in the manner appropriate to the matter under investigation, as required by law, whether through warrant, a grand jury subpoena, or administrative request. Administrative requests for records, for example, should not permit law enforcement officials to request patient records from health care providers and plans based on a written request only and without judicial review.

3. Disclosure of records during an investigation of health care fraud.

Section 164.510(f)(5) would permit a covered entity, such as a managed health plan, to disclose unauthorized protected patient health information to law enforcement officials if the covered entity believes in good faith that the information shows evidence of criminal health care fraud and abuse.” If this proposal is retained in its current form with no additional safeguards, it will provide a loophole so large that it swallows the rule. As we have repeatedly stated throughout this commentary, health care records, particularly mental health care records, deserve more – not less – protection.

Notably absent from this section are key procedural protections for patients, such as: (1) prior review of the request by an administrative body, which then weighs law enforcement's need for the information against the patient's privacy interests; and (2) prior notice to the patient with an opportunity to contest the proposed disclosure. The **APA** believes that inclusion of these protections is crucial to protecting patient privacy while still allowing the investigation of health care fraud and abuse. Legislative

³⁹ 64 Fed. Reg. at 60057 (to be codified at 45 C.F.R. §164.510(f)(5)).

proposals, such as Senator Leahy's privacy bill, S. 573, contain both of these types of restrictions on law enforcement's access to patients' protected health care information."

Further, the NCVHS supports these types of safeguards. As the NCVHS recommended, and as the **APA** agrees:

Investigations of health fraud and abuse are important. Nevertheless, the Committee believes that patients need strong substantive and procedural protections if their health records are to be disclosed to law enforcement officials.. The Committee is confident that strong protections for patient privacy interests can be compatible with fraud and abuse investigations.⁴¹

Closing.

The **APA** recognizes that the proposed rule is a beginning point toward affording patients greater privacy protections regarding their health care records. We urge the Secretary to incorporate our suggestions, which we believe will improve the rule, particularly as it encompasses the protection of mental health records.

We would appreciate the opportunity to work further the Department of Health and Human Services to improve the rule and specifically, to incorporate our suggestions. Please contact Doug Walter, J.D., Legislative and Regulatory Counsel, Government Relations, Practice Directorate, at (202) 336-5889, if you have further questions regarding our comments.

Sincerely,



Russ Newman, Ph.D., J.D.
Executive Director for Professional Practice

⁴⁰ S. 573, 106th Cong., 1st Sess. § 208.

⁴¹ NCVHS, *Health Privacy and Confidentiality Recommendations*, p. 13 (June 1997)