

April 26, 2002

The Honorable Tommy G. Thompson
Secretary, U.S. Department of Health and Human Services
Attention: Privacy 2
Hubert H. Humphrey Building
Room 425A
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Comments on Proposed Rule; Modification: Standards of Privacy
of Individually Identifiable Health Information

Dear Secretary Thompson:

The American Psychoanalytic Association (“APsa”) and the National Coalition of Mental Health Professionals and Consumers provide the following comments on the proposed rule to modify the Standards for Privacy of Individually Identifiable Health Information published in the Federal Register on March 27, 2002. 67 Fed. Reg. 14,776. APsa is one of the oldest mental health provider organizations in the country, having been established in 1911, and includes among its 3,500 members, therapists who are physicians, psychiatrists, psychologists, social workers, researchers, and professors of academic medicine. The National Coalition of Mental Health Professionals and Consumers, in existence over 10 years, is the only national grassroots organization uniting consumers with the three major professional mental disciplines (MDs, PhDs, MSWs) dedicated to working to achieve a truly pro-consumer, pro-patient mental health care system, based on privacy and a consumer directed decision-making and treatment process. It has approximately 1,500 members.

For the reasons set forth more fully below, we are extremely concerned that several provisions of the proposed rule (such as elimination of the right of consent and broader use of information for marketing) will cause serious and irreparable harm to the quality of health care generally and will eliminate access to effective psychotherapy specifically for many individuals. We also believe that the proposals to weaken individual control over identifiable health information are inconsistent with the findings in the current final rule and that no basis has been cited to warrant rescinding those findings. Wherever possible, we will suggest alternative solutions to the issues raised that are less likely to damage quality health care.

- 1. The rule-making process is inadequate because it fails to adequately inform the public of the impact on their privacy rights, fails to provide individuals with a realistic opportunity to comment, and fails to consider less drastic alternatives, including those recommended by the National Committee on Vital and Health Statistics (Section II, Overview of the Proposed Rule, 67 Fed. Reg. at 14,777).**

The proposed rule was published in the Federal Register on March 27, 2002 and permits public comments to be submitted only until 5:00 p.m. on April 26, 2002. 67 Fed. Reg. at 14,776-78. The rule states that the Department believes that “30 days should be sufficient for the public to state its views.”

However, the rule proposes to make numerous changes in at least nine areas that the proposal itself refers to as “key areas” of the Privacy Rule. 67 Fed. Reg. at 14,778. The Privacy Rule sets forth “[t]he rights that an individual who is a subject of individually identifiable health information should have” as well as the procedures for exercising those rights. Health Insurance Portability and Accountability Act of 1996 § 264(b). Some of the proposed changes, such as the elimination of the right of consent, would eliminate federal rights that were conferred upon all individuals by the current Privacy Rule.

Further, the rights that are set forth in the current Privacy Rule were the product of one of the most extensive rule-making processes in the history of the Department, with “more than 52,000 public” comments being submitted on the rule that was proposed on November 3, 1999, and more than 11,000 public comments submitted when the comment period was reopened in March 2001. 67 Fed. Reg. at 14,777. The original 60-day comment period was extended because of the high degree of interest in the Privacy Rule. The decision was made to give federal recognition to the individual’s right of consent for the use and disclosure of identifiable health information by both the prior and the current Administrations based on the evaluation of nearly 65,000 comments over a span of more than 18 months. The public should be given at least 60 days to submit comments on a proposal to eliminate the public’s right of consent, particularly in view of the fact that this issue “drew the most comments overall.” 65 Fed. Reg. at 82,472.

Additional time is also justified by the fact that those who have opposed federal recognition of the right of consent have had their arguments rejected on three prior occasions—once when the final Privacy Rule was adopted, a second time when the National Committee on Vital and Health Statistics refused to adopt their proposal, and a third time when the Department elected to make the current Privacy Rule effective on April 14, 2001. The Department is adopting a policy it has considered and rejected multiple times and is only giving the public a brief time to understand and comment on this dramatic reversal.

In addition, the notice does not adequately inform the public of the effect of the proposed change in that it fails to state that the change will result in individuals losing the control over the use and disclosure of their identifiable health information that is provided under the current Privacy Rule. The public is more likely to be misled since the Department issued a public statement last April, when the current Privacy Rule was allowed to become effective, that the Department would “immediately begin the process of implementing the patient privacy rule that will give patients...more control over how their personal information is used.” (emphasis added). The Department further stated that “we are giving patients peace of mind in knowing that their medical records are indeed confidential and their privacy is not vulnerable to intrusion.” See Statement by Secretary Tommy G. Thompson, “Regarding the Patient Privacy Rule” (April 12, 2001).

The proposed amendment does not state that patients’ control over the use and disclosure of their identifiable health information is being reduced or eliminated and that the effect of “regulatory permission” will be to make their identifiable health information vulnerable to intrusion by thousands of covered entities for treatment, payment, and health care operations without their knowledge or consent. This is a major policy reversal that should be fully described and explained. At least the same amount of time should be afforded to the public to comment on this change as was afforded when the right of consent was included in the current Privacy Rule.

The likelihood that the public will be misled is compounded by the press release and the fact sheet distributed to the public on March 21, 2002. See “HHS Proposes Changes That Protect Privacy, Access to Care,” HHS Press Release. The press release states that “the proposal would promote access to care by removing the consent requirements for treatment, payment and health care operations that could interfere with efficient delivery of health care, while strengthening requirements for providers to notify patients about their privacy rights and practices.” The press release does not provide the slightest indication that the proposed changes would eliminate the right of consent that individuals currently possess under the Privacy Rule, as well as reduce individuals’ control over how personal information is used, which was one of the principal points mentioned in the announcement from the Department of April 2001. The Fact Sheet similarly states that “this change would give patients the opportunity to consider a provider’s privacy policies before making health decisions, while eliminating barriers that could delay or block patients’ access to care.” Again, there is no indication to the public that the change would reduce individuals’ rights to control the use and disclosure of their health information, which the final Privacy Rule found essential for quality health care.

Further, it appears that the public is not even given 30 days to comment if the day of publication is not counted, as is traditionally the case. A 30-day comment period from March 27 would expire on April 27, which is a Saturday,

thereby extending the 30-day comment period to the next business day, which is Monday, April 29, 2002.

The Department's contention that a truncated comment period is necessary because the Privacy Rule's compliance date is imminent (67 Fed. Reg. at 14,778) cannot serve as a valid justification for depriving the public of a full and fair opportunity to comment. The timing of the publication of the proposed amendments is under the Department's control, and it decided to delay publishing this proposed amendment until now.

Further, the notice is misleading and inaccurate in stating that the National Committee on Vital and Health Statistics "did not address whether the Privacy Rule should or should not require consent." 67 Fed. Reg. at 14,780. In fact, the groups that have been opposing the right of consent throughout the rule-making process made a concerted effort to get the NCVHS to make such a recommendation. See National Committee on Vital and Health Statistics Subcommittee on Privacy and Confidentiality, Transcript of August 21, 2001 Hearing. In its report to the Secretary, the NCVHS summarized the arguments of those who wanted "HHS to delete the mandatory consent requirement and make consent optional for all covered entities...." See Letter from National Committee on Vital and Health Statistics to Secretary of Health and Human Services at 2 (October 1, 2001). The Committee refused to adopt those arguments and, instead, made specific recommendations with respect to how the problems could be addressed without the wholesale elimination of the right of consent.

So it is misleading, at best, for the public notice to state that the NCVHS "did not address" the elimination of consent when it expressly evaluated and rejected the very amendment contained in the proposed rule. This is an especially disturbing defect in the notice since Section 264(d) of HIPAA requires the Secretary "to consult with" the NCVHS. Health Insurance Portability and Accountability Act of 1996 § 264(d). The notice simply ignores the recommendations of the NCVHS with respect to the right of consent without analysis or explanation.

The incomplete and misleading statements to the public about the proposed changes with respect to consent coupled with the abbreviated comment period raise the very real threat that the public's right to medical privacy is about to be eliminated without the type of public notice and opportunity for comment that is required by law.

Recommendation

Accordingly, we recommend that a new notice be issued that adequately informs the public of the change that is being proposed and its effect on their rights. In any event, we recommend that the comment period on the proposed amendments be extended to at least 60 days.

2. The elimination of the right of consent will eliminate a privacy right that is essential to quality health care. Proposed 45 C.F.R. § 164.506.

A. The proposed amendments eliminate a vested privacy right through federal action.

There can be no doubt that all individuals in the country currently have a right to not have their identifiable health information used or disclosed for treatment, payment, or health care operations without their consent. Section 164.506(a). That right is part of the “federal floor of privacy protections” that became effective on April 14, 2001. Accordingly, those rights, including federal recognition of the right of consent, vested in all Americans on that date.

The proposed amendments do not merely seek to repeal recognition of the right of privacy without consent, but affirmatively seek to grant access to the identifiable health information of all individuals by all covered entities through a blanket “regulatory permission” by the federal government. 67 Fed. Reg. at 14, 780-81. This would appear to violate the privacy rights of all individuals protected by the Fourth and Fifth Amendments of the U.S. Constitution. In fact, the current Privacy Rule notes that “the need for security of ‘persons’ is consistent with obtaining patient consent before performing invasive medical procedures....Similar concerns apply to intrusions on information about the person.” 65 Fed. Reg. at 82,464 (emphasis added). The current Privacy Rule also contains a finding to the effect that “few experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal information.” 65 Fed. Reg. at 82,464. Thus, the power to control whether and how personal information is used is essential to a right to privacy.

It is this power of individuals to exercise some control over the use and disclosure of their identifiable health information that the proposed amendments seek to eliminate. Even though the current Privacy Rule states unequivocally that “privacy is a fundamental right,” the proposed amendments make no mention of this or the other findings with respect to the right to privacy. 65 Fed. Reg. at 82,464.

Recognition of the right of consent in the final Privacy Rule and the fact that this rule has been effective for more than a year reflects a settled course of behavior by the Department. Accordingly, rescinding this right requires a more, rather than a less, reasoned analysis.

B. The right of consent is an essential component of the privacy necessary for quality health care.

In addition to being essential for preservation of basic liberties, the right of consent, according to the current Privacy Rule, is essential for quality health care. 65 Fed. Reg. at 82,467. The current Privacy Rule stated that:

“While privacy is one of the key values on which our society is built, it is more than an end in itself. It is also necessary for the effective delivery of health care, both to individuals and to populations.” 65 Fed. Reg. at 82,467.

“[T]he entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers.” 65 Fed. Reg. at 82,467.

“Privacy violations reduce consumers’ trust in the health care system and institutions that serve them. Such a loss of faith can impede the quality of the health care they receive, and can harm the financial health of health care institutions.” 65 Fed. Reg. at 82,468.

The current Privacy Rule then lists numerous examples of how identifiable health information has been used without consent to the detriment of individuals (65 Fed. Reg. at 82,467-68), numerous surveys showing “increasing public concern about loss of privacy” including medical privacy (65 Fed. Reg. at 82,465-66), and studies showing that individuals are increasingly taking action to protect the privacy of their own identifiable health information, including “providing inaccurate information to a health provider, changing physicians, or avoiding health care altogether.” 65 Fed. Reg. at 82,468. The current rule also noted that “[h]ealth care professionals who lose the trust of their patients cannot deliver high-quality care.” 65 Fed. Reg. at 82,468.

The current Privacy Rule also concluded, after a review of the more than 52,000 comments, that preserving the right of consent in federal law was essential to providing access to quality health care based on the following findings:

“Comments from individuals revealed a common belief that, today, people must be asked permission for each and every release of their health information.” 65 Fed. Reg. at 82,472

“[The Department’s] review of professional codes of ethics revealed partial, but loose, support for individuals’ expectations of privacy.” Id.

Half of the states have “general” statutory laws requiring consent for the disclosure of identifiable health information. 65 Fed. Reg. at 82,473.

Other states have common law or professional licensure laws that prohibit “breaches of confidentiality;” i.e., disclosures of identifiable health information without patient consent. Id.

“[I]ndividuals, health care professionals, and organizations that represent them indicated that both patients and practitioners believe that patient consent is an important part of the current health care system and should be retained.” 65 Fed. Reg. at 82,473.

“The comments and fact-finding indicate that our approach [recognizing the individual’s right to consent] will not significantly change the administrative aspect of consent as it exists today. 65 Fed. Reg. at 82,474 (emphasis added).

The current Administration did not change, but rather appeared to support, these findings when it allowed the final Privacy Rule to become effective on April 14, 2001.

C. The right of consent is necessary for effective psychotherapy.

The preservation of privacy, as manifested by the right of consent, is even more critical in the area of mental health services. As the Supreme Court noted in Jaffee v. Redmond, 116 S. Ct. 1923, 1928 (1996), “[e]ffective psychotherapy...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.” Accordingly, the Court recognized, as a matter of federal common law, that communications between a therapist and a patient are “privileged” and may not be disclosed without the patient’s consent.

The Court found support for its position in the “reason and experience” reflected in the history of the nation as well as the history of medicine. The Court found that the right of privacy and consent was so important to quality psychotherapy services that it could not be subjected to a “balancing test” because “an uncertain privilege, or one which purports to be certain but results in widely varying applications by the courts, is little better than no privilege at all.” 116 S. Ct. at 1932. The Court also found that access to effective psychotherapy is in the interest of the public as well as the individual. The holding and rationale of the Jaffee decision have been followed in more than 170 cases decided since 1996.

The proposed amendments appear to retain the requirements of patient authorization for the use and disclosure of “psychotherapy notes,” and for that, we are grateful. There are, however, types of mental health information that may not fall within the definition of “psychotherapy notes,” the privacy of which may be protected principally by the patient’s right of consent. See, e.g., information that is not separated from the rest of the medical record, medication prescriptions, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and summaries of diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date, among other types of information. Section 164.501. The loss of the right of consent for such information would damage or completely eliminate access to effective psychotherapy as noted by the Supreme Court.

Further, the public alarm and confusion over a federal policy to permit access to identifiable health information without consent is likely to have a “chilling effect” on patients who need mental health services but fear that obtaining them will result in information being used and disclosed without their consent. Accordingly, we believe that the right of consent must be preserved in order to maintain access to effective psychotherapy.

D. The current right of consent is a workable, effective means of preserving the privacy that is essential for quality health care.

The current consent requirement is an effective means of giving individuals some control over the use and disclosure of their health information. The proposed rule contends that the consent procedure in the Privacy Rule is not effective because it is a “single, one-time, general permission” and the provider can refuse treatment for a patient who refuses to provide it. 67 Fed. Reg. at 14,778. However, the consent process under the Privacy Rule in effect today is much more flexible.

First, the Privacy Rule requires consent to be obtained “prior to using or disclosing protected health information.” Section 164.506(a). Accordingly, an individual may consent to the disclosure of information necessary to treat his infected finger but not his psychiatric information. While consents may be general, they may also be more limited.

Second, consents may be for uses **or** disclosures for treatment, payment **or** health care operations. This preserves the right of the individual to consent to uses for treatment but to not consent to disclosures for payment and to pay out of pocket or have the services rendered for free. An individual may also consent to the **use** of information by his or her provider but not to the **disclosure** to any other entity. See specifically 65 Fed. Reg. at 82,512.

Under this process, physicians and patients would have the opportunity to discuss whether the health care could be rendered safely and effectively with the

information that the patient is comfortable disclosing and with the further disclosures that the patient is willing to permit. Thus, the patient's confidence that his or her privacy will be protected is preserved, and the patient is likely to make the kind of disclosures that are necessary for an accurate diagnosis and treatment.

The current Privacy Rule expressly analyzed the "workability" of the consent and other provisions and made the following findings:

"Achieving workability without sacrificing protection means some level of complexity, because the rule must track current practices and current practices are complex." 65 Fed. Reg. at 82,472

"The comments and fact-finding indicate that our approach will not significantly change the administrative aspect of consent as it exists today." 65 Fed. Reg. at 82,474.

The proposed amendments do not dispute the Privacy Rule's findings with respect to workability, and in fact, admit that "consent [is] an integral part of the ethical and other practice standards for many health care professionals." 67 Fed. Reg. at 14,781.

So the Department's contention that the right of consent must be eliminated for "workability" reasons is not supported by the rule-making record and the Department's own findings.

E. Privacy that is essential for quality health care is not adequately protected by "regulatory permission," the "opportunity to engage in discussions," or "optional" consent.

Under the proposed amendment, the general rule is that all of an individual's identifiable health information may be used and disclosed for treatment, payment, and health care operations without consent and even against the patient's will. This information could be used and disclosed for health care operations, for example, even if the patient paid privately or the care was rendered for free. (The only exception would appear to be "psychotherapy notes" for which an "authorization" would be required.)

According to the proposed rule, this amended process would afford patients "the opportunity to engage in important discussions regarding the use and disclosure of their health information." 67 Fed. Reg. at 14,780. Also, covered entities would be permitted the "option" of obtaining health information with consent.

The process envisioned by the proposed rule deprives the patient of any decision-making power with respect to the use or disclosure of his or

her identifiable health information. The “opportunity to engage in important discussions” has little meaning if the patient has no power to limit how his or her health information will be used and disclosed.

The “option” of obtaining health information with consent is available only at the discretion of the covered entity. Therefore, the patient has no power to assert a right of consent for the use or disclosure of health information.

Furthermore, it is unlikely that any such “option” would prevent the disclosure of health information to a health plan because the health plan will simply compel participating physicians to disclose all patient information needed for health care operations or be excluded from the plan. Physicians will then be in the untenable position of deciding whether to honor the “optional” consent arrangement with the patient or to be excluded from the plan’s participating providers. Further, the health plans will contend that all requested information must be disclosed in any event because they were not parties to the “optional” consent arrangements. This would appear to apply, as well, even if the provider agreed, which it is under no obligation to do, to a request to restrict the use or disclosure of health information. See Section 164.522(a)(1)(iii) which states that agreements to restrict apply “to the covered entity that agrees to a restriction.” It would not appear that health plans and others would be bound by the agreement.

Thus, patients and providers face the following decision under the existing Privacy Rule: How much identifiable health information must be used or disclosed for treatment, payment, or health care operations?

Under the proposed amendments, by contrast, the patients and the providers face a different decision: Will the patients retain their right to privacy or receive needed health care? These options are mutually exclusive.

The goal of the current Privacy Rule is to “[a]chiev[e] workability without sacrificing [privacy] protection....” 65 Fed. Reg. at 82,472. Under the proposed amendments, “the Department’s goal is to permit these activities [treatment, payment, and health care activities] to occur with little or no restriction.” 67 Fed. Reg. at 14,778. The “reason and experience” of the country, as well as one of the largest rule-making records in the history of the Department, show that the Department’s new goal is not consistent with the wishes of the public, the requirements for quality health care, or the intent of Congress under HIPAA. As the current Privacy Rule found:

“The Congress recognized that adequate protection of the security and privacy of health information is a *sine qua non* of the increased efficiency of information exchange brought about by the electronic revolution, by enacting the security and privacy provisions of the law.” 65 Fed. Reg at 82,474.

The new goal expressed in the proposed amendments is simply not consistent with the objectives of the statute as recognized in the current Privacy Rule.

F. The proposed rule will increase, rather than decrease, administrative burdens on providers.

One of the reasons mentioned by the proposed amendments for eliminating the right of consent is that some providers raised concerns about the burden of perhaps needing to obtain consent “for each patient encounter.” 67 Fed. Reg. at 14,780. (Those providers apparently agree, however, that consent for treatment for each patient encounter is appropriate and not overly burdensome.)

If the individual’s right to not have health information used or disclosed without consent were eliminated, health plans would demand that every physician, hospital, and other provider disclose all of their patients’ identifiable health information initially and continually under the guise of needing it for “health care operations.” The right of consent for disclosure and the confidential nature of the physician-patient relationship traditionally has been the only effective deterrent to unlimited requests for patient information by health plans. If the patients’ right of consent is eliminated as part of the federal floor of privacy protections, practitioners will become the information collection conduits for health plans, and the privacy of the physician-patient relationship will be severely eroded.

Recent implementation data (as well as the findings in the current Privacy Rule, 65 Fed. Reg. at 82,471-72) shows that the consent provisions are “workable.” Survey information shows that providers, including hospitals and physicians, believe that the consent provisions of the Privacy Rule are “workable” without amendment. At an April 16 hearing before the Senate Health, Education, Labor and Pensions Committee, the California HealthCare Foundation presented the results of a survey conducted in February and March 2002 of a national sample of covered entities to determine the extent to which they were finding various provisions of the Privacy Rule “workable.” According to the survey, 80% of the respondents found that the consent requirements are either “somewhat workable,” “workable,” or “very workable.” See California HIPAA Privacy Implementation Survey, Executive Summary, at 5 (April 2002). “Hospitals, others and physician groups” were even more likely to feel that the consent requirements are somewhat workable, workable, or very workable. Payers were less likely to feel that the consent requirements are workable.

This survey reveals that providers, such as physicians and hospitals, are capable of implementing the consent provisions of the Privacy Rule and that there is no justification for the wholesale elimination of the patients’ right of consent.

G. Less radical alternatives would preserve the right of consent and address the isolated problems raised by some commenters.

The proposed amendments state that the Department welcomes comments and suggestions for “alternative ways effectively to protect patient privacy without adversely affecting access to, or the quality of, health care” if privacy will be “unduly compromised” by the proposed modifications. 67 Fed. Reg. at 14,778. Given that the extensive rule-making record and the history of medicine show that privacy is an indispensable element of quality health care, the question should be how to preserve the privacy that is essential for quality health care while permitting payment and health care operations to be conducted.

According to the proposed amendments, the most significant reason for proposing to eliminate the right of consent is that there are some circumstances where providers might need access to identifiable health information before being able to obtain consent in a face-to-face contact with the patient. 67 Fed. Reg. at 14,779. Using the above guideline, we must ask: What would the patient want and expect while feeling assured that his or her privacy would be protected? (In fact, Deputy Secretary Claude Allen, testifying before the Senate Health, Education, Labor and Pensions Committee on April 16, stated that the Department was employing just such a “patient oriented” approach to the amendments.) Based on the undisputed evidence in the rule-making record, it is clear that patients would **not** want their general right of consent to be eliminated in order to accommodate the temporary need for health information in first encounters.

The specific concerns that the proposed amendments cite as the basis for proposing to eliminate the right of consent are as follows:

1. Pharmacies would not be able to fill prescriptions for new patients without having the patients first come in and provide a written consent.
2. Specialists might need access to patient records before seeing the patient.
3. Hospitals might need access to identifiable health information prior to seeing the patient in order to schedule a procedure.
4. Emergency medical personnel may find it difficult to obtain consent after emergency services are provided because they may not have an ongoing relationship with the patient. 67 Fed. Reg. at 14,779-80.

An alternative that would preserve the patients’ right of consent while addressing the above concerns would be to allow a provider to regard a

physician's order as evidence of the patient's consent to use and disclose identifiable health information necessary to carry out that order until such time as a written consent can be obtained from the patient. If a physician has issued an order for a prescription, a referral to a specialist, or a hospital procedure, it is reasonable to assume that the patient gave consent for the treatment mentioned in the order and that the patient would want identifiable health information used and disclosed to the extent that it is necessary to carry out that order.

This alternative could be implemented merely by inserting the following sentence into Section 164.506(a)(3)(C): "The individual's consent to receive treatment will be inferred by the receipt of a physician's order for care until such time as written consent can be obtained." This would permit the use and disclosure of identifiable health information under the existing exception for "substantial barriers" to communications where the individual's wishes can be "clearly inferred," but written consent cannot be obtained.

The emergency services concern could be addressed by revising the current exception for emergency treatment to permit use and disclosure of health information as follows:

"In emergency treatment situations where prior consent cannot reasonably be obtained prior to treatment." Section 164.506(a)(3)(i)(A)

This is consistent with the way emergency treatment is provided today and would eliminate the requirement for emergency treatment providers who do not have an ongoing relationship with the individual to "circle back" and obtain consent for the use and disclosure of identifiable health information after the services are rendered.

These revisions are more consistent with the Department's professed "patient oriented" approach and preserve the individual's right of consent. These alternatives, therefore, avoid "unduly compromising" the privacy that is necessary for quality health care while permitting access to that care. They are also more consistent with the specific recommendations of the National Committee on Vital and Health Statistics. See Letter from NCVHS to Secretary of Health and Human Services at 2-3 (October 1, 2001).

The proposed amendments state that the Department considered not changing the Privacy Rule as well as other alternatives mentioned in the proposal. 67 Fed. Reg. at 14,807. None of the alternatives listed above or described by the NCVHS are mentioned in the proposed amendments, so it must be assumed that they were not considered.

H. Recommendations

1. Revise the consent requirements to address the limited, hypothetical concerns raised rather than eliminate the current right of consent and thereby cause the type of damage to quality health care documented in the rule-making record.
2. Make sure that individuals will be able to protect the privacy of their own identifiable health information by paying privately or having the services provided for free and not filing a claim for coverage or reimbursement. (This is permitted under the current Privacy Rule. 65 Fed. Reg. at 82,512.)
3. Make clear that any agreement or understanding between a patient and a provider to not use or disclose identifiable health information is binding on third party payers so that they may not coerce providers into violating those agreements by threatening to exclude them from participation in the health plan.
4. Make clear that any “regulatory permission” or other permission for the use or disclosure of identifiable health information under the Privacy Rule should not be construed to waive, directly or indirectly, any privilege granted under federal, state, or local laws or procedures. (Such a statement appears in the current Privacy Rule, 65 Fed. Reg. at 82,521.)
5. Make clear that no revision by these amendments would eliminate any right to give or withhold consent for the use and disclosure of identifiable health information under state law, federal common law, or professional standards of practice. (This appeared to be the position taken by the Department in the hearing before the Senate Committee on Health, Education, Labor and Pensions on April 16, 2002.)
3. **The application of the minimum necessary requirements should not be narrowed or weakened. Section 164.502(b) and 164.508 (67 Fed. Reg at 14,785, 14,797).**

The proposed amendments would exempt from the “minimum necessary” requirements any uses or disclosures for which the covered entity has received authorization. 67 Fed. Reg. at 14,785-86. This would seem to be inconsistent with the requirement for authorization, which is retained in the proposed amendments, that states that any authorization must contain “a description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.” 67 Fed. Reg. at 14,813. This change would also seem to be inconsistent with the assurance under the consent discussion that “the Department intends to enforce strictly the requirements for obtaining an individual’s authorization.” 67 Fed. Reg. at 14,781.

The requirement for an authorization is the only provision in the Privacy Rule that gives the individual the kind of control over “psychotherapy notes” that is necessary for effective psychotherapy. Thus, it is important for quality health care for an individual who authorizes the disclosure of information from psychotherapy notes in a “specific and meaningful fashion” to be assured that the limitations of that authorization will be strictly enforced through the application of the “minimum necessary” standard.

We support the position taken in the proposed amendments that the minimum necessary standard “is not intended to override the professional judgment of the covered entity.” 67 Fed. Reg. at 14,786. A similar statement appears in the preamble to the current Privacy Rule. 65 Fed. Reg. at 82,544. Because this principle is so important, we recommend that it be included in the language of the regulation itself. We recommend that Section 164.502(b)(1) be revised by adding the following statement: “This standard is intended to be consistent with, and not override, professional judgment and standards.”

Recommendations

1. The minimum necessary requirement should continue to apply to identifiable health information that is the subject of an authorization.
 2. The minimum necessary standard should be clarified to reflect the intent that it is to not override professional judgment and standards.
- 4. The definition of marketing should not be narrowed to exclude communications about health related products and services for which the covered entity is compensated. Sections 164.501 and 164.508(a)(3).**

We support the Department’s proposed modification that would require authorization for any use or disclosure for “marketing.” 67 Fed. Reg. at 14,790. We oppose, however, the proposal to eliminate from the definition of marketing any communications intended “to direct or recommend alternative treatments, therapies, health care providers, or settings of care to that individual” even if they are financed by a third party. This use of information would be regarded by most individuals as “marketing,” and the payment to a covered entity to make these communications creates a clear conflict of interest between the interest of the patient and the interest of the covered entity.

We are further quite concerned that the proposed amendments appear to eliminate the requirement that marketing communications include “opt out” instructions. See 164.514(e)(3)(i)(C). It appears that the proposed amendments do not provide any mechanism by which a patient can avoid being contacted

repeatedly, and against his or her wishes, about using alternative health products and services.

Both of these features are likely to be detrimental to the quality of mental health services. Patients suffering from emotional instability are likely to be made more anxious and upset to know that their identifiable health information is being used without their authorization or consent to try to sell them a different product or service. Mental health patients are likely to be even more concerned to find that they cannot stop the dunning calls.

Recommendations

1. Restore the requirement for authorization of the use or disclosure of identifiable health information for communications by a covered entity that are designed to convince a patient to purchase or use a product or service where the covered entity is compensated for making the communication.
2. Permit an individual to “opt out” of receiving marketing communications.
5. **The right of privacy should remain linked to the right of consent for minors. Section 164.502(g)(3).**

The proposed amendments seek to de-link the right of a minor to give consent for treatment and the right to keep information related to that treatment private with respect to parents and guardians. The amendments would permit any covered entity to disclose health information about a minor to a parent or guardian even if state law permits the minor to consent to, and obtain, the health care service independently.

This amendment would deter access by minors to such sensitive health care services as mental health, substance abuse and testing for pregnancy, and sexually transmitted diseases. Numerous studies have shown that many adolescents delay or forego health care because of concerns that their health information will be disclosed to parents or others. See generally, T.L. Cheng, Confidentiality in Health Care: A Survey of Knowledge, Perceptions, and Attitudes Among High School Students, 269 JAMA 1404 (1993). If the disaster at Columbine High School teaches nothing else, it should teach us that access to mental health services for adolescents should be improved rather than reduced.

Recommendation

1. We recommend that the Department retain the current version of Section 164.502(g)(3) that would permit minors who have the right under state law to consent to treatment to preserve the privacy of the identifiable health information related to that treatment.

6. The use of de-identified health information should be encouraged. Section 164.514 (67 Fed. Reg. at 14,799).

The proposed amendment asks for comment on whether a class of “facially de-identifiable” information should be established for research, public health, and health care operations purposes. It would not include name, street address, telephone and fax numbers, e-mail address, social security number, certificate/license number, vehicle identifiers and serial numbers, URLs and IP addresses, full face photos, and any other comparable images. It would include admission, discharge, and service dates, date of death, age (including age 90 or over), and five-digit zip code.

We would support such an amendment to the regulations as an alternative to eliminating consent for treatment, payment, and health care operations. We believe that such an alternative is consistent with the Department’s commitment “to strongly encourage the use of de-identified information wherever feasible.” 67 Fed. Reg. at 14,783. As the Department noted in the discussion on the minimum necessary standard, “covered entities may be tempted to disclose an entire medical record when only a few items of information are necessary to avoid the administrative step of extracting or redacting information.” 67 Fed. Reg. at 14,786. The same can be said of requests for identifiable health information.

We have long been of the view that the Privacy Rule should create incentives to use de-identified health information wherever possible by making it more difficult to use and disclose identifiable health information. The proposed elimination of the right of consent is a step in the opposite direction which will lead to requests and disclosures of identifiable health information when de-identifiable health information could be used. For example, many quality assurance and health care operations activities could be accomplished with de-identified information. As the proposed amendments acknowledge, patients generally do not want or expect their identifiable health information to be used for health care operations purposes that are not related to their health care. 67 Fed. Reg. at 14,783.

Recommendation

1. The Privacy Rule should create incentives for covered entities to use and disclose de-identified information wherever possible.

We appreciate the opportunity to provide comments and look forward to working with the Department to implement a Privacy Rule that fulfills its stated objectives (1) “to protect and enhance the rights of consumers,” (2) “to improve the quality of health care in the U.S. by restoring trust in the health care system,”

and (3) “to improve the efficiency and effectiveness of health care delivery.” 65 Fed. Reg. at 82,463.

Very truly yours,

James C. Pyles
On behalf of:

The American Psychoanalytic
Association

and

The National Coalition of
Mental Health
Professionals and
Consumers