contract, the covered entity take steps to cure the breach or end the violation. Accordingly, the Department, in its July 6 guidance, clarified that active monitoring of the actions of business associates is not required of covered entities, and more importantly, that covered entities are not responsible or liable for the actions of their business associates.

A number of commenters urged the Department to exempt covered entities from having to enter into contracts with business associates who are also covered entities under the Privacy Rule. The Department continues to believe, as stated in the preamble to the Privacy Rule, that a covered entity that is a business associate should be restricted from using or disclosing the protected health information it creates or receives through its business associate function for any purposes other than those explicitly provided for in its contract. In addition, the contract serves to clarify the uses and disclosures made as, and the protected health information held by, the covered entity, versus those uses and disclosures made as, and the protected health information held by, the same entity as the business associate.

Many commenters continued to express concerns that requiring business associate contracts between health care providers in treatment situations would burden and impede quality care. The Department clarifies that the Privacy Rule does not require a contract for a covered entity to disclose protected health information to a health care provider for treatment purposes. In fact, such disclosures are explicitly excepted from the business associate requirements. See § 164.502(e)(1). For example, a hospital is not required to have business associate contracts with health care providers who have staff privileges at

the institution in order for these entities to share protected health information for treatment purposes. Nor is a physician required to have a business associate contract with a laboratory as a condition of disclosing protected health information for the treatment of an individual.

Some commenters requested clarification as to whether business associate contracts were required between a health plan and the health care providers participating in the plan's network. Participation in a plan network in and of itself does not give rise to a business associate relationship to the extent that neither entity is performing functions or activities, or providing services to, the other entity. For example, each covered entity is acting on its own behalf when a provider submits a claim to a health plan, and when the health plan assesses and pays the claim. Discount payment arrangements do not require business associate relationships. However, this does not preclude a covered entity from establishing a business associate relationship with the health plan or another entity in the network for some other purpose. If the health plan and one or more of the providers participating in its network do perform covered functions on behalf of each other, a business associate agreement is required. For example, if one health care provider handles the billing activities of another health care provider in the same network, a business associate contract would be required before protected health information could be disclosed for this activity.

Proposed Modifications

The Department proposes new transition provisions at § 164.532(d) and (e) to

would be eligible for the extension and that deemed compliance would not terminate when these contracts automatically roll over.

Covered entities that were concerned about timely compliance wanted to be able to incorporate the business associate contract requirements at the time they would otherwise be modifying or renewing the contract. Therefore, the extension would only apply until such time as the contract is modified or renewed following the effective date of this modification. Furthermore, the Department proposes to limit the deemed compliance period to one year, as the appropriate balance between maintaining individuals' privacy interests and alleviating the burden on the covered entity.

These transition provisions would apply to covered entities only with respect to written contracts or other written arrangements as specified above, and not to oral contracts or other arrangements. In addition, a covered entity that enters into a contract after the effective date of this modification must have a business associate contract that meets the applicable requirements of §§ 164.502(e) and 164.504(e) by April 14, 2003.

The proposed transition provisions would not apply to small health plans, as defined in the Privacy Rule. Small health plans would still be required to have business associate contracts that are in compliance with the Privacy Rule's applicable provisions, by the Privacy Rule's compliance deadline for such covered entities of April 14, 2004. The Department proposes to exclude this subset of covered entities from these provisions because the statute already provides an additional year for these smaller entities to come into compliance, which should be sufficient for compliance with the Privacy Rule's business associate provisions. In addition, the Department believes that the proposed

model contract provisions (see the Appendix to the preamble) will assist small health plans and other covered entities in their implementation of the Privacy Rule's business associate provisions by April 14, 2004.

Proposed § 164.532(e)(2) provides that, after the Privacy Rule's compliance date, these new provisions would not relieve a covered entity of its responsibilities with respect to making protected health information available to the Secretary, including information held by a business associate, as necessary for the Secretary to determine compliance. Similarly, under proposed § 164.532(e)(2), these provisions would not relieve a covered entity of its responsibilities with respect to an individual's rights to access or amend his or her protected health information held by business associates, or receive an accounting of uses and disclosures by business associates, as provided for by the Privacy Rule's requirements at §§ 164.524, 164.526, and 164.528. Covered entities would still be required to fulfill individuals' rights with respect to their protected health information, including information held by a business associate of the covered entity. Covered entities must ensure, in whatever manner effective, the appropriate cooperation by their business associates in meeting these requirements.

The Department retains without modification the standards and implementation specifications that apply to business associate relationships as set forth at §§ 164.502(e) and 164.504(e), respectively, of the Privacy Rule.

E. Uses and Disclosures of Protected Health Information for Marketing

The Privacy Rule defines "marketing" at § 164.501 as a communication about a

product or service, a purpose of which is to encourage recipients of the communication to purchase or use the product or service, subject to certain limited exceptions. The definition does not limit the type or means of communication that is considered marketing. In general, a covered entity is not permitted to use or disclose protected health information for the purposes of marketing products or services that are not health-related without the express authorization of the individual. Moreover, the Privacy Rule prohibits a covered entity from selling lists of patients or enrollees to third parties, or from disclosing protected health information to a third party for the independent marketing activities of the third party, without the express authorization of the individual.

The Department understands that covered entities need to be able to discuss their own health-related products and services, or those of third parties, as part of their everyday business and as part of promoting the health of their patients and enrollees. For example, a health care provider may recommend to a patient a particular brand name drug for the treatment of that patient. Even though these communications also meet the above definition of "marketing," the Privacy Rule does not require an authorization for such communications. Instead, the Privacy Rule addresses these types of health-related communications in two ways.

First, the Department did not want to interfere with or unnecessarily burden communications about treatment or about the benefits and services of plans and providers. Therefore, the Privacy Rule explicitly excludes from the definition of "marketing" certain health-related communications that may be part of a covered entity's treatment of the individual or its health care operations, but that may also promote the use or sale of a

service or product. For example, communications made by a covered entity for the purpose of describing the participating providers and health plans in a network, or describing the services offered by a provider or the benefits covered by a health plan, are excluded from the definition of "marketing." In addition, communications made by a health care provider as part of the treatment of a patient and for the purpose of furthering that treatment, or made by a covered entity in the course of managing an individual's treatment or recommending an alternative treatment, are not considered marketing under the Privacy Rule. These exceptions do not apply, however, to written communications for which a covered entity is compensated by a third party. The Department intended that covered entities be able to discuss freely their products and services and the products and services of others in the course of managing an individual's health care or providing or discussing treatment alternatives with an individual. Under the Privacy Rule, therefore, covered entities are permitted to use and disclose protected health information for these excepted activities without authorization under § 164.508.

Second, the Privacy Rule permits, at § 164.514(e), covered entities to use and disclose protected health information without individual authorization for other health-related communications that meet the definition of "marketing," subject to certain conditions on the manner in which the communications are made. The Privacy Rule does not condition the substance of health-related marketing communications. Rather, it attempts to assure that individuals are aware of the source of the communication and the reason they received such communications, as well as to provide individuals with some control over whether or not they receive these communications in the future.

Specifically, the Privacy Rule permits a covered entity to use or disclose protected health information to communicate to individuals about the health-related products or services of the covered entity or of a third party if the communication: (1) identifies the covered entity as the party making the communication; (2) identifies, if applicable, that the covered entity received direct or indirect remuneration from a third party for making the communication; (3) generally contains instructions describing how the individual may opt out of receiving future communications about health-related products and services; and (4) where protected health information is used to target the communication about a product or service to individuals based on their health status or health condition, explains why the individual has been targeted and how the product or service relates to the health of the individual. The Privacy Rule also requires a covered entity to make a determination, prior to using or disclosing protected health information to target a communication to individuals based on their health status or condition, that the product or service may be beneficial to the health of the type or class of individual targeted to receive the communication.

For certain permissible marketing communications, however, the Department did not believe these conditions to be practicable. Therefore, § 164.514(e) also permits, without the above conditions, a covered entity to make a marketing communication that occurs in a face-to-face encounter with the individual, or that involves products or services of only nominal value. These provisions permit a covered entity to discuss services and products, as well as provide sample products without restriction, during a face-to-face communication, or distribute calendars, pens, and other merchandise that

generally promote a product or service if they are of only nominal value.

Public Comments

The Department received many comments on the Privacy Rule's marketing requirements, as well as recommendations from the NCVHS, based on public testimony from trade associations, medical associations, insurance commissioners, academic medical centers, non-profit hospitals, and consumers. Both industry and consumer groups argued that the marketing provisions were complicated and confusing. Covered entities expressed confusion over the Privacy Rule's distinction between health care communications that are excepted from the definition of "marketing" versus those that are marketing but permitted subject to the special conditions in § 164.514(e). For example, commenters questioned if, and if so, when, disease management communications or refill reminders are "marketing" communications subject to the special disclosure and opt-out conditions in §164.514(e). Commenters also stated that it was unclear how to characterize various health care operations activities, such as general health-related educational and wellness promotional activities, and therefore unclear how to treat such activities under the marketing provisions of the Privacy Rule.

The Department also learned of a general dissatisfaction by consumers with the conditions required by § 164.514(e). Many commenters questioned the general effectiveness of the conditions and whether the conditions would properly protect consumers from unwanted disclosure of protected health information to commercial entities, the re-disclosure of the information by these commercial entities, and the intrusion

of unwanted solicitations. They did not feel that they were protected by the fact that commercial entities handling the protected health information would be subject to business associate agreements with covered entities. In addition, commenters expressed specific dissatisfaction with the provision at § 164.514(e)(3)(iii) for individuals to opt out of future marketing communications. Many argued for the opportunity to opt out of marketing communications before any marketing occurred. Others requested that the Department limit marketing communications to only those consumers that affirmatively chose to be the target of such communications.

Proposed Modifications

In response to these concerns, the Department proposes to modify the Privacy Rule to make the marketing provisions clearer and simpler. First, and most significantly, the Department proposes to simplify the Privacy Rule by eliminating the special provisions for marketing health-related products and services at § 164.514(e). Instead, any communication defined as "marketing" in § 164.501 would require authorization by the individual. In contrast to the Privacy Rule, under these proposed modifications, covered entities would no longer be able to make any type of marketing communications without authorization simply by meeting the disclosure and opt-out provisions in the Privacy Rule. The Department believes that requiring authorization for all marketing communications would effectuate greater consumer privacy protection not currently afforded by the disclosure and opt-out conditions of § 164.514(e) of the Privacy Rule.

Second, the Department proposes to maintain the substance of the Privacy Rule's

definition of "marketing" at § 164.501, with minor clarifications. Specifically, the Department proposes to define "marketing" as "to make a communication about a product or service to encourage recipients of the communication to purchase or use the product or service." The proposed modification retains the substance of the "marketing" definition, but changes the language slightly to avoid the implication that marketing is tied to the intent of the communication. Removing language referencing the purpose of the communication would shift the assessment of whether a communication is marketing from the intent of the speaker to the effect of the communication. If the effect of the communication is to encourage recipients of the communication to purchase or use the product or service, the communication would be marketing.

Third, with respect to the exclusions from the definition of "marketing" in § 164.501, the Department has tried to simplify the language to avoid confusion and better conform to other sections of the regulation, particularly in the area of treatment communications, and is proposing one substantive change. The modified language reads as follows: "(1) to describe the entities participating in a health care provider network or health plan network, or to describe if, and the extent to which, a product or service (or payment for such product or service) is provided by a covered entity or included in a plan of benefits; (2) For treatment of that individual; or (3) For case management or care coordination for that individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to that individual."

With respect to the third exclusion, the Department is proposing to replace a communication made "in the course of managing the treatment of that individual," with a

communication for "case management" or "care coordination" for that individual. The Department is proposing these changes for clarity because "case management" and "care coordination" are the terms that are used in the definition of "health care operations," while "managing the treatment of that individual" is not. These changes are not intended to increase the scope of the marketing exclusions.

The Department is proposing to eliminate the distinction in the definition of "marketing" at §164.501 pertaining to written communications for which a covered entity is compensated by a third party. Under the Privacy Rule, exceptions from the definition of "marketing" are only applicable if the communication is made either orally or in writing when no remuneration from a third party has been paid to a covered entity for making the communication. The Department found that these rules led to confusion and many questions about treatment-related communications, such as prescription refill reminders. Many commenters felt that these restriction rules could burden the ability of providers and patients to communicate freely about treatment. Most commenters did not want any treatment communications to be considered marketing. The Department understands these concerns and wants to avoid situations where a health care provider would be required to obtain an authorization to send out a prescription refill reminder, even if the provider is compensated by a third party for the activity. Therefore, the Department proposes to eliminate this provision in order to facilitate necessary and important treatment communications.

None of these proposed modifications change the basic prohibition in the Privacy Rule against covered entities selling lists of patients or enrollees to third parties, or from

disclosing protected health information to a third party for the independent marketing activities of a third party, without the express authorization of the individual.

The Department received numerous comments suggesting that the Privacy Rule's marketing exceptions in the definition and under §164.514(e) may not allow for certain common health care communications, such as disease management, wellness programs, prescription refill reminders, and appointment notifications that individuals expect to receive as part of their health care to continue unimpeded. The Department believes that these types of communications are allowed under the exceptions to the definition of "marketing" in the Privacy Rule, and therefore would continue to be allowed under the proposed modification. The Department is interested in comments identifying specific types of communication that should or should not be considered marketing.

To reinforce the policy requiring an authorization for most marketing communications, the Department proposes to add a specific marketing provision at § 164.508(a)(3) explicitly requiring an authorization for a use or disclosure of protected health information for marketing purposes. Additionally, if the marketing is expected to result in direct or indirect remuneration to the covered entity from a third party, the Department proposes that the authorization state this fact. As in the Privacy Rule at § 164.514(e)(2), proposed § 164.508(a)(3) would exclude from the marketing authorization requirements face-to-face communications made by a covered entity to an individual. The Department proposes to retain this exception in the Privacy Rule so that the marketing provisions would not interfere with the relationship and dialogue between health care providers and individuals. Similarly, the Department proposes to retain the Privacy Rule's

exception to the authorization requirement for a marketing communication that concerns products or services of nominal value, but proposes to replace the language with the common business term "promotional gift of nominal value."

Given the above proposal, the Department also proposes to remove § 164.514(e) as unnecessary. Accordingly, conforming changes to remove references to § 164.514(e) are proposed at § 164.502(a)(1)(vi) and in paragraph (6)(v) of the definition of "health care operations" in § 164.501.

With the elimination of the special rules in § 164.514(e), the Department thereby proposes to eliminate the requirement that disclosures for health-related marketing are limited to disclosures to business associates hired to assist the covered entity with the communication. Under the proposed rule, this distinction would serve no purpose, because an authorization would be required for such disclosures and thus the individual would know from the face of the authorization who will receive the information. Similarly, this simplification also would eliminate the requirement that a marketing communication identify the covered entity responsible for the communication. Under the proposal, the individual would have authorized the disclosure and thus would know which plans and providers are disclosing health information for marketing purposes. There would be added burden but no benefit in retaining an additional notification requirement.

F. Parents as Personal Representatives of Unemancipated Minors[1]

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[1]Throughout this section of the preamble, "minor" refers to an unemancipated minor and "parent" refers to a parent, guardian, or other person acting *in loco parentis*.

The Privacy Rule is intended to assure that parents have appropriate access to health information about their children. By generally creating new protections and individual rights with respect to individually identifiable health information, the Privacy Rule establishes new rights for parents with respect to the health information about their minor children in the vast majority of cases. In addition, the Department intended that State or other applicable law regarding disclosure of health information about a minor child to a parent should govern where such law exists.

Under the Privacy Rule, parents are granted new rights with respect to health information about their minor children as the personal representatives of their minor children. See § 164.502(g). Generally, parents will be able to access and control the health information about their minor children. See § 164.502(g)(3).

The Privacy Rule recognizes a limited number of exceptions to this general rule. These exceptions generally track the ability of certain minors to obtain specified health care without parental consent under State or other applicable laws. For example, every State has a law that permits adolescents to be tested for HIV without the consent of a parent. These laws are created to assure that adolescents will seek health care that is essential to their own health, as well as public health. In these exceptional cases, where a minor can obtain a particular health care service without the consent of a parent under State or other applicable law, it is the minor and not the parent who may exercise the privacy rights afforded to individuals under the Privacy Rule. See § 164.502(g)(3)(i)-(ii).

The Privacy Rule also allows the minor to exercise control of the protected health information when the parent has agreed to the minor obtaining confidential treatment (see

§ 164.502(g)(3)(iii)), and allows a covered health care provider to choose not to treat a parent as a personal representative of the minor when the provider is concerned about abuse or harm to the child. See § 164.502(g)(5).

Of course, a covered provider always may disclose health information about a minor to a parent in the most important cases, even if one of the limited exceptions discussed above apply. Disclosure of such information is always permitted as necessary to avert a serious and imminent threat to the health or safety of the minor. See § 164.512(j). The Privacy Rule also states that disclosure of health information about a minor to a parent is permitted if State law authorizes or requires disclosure to a parent, thereby allowing such disclosure where State law determines it is appropriate. See § 160.202, definition of "more stringent." Finally, health information about the minor may be disclosed to the parent if the minor involves the parent in his or her health care and does not object to such disclosure. See §§ 164.502(g)(3)(i) and 164.510(b). The parent will retain all rights concerning any other health information about his or her minor child that does not meet one of the exceptions.

Rationale for Privacy Rule's Provisions Regarding Parents and Minors

The Department continues to balance multiple goals in developing standards in the Privacy Rule with respect to parents and minors. First, the standards need to operate in a way that facilitates access to quality health care. This is an overarching goal throughout the Privacy Rule and is equally important here. Thus, the Department wants to ensure that parents have appropriate access to the health information about their minor children to

make important health care decisions about them. The Department also wants to make sure that the Privacy Rule does not interfere with a minor's ability to consent to and obtain health care under current State or other applicable law. Second, the Department does not want to interfere with State or other applicable laws related to competency or parental rights, in general, or the role of parents in making health care decisions about their minor children, in particular. Third, the Department does not want to interfere with the professional requirements of State medical boards or other ethical codes of health care providers with respect to confidentiality of health information or health care practices of such providers with respect to adolescent health care.

As a result of these competing goals, the Department's approach continues to be that the standards, implementation specifications, and requirements with respect to parents and minors defer to, and are consistent with, State or other applicable law and professional practice. Where State and other applicable law is silent, the Department has attempted to create standards that are consistent with such laws and that permit States the discretion to continue to decide the rights of parents and minors with respect to health information without interference from the federal Privacy Rule.

Public Comments

Since December 2000, the Department has heard concerns about the impact of the Privacy Rule on both parental and minor rights. Physicians and other health care professionals who treat adolescents support the existing provisions in the Privacy Rule. These commenters assert that these provisions allow health care providers to deliver care

in a manner consistent with their ethical and legal obligations, and that they strike the appropriate balance by permitting providers to render confidential care to minors in limited circumstances, while providing States the ultimate discretion to determine the extent of parents' access to information.

Other commenters oppose the Privacy Rule on the grounds that the Privacy Rule unduly interferes with parental rights to control health care for their minor children and to access health information about their minor children. They assert that failure to provide parents with access to all health information about their minor children could result in negative health outcomes because parents could be making health care decisions for their children based on incomplete information.

Finally, some commenters believe, incorrectly, that the Privacy Rule creates new rights for minors to consent to treatment. The Department issued guidance to clarify that the Privacy Rule does not address access to treatment or the ability to consent to treatment. It is State or other applicable law, and not the Privacy Rule, that governs who can consent to treatment. The Privacy Rule does not in any way alter the ability of a parent to consent to health care for a minor child or the ability of a minor child to consent to his or her own health care.

Proposed Modifications

The Department has reassessed the parents and minors provisions in the Privacy Rule, and does not propose to change its approach. The Department will continue to defer to State or other applicable law and to remain neutral and preserve the status quo to

the extent possible. However, the Department is proposing changes to these standards where they do not operate as intended and are inconsistent with the Department's underlying goals.

The Privacy Rule accomplishes the goals of deferring to State law and preserving the status quo when State law is definitive, that is, when State law requires or prohibits disclosure or access. However, when State law provides discretion or is silent, the Privacy Rule may not always accomplish these goals. In particular, the Department has identified two areas in which the standard does not work as intended. First, the language regarding deference to State law that authorizes or prohibits disclosure of health information about a minor to a parent fails to assure that State law governs when the law grants a provider discretion to disclose protected health information to a parent in certain circumstances. Second, the Privacy Rule may prohibit parental access in cases where State law is silent, but where a parent could get access today, consistent with State law.

First, in order to assure that State and other applicable laws that address disclosure of health information about a minor to his or her parent govern in all cases, the Department proposes to move the relevant language about the disclosure of health information from the definition of "more stringent" (see § 160.202) to the standards regarding parents and minors (see § 164.502(g)(3)). This change would make it clear that State and other applicable law governs not only when a State explicitly addresses disclosure of protected health information to a parent but also when such law provides discretion to a provider.

The language itself is also changed in the proposal to adapt it to the new section.

The proposed language in § 164.502(g)(3)(ii) states that a covered entity may disclose protected health information about a minor to a parent if an applicable provision of State or other law, including applicable case law, permits or requires such disclosure, and that a covered entity may not disclose protected health information about a minor to a parent if an applicable provision of State or other law, including applicable case law, prohibits such disclosure. This new language would help clarify when disclosure of health information about a minor to his or her parent is permitted or prohibited based on State or other law. The revision would also clarify that the deference to State or other applicable law includes deference to established case law as well as an explicit provision in a statute or regulation.

Second, the Department proposes to add a new paragraph (iii) to § 164.502(g)(3) to establish a neutral policy regarding the right of access of a parent to health information about a minor under § 164.524, in the rare circumstance in which the parent is technically not the personal representative of the minor under the Privacy Rule. This policy would apply particularly where State or other law is silent or unclear. The new paragraph would not change the right of access, but would simply provide that the person who can exercise the right of access to health information under the Privacy Rule must be consistent with State or other applicable law. It would assure that the Privacy Rule would not prevent a covered entity from providing such access, in accordance with the Privacy Rule, to a parent, as if a personal representative of the minor child, if access would be consistent with State or other applicable law.

This modification also would not affect a parent's right of access under the Privacy Rule in the vast majority of cases where the parent is the personal representative of the

minor. In those cases, the parent could exercise the right of access in accordance with the Privacy Rule. This provision would be relevant only in the rare exceptions in which the parent is not the personal representative of the minor.

The Department proposes to use the phrase "consistent with State or other applicable law" with regard to access in the personal representatives section of the Privacy Rule. This is different than the proposed language in the section about personal representatives that relates to disclosures, in which a disclosure to a parent is permitted if such disclosure is permitted or required by an "applicable provision of State or other law, including applicable case law." The language in the disclosure paragraphs requires an explicit law for such disclosure to be permitted by the Privacy Rule. The language in the access paragraphs permits parental access in accordance with the Privacy Rule if such access is consistent with State or other law, regardless of whether such law is explicit. Therefore, if a State permits a minor to obtain care without the consent of a parent, but is silent as to whether the parent can access the related medical records of the minor, as is typically the case, then the provider may provide access to the parent if such access is consistent with State law and could deny access to the parent if such denial of access is consistent with State law. This may be based on interpretation of State consent law or may be based on other law. The provider could not, however, abuse this provision to deny access to both the parent and the minor.

This provision would not significantly change the operation of the Privacy Rule with respect to parental access. In cases where the parent is not the personal representative of the minor under the Privacy Rule, the proposed language would not

require a provider to grant access to a parent. In these cases, a provider would have discretion to provide access to a parent when permitted to do so under State or other applicable law despite the ability of the minor to obtain health care confidentially or without parental consent under applicable law or professional practice. The Department further assumes that current professional health care provider practices with respect to access by parents and confidentiality of minor's records are consistent with State and other applicable law. In any event, parental access under this section would continue to be subject to any relevant limitations on access in § 164.524. This proposed change provides States with the option of clarifying the interaction between their consent laws and the ability for parents to have access to the health information about the care that their minor children received in accordance with such laws. As such, this change should more accurately reflect current State law.

G. Uses and Disclosures for Research Purposes

1. Institutional Review Board (IRB) or Privacy Board Approval of a Waiver of Authorization

Much of the biomedical and behavioral research conducted in the U.S. is governed either by the rule entitled "Federal Policy for the Protection of Human Subjects" (the "Common Rule") and/or the Food and Drug Administration's (FDA) human subject protection regulations. Although these regulatory requirements, which apply to federally-funded and to some privately-funded research, include protections to help ensure the privacy of subjects and the confidentiality of information, the intent of the Privacy Rule,

among other things, is to supplement these protections by requiring covered entities to implement specific measures to safeguard the privacy of individually identifiable health information.

The Common Rule applies to all human research that is supported, conducted, or regulated by any of the seventeen federal agencies that have adopted the Common Rule, including research that uses individually identifiable health information. FDA's human subject protection regulations generally apply to clinical investigations under FDA's jurisdiction, whether or not such research is federally funded. Both sets of regulations have requirements relating to review by an institutional review board (IRB) to ensure that the risks to research participants, including privacy risks, are minimized. As part of this review, generally, IRBs must consider the informed consent document that will be used to inform prospective research participants about the study. Both the Common Rule and FDA regulations have provisions relating to the waiver of informed consent. The Common Rule waiver provisions allow research covered by the Common Rule to be conducted if an IRB determines that certain criteria specified in the Common Rule have been met. FDA's regulations do not contain equivalent waiver provisions since the criteria for a waiver of informed consent are generally not appropriate for clinical research. However, FDA's human subject protection regulations contain exceptions to informed consent for emergency research and for the emergency use of an investigational product.

The Common Rule and FDA's regulations explicitly address privacy and confidentiality in the following places: (1) the informed consent document is required to include "a statement describing the extent, if any, to which confidentiality of records

identifying the subject will be maintained" (Common Rule §___.116(a)(5), 21 CFR 50.25(a)(5)); and (2) to approve a study an IRB must determine that "when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data" (Common Rule §____.111(a)(7), 21 CFR 56.111(a)(7)).

Privacy Rule

The Privacy Rule builds upon these existing federal regulations. The requirements are intended to strike a balance by minimizing the privacy risks of research participants, while not impeding the conduct of vital national and international research. For research participants, this means that they will have more information about how their protected health information may be used for research purposes. The Privacy Rule requires researchers who are subject to the Common Rule or FDA's human subject protection regulations to make some changes to the way they use and disclose protected health information. Researchers who are not currently subject to these requirements may, however, need to make more significant changes to current practice.

The Privacy Rule at §§ 164.508 and 164.512(i) establishes the conditions under which covered entities may disclose protected health information for research purposes. In general, covered entities are permitted to use or disclose protected health information for research either with individual authorization, or without individual authorization in limited circumstances and under certain conditions.

A covered entity is permitted to use and disclose protected health information for research purposes with an authorization from the research participant that meets the

requirements of § 164.508 of the Privacy Rule. Additional requirements apply to research that is not solely record-based but, rather, involves the treatment of individuals. Specifically, in order for a covered entity to use or disclose protected health information that it creates from a research study that includes treatment of individuals (e.g., a clinical trial), the Privacy Rule at § 164.508(f) requires that additional research-specific elements be included in the authorization form, which describes how protected health information created for the research study will be used or disclosed. The Privacy Rule provides that such an authorization pursuant to § 164.508(f) may be combined with the traditional informed consent document used in research, as well as the consent required under § 164.506 and the notice of privacy practices required under § 164.520. In addition, a covered entity is permitted to condition the provision of the research-related treatment on the individual's authorization for the covered entity to use and disclose protected health information created from the study. The Privacy Rule, however, does not permit an individual authorization form for a research use or disclosure of existing protected health information to be combined with a research informed consent document or an authorization form for research that involves treatment.

Alternatively, a covered entity is permitted to use or disclose protected health information for research purposes without authorization by the research participant if the covered entity first obtains either of the following:

• Documentation of approval of a waiver of authorization from an IRB or a Privacy Board. The Privacy Rule delineates specific requirements for the elements that must be documented, including the Board's determinations with respect to eight defined

waiver criteria.

• Where a review is conducted preparatory to research or where research is conducted on decedent's information, certain representations from the researcher, including that the use or disclosure is sought solely for such a purpose and that the protected health information is necessary for the purpose.

Public Comment

A number of commenters argued that the waiver criteria in the Privacy Rule were confusing, redundant, and internally inconsistent. These commenters urged the Department to simplify the provisions, especially for entities subject to both the Privacy Rule and the Common Rule. Consequently, these commenters recommended that the Privacy Rule be modified to allow protected health information to be used or disclosed for research without individual authorization if informed consent is obtained as stipulated by the Common Rule or FDA's human subject protection regulations, or waived as stipulated by the Common Rule. Commenters who favored these changes asserted that the existing federal human subject protection regulations adequately protect all of the rights and welfare of human subjects, and therefore, the Privacy Rule's provisions are unnecessary and duplicative for research currently governed by federal regulations. These commenters also argued that the Privacy Rule's waiver criteria and requirements for individual authorization, in effect, inappropriately modify the Common Rule, since the Privacy Rule prohibits covered entities from honoring an IRB's decisions unless the Privacy Rule's requirements are met. Some of these commenters further suggested that the

confidentiality provisions of the Common Rule and FDA's human subject protection regulations be reviewed to determine if they adequately protect the privacy of research participants, and if found to be inadequate, these regulations should be modified.

The Department understands commenters' recommendations to simplify the Privacy Rule as it applies to research. However, as stated in the preamble to the Privacy Rule and the Department's July 6 guidance, the Department disagrees that the Privacy Rule will modify the Common Rule. The Privacy Rule regulates only the content and conditions of the documentation that covered entities must obtain before using or disclosing protected health information for research purposes.

The NCVHS also heard a number of concerns and confusion in testimony at the August 2001 hearing regarding the research provisions in the Privacy Rule. As a result, the NCVHS generally recommended that the Department provide additional guidance in this area. Consistent with this recommendation, the HHS Office for Civil Rights and the HHS Office for Human Research Protections intend to work together to provide interpretations, guidance, and technical assistance to help the research community in understanding the relationship between the Privacy Rule and the Common Rule.

The NCVHS also received testimony requesting that uses and disclosures of protected health information for research be characterized as an element of treatment, payment, and health care operations under the Privacy Rule, and thus be permitted without individual authorization. The NCVHS, in their recommendations to the Department, disagreed with this viewpoint, and expressed support for the policy embodied in the Privacy Rule, permitting uses and disclosures for research pursuant to an

authorization or an IRB or Privacy Board waiver of authorization.

In addition, the NCVHS received testimony regarding the issue of recruiting research subjects. Commenters expressed concern and confusion as to how researchers would be able to recruit research subjects when the Privacy Rule does not permit protected health information to be removed from the covered entity's premises during reviews preparatory to research. The NCVHS recommended that the Department provide guidance on this issue. The Department clarifies that the Privacy Rule's provisions for IRB or Privacy Board waiver of authorization are intended to encompass a partial waiver of authorization for the purposes of allowing a researcher to obtain protected health information necessary to recruit potential research participants. For example, even if an IRB does not waive informed consent and individual authorization for the study itself, it may waive such authorization to permit the disclosure of protected health information to a researcher as necessary for the researcher to be able to contact and recruit individuals as potential research subjects.

Many researchers also expressed concerns that the Privacy Rule's de-identification safe harbor was so strict that it would result in more research being subject to IRB review than is currently the case. These commenters requested that the standards for de-identification be changed in order to make de-identification a more plausible option for the sharing of data with researchers.

The Privacy Rule's de-identification safe harbor was not designed to be used for research purposes. Rather, the Privacy Rule permits uses and disclosures of protected health information for research purposes with individual authorization, or pursuant to an

IRB or Privacy Board waiver of authorization as permitted by § 164.512(i). The Department is aware, however, that some research is conducted today without IRB oversight because the information is not facially identifiable. While the Department is not convinced of the need to modify the safe harbor standard for de-identified information, the Department is requesting comment on an alternative approach that would permit uses and disclosures of a limited data set for research purposes which does not include facially identifiable information but in which certain identifiers remain. See section III.I of the preamble regarding de-identification of protected health information for a detailed discussion of this proposed approach.

A number of commenters were concerned about the Privacy Rule's requirement for "a statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke...", because this provision would prohibit researchers from analyzing the data collected prior to the individual's decision to revoke his or her authorization. The Department is not proposing to modify this provision. The Privacy Rule limits an individual's right to revoke his or her authorization by the extent to which the covered entity has taken action in reliance on the authorization. Therefore, even though a revocation will prohibit a covered entity from further disclosing protected health information for research purposes, the exception to this requirement is intended to allow for certain continued uses of the information as appropriate to preserve the integrity of the research study, e.g., as necessary to account for the individual's withdrawal from the study.

The Department believes that researchers have established practices for

accommodating an individual's decision to withdraw from a research study. Indeed, the Common Rule at §__46.116 and FDA's human subject protection regulations at 21 CFR 50.25(a)(8) contain similar provisions that require the informed consent document include a statement that "...the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." However, the Department understands that these practices may not be uniform and may vary depending on the nature of the research being conducted, with respect to the continued use or disclosure of data collected prior to the participant's withdrawal. If covered entities were permitted to continue using or disclosing protected health information for the research project even after an individual had revoked his or her authorization, this would undermine the primary objective of the authorization requirements to be a voluntary, informed choice of the individual. The Department believes that limiting uses and disclosures following revocation of an authorization to those necessary to preserve the integrity of the research appropriately balances the individual's right of choice and the researcher's reliance on the authorization. However, the Department solicits comment on other means of achieving this balance.

Specific comments, including testimony to the NCVHS, are addressed below where relevant to the corresponding proposed modifications to the Privacy Rule.

Proposed Modifications to Waiver Criteria

The Department understands commenters' concerns that several of the Privacy Rule's criteria for the waiver of a research participant's authorization are confusing and

redundant, or inconsistent and conflicting with the Common Rule's requirements for the waiver of an individual's informed consent. However, since the Common Rule's criteria for the waiver of informed consent do not explicitly require IRBs to consider issues related to the privacy of prospective research participants, the Department disagrees with the recommendation to exempt from the Privacy Rule research uses and disclosures that are made with a waiver of informed consent pursuant to the Common Rule.

In response to commenter concerns, the Department proposes the following modifications to the waiver criteria to maintain uniform standards in the Privacy Rule for all research, whether or not the research is subject to the Common Rule, as well as to ensure that the Privacy Rule's waiver process works more seamlessly with the Common Rule's waiver process. The Department, in reassessing the waiver criteria defined by the Common Rule, believes that only two of the Common Rule waiver criteria are practicable when focused solely on patient privacy. Accordingly, the Department proposes to retain the following two criteria in the Privacy Rule that are comparable to two of the Common Rule criteria: (1) the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals; and (2) the research could not practicably be conducted without the waiver or alteration. The criterion in the Common Rule to determine that the rights and welfare of subjects will not adversely be affected, when limited to privacy, seems to conflict with the criterion regarding assessing minimal privacy risk; it is not clear how both criteria can be met when the focus is solely on privacy. The Department therefore proposes to delete the criterion in the Privacy Rule that the alteration or waiver will not adversely affect the privacy rights and the welfare of the

individuals.

Moreover, the Department understands commenters' concerns that substantial overlap and potential inconsistency may exist among three of the Privacy Rule's criteria and the criterion that the use or disclosure involves no more than a minimal risk to the individuals. The Department believes that the three criteria in the Privacy Rule that focus on (1) plans to protect identifiers from improper use and disclosure, (2) plans to destroy the identifiers at the earliest opportunity, and (3) adequate written assurances against redisclosure, essentially help to define when the research use or disclosure poses only a minimal risk to the individual's privacy interests, rather than operate as stand-alone criteria. As such, the Department proposes to require the assessment of these three factors as part of the waiver criterion for assessment of minimal privacy risk. This provision does not preclude the IRB or Privacy Board from assessing other criteria as necessary to determine minimal privacy risk, e.g., whether the safeguards included in the protocol are appropriate to the sensitivity of the data.

In addition, the Department agrees with commenters that the following waiver criterion is unnecessarily duplicative of other provisions to protect patients' confidentiality interests, and therefore, proposes to eliminate it: the privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individual, and the importance of the knowledge that may reasonably be expected to result from the research.

Lastly, the Department proposes to retain the criterion that the research could not practicably be conducted without access to and use of the protected health information.

The Privacy Rule permits a covered entity to reasonably rely on a researcher's documentation of approval of these waiver criteria, and a description of the data needed for the research as approved by an IRB or Privacy Board, to satisfy it's obligation with respect to limiting the disclosure to the minimum necessary.

In sum, the Department proposes that the following wavier criteria replace the waiver criteria listed in the Privacy Rule at § 164.512(i)(2)(ii):

(1) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

(a) an adequate plan to protect the identifiers from improper use and disclosure;

(b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(c) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(2) The research could not practicably be conducted without the waiver or alteration; and

(3) The research could not practicably be conducted without access to and use of the protected health information.

The Department believes that the proposed modifications to the waiver criteria in

the Privacy Rule would eliminate both the redundancies in the waiver criteria and the conflicts these provisions pose to research conducted pursuant to the Common Rule.

2. Research Authorizations

Several commenters argued that certain authorization requirements in the Privacy Rule at § 164.508 are problematic as applied to research uses and disclosures. Generally, commenters raised concerns that the requirements for individual authorization for uses and disclosures for research purposes are unduly complex and burdensome. In response to these concerns, the Department proposes to make a number of modifications to simplify the authorization requirements, both generally and in certain circumstances as they specifically apply to uses and disclosures of protected health information for research. The discussion below focuses on the proposed modifications specific to uses and disclosures for research. See section III.H of the preamble for a discussion of the Department's general proposal to modify the Privacy Rule's authorization requirements.

In particular, the Department proposes a single set of requirements that generally apply to all types of authorizations, including those for research purposes. This modification would eliminate the specific provisions at § 164.508(f) for authorizations for uses and disclosures of protected health information created for research that includes treatment of the individual. As a result, an authorization for such purposes would not require any additional elements above and beyond those required for authorizations in general at § 164.508(c). To conform to this proposed change, the Department also proposes to modify the requirements for prohibiting conditioning of authorizations at §

164.508(b)(4)(i) to remove the reference to § 164.508(f). A covered health care provider, thus, would be able to condition the provision of research-related treatment on provision of an authorization for the use and disclosure of protected health information for the particular research study.

Additionally, the Department proposes to modify § 164.508(b)(3)(i) to reflect its intent to eliminate the special authorization requirements for research studies that involve treatment in § 164.508(f), as well as to clarify that the Privacy Rule would allow an authorization for the use or disclosure of protected health information for research to be combined with any other legal permission related to the research study, including another authorization or consent to participate in the research. The Department heard from several provider groups who thought the authorization provisions as they relate to research to be too complex. These commenters argued in favor of permitting covered entities to combine all of the research authorizations required by the Privacy Rule with the informed consent to participate in research. To simplify the requirements in response to these concerns, the Department proposes to modify the Privacy Rule to allow for the combining of such permissions.

Finally, the Department proposes to include provisions specific to authorizations for research within the core element proposed at § 164.508(c)(1)(v) for an expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. First, the Department proposes to explicitly provide that the statement "end of the research study" or similar language is sufficient to meet this requirement for an expiration date or event where the authorization is for a use or disclosure of protected health

information for research. This modification is proposed in response to commenter concerns that the particular end date of a research study may not be known and questions regarding whether the end of a research study is an "event". In addition, such a statement would also be sufficient to encompass additional time, even after the conclusion of the research, to allow for the use of protected health information as necessary to meet record retention requirements to which the researcher is subject. The Department, therefore, proposes to clarify that including such a statement on the research authorization would fulfill the requirement to include an expiration event.

Similarly, the Department proposes to explicitly provide that the statement "none" or similar language is sufficient to meet this provision if the authorization is for a covered entity to use or disclose protected health information for the creation or maintenance of a research database or repository. The Department proposes this modification in response to commenter concerns that the Privacy Rule's requirement for an "expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure" will create a significant obstacle for the development of research databases or repositories. Commenters stated that research databases and repositories are often retained indefinitely, and the requirement that an authorization include an expiration date or event was found to be counter to the purpose of developing such research resources. The Department understands these concerns and, therefore, proposes to permit an individual's authorization to use or disclose protected health information for the creation and maintenance of a research database or repository to be valid without an expiration date or event. The Department emphasizes that this provision is intended to apply only in the

limited circumstances where a use or disclosure is sought solely for the creation or maintenance of a database or repository, and does not extend to authorizations for further research or any other purpose. Therefore, subsequent research using the information maintained in the database or repository pursuant to an authorization would require that the authorization include the term "end of the research study" or other explicit expiration date or event.

3. Research Transition Provisions

The Privacy Rule includes at § 164.532 different transition requirements for research that includes treatment (i.e., clinical trials) and for research that does not include treatment (i.e., records research). For research that includes treatment, the Privacy Rule states that as long as legal permission was obtained to use or disclose protected health information for a specific research project, that legal permission will continue to be valid until the completion of the research project; a new permission will not be required to use or disclose protected health information that was created or received either before or after the compliance date. However, for research that does not include treatment, a legal permission obtained before the compliance date will only be valid for the use and disclosure of protected health information obtained before the compliance date. The Privacy Rule does not prescribe the form of the express legal permission in either case. Express legal permission could be a signed agreement by the individual to participate in a privately-funded research study.

The Privacy Rule does not explicitly address transition provisions for research

studies ongoing after the compliance date where the legal permission of the individual had not been sought. This point was noted by several of those who commented on the Privacy Rule's transition provisions as they apply to research. Some of these commenters recommended that the Privacy Rule be revised to grandfather in the research use and disclosure of all protected health information that existed prior to the compliance date. These commenters expressed concern that much data would be lost to the research community since it would often be infeasible or impossible to obtain individuals' permission to use this archival information.

Given the confusion about the transition provisions and to assure that ongoing, vital research will not be impeded, the Department reassessed the relevant provisions and proposes that there be no distinction between research that includes treatment and research that does not, and no distinction between requirements for research conducted with patients' informed consent versus research conducted with an IRB-approved waiver of patients' informed consent. Therefore, the Department proposes to permit a covered entity to use or disclose for a specific research study protected health information that is created or received either before or after the compliance date (if there is no agreed-to restriction in accordance with § 164.522(a)), if the covered entity has obtained, prior to the compliance date an authorization or other express legal permission from an individual to use or disclose protected health information for the research study. In addition, the Department proposes to grandfather in research in which the individual has signed an informed consent to participate in the research study, or an IRB has waived informed consent for the research study, in accordance with the Common Rule or FDA's human

subject protection regulations.

These proposed provisions are intended to apply once any of the permissions described above has been granted, regardless of whether the research study actually has begun by the compliance date or not, provided that the permission was obtained prior to the compliance date. In addition, with respect to the informed consent of the individual, the Department proposes not to limit the transition provisions to an informed consent pursuant to the Common Rule, but rather intends to allow for the transition of an informed consent for privately-funded research. Research studies that do not obtain such express legal permission, informed consent, or IRB waiver prior to the compliance date must obtain either authorization, as required by § 164.508, or a waiver of authorization from an IRB or Privacy Board, as required by § 164.512(i).

H. Uses and Disclosures For Which Authorization Is Required

The Privacy Rule permits covered entities to use and disclose protected health information for treatment, payment, and health care operations (subject to the individual's consent, if applicable) and as necessary for public policy purposes, such as public health and safety, health oversight activities, and enforcement. Covered entities must obtain an individual's voluntary and informed authorization before using or disclosing protected health information for any purpose that is not otherwise permitted or required under the Privacy Rule.

The Privacy Rule provides for the individual's voluntary authorization for uses and disclosure of his or her protected health information by prohibiting, with very limited

exceptions, covered entities from conditioning treatment, payment, or eligibility for benefits or enrollment in a health plan, on obtaining an authorization. Furthermore, in § 164.508(b)(5), the Privacy Rule permits individuals, with limited exceptions, to revoke an authorization at any time. These provisions are intended to prevent covered entities from coercing individuals into signing an authorization that is not necessary for their health care.

To help ensure that individuals give their authorization for the use or disclosure of their protected health information on an informed basis, the Privacy Rule, under § 164.508(c), sets out core elements that must be included in any authorization. These core elements are intended to provide individuals with information needed to make an informed decision about giving their authorization. This information includes specific details about the use or disclosure, as well as providing the individual fair notice about his or her rights with respect to the authorization and the potential for the information to be redisclosed. The Privacy Rule requires authorizations to provide individuals with additional information for specific circumstances under the following three sets of implementation specifications: in § 164.508(d), for authorizations requested by a covered entity for its own uses and disclosures; in §164.508(e), for authorizations requested by a covered entity for disclosures by others; and in §164.508(f), for authorizations for research that includes treatment of the individual. Additionally, the authorization must be written in plain language so individuals can understand the information presented in the authorization.

Public Comments

The Department received a number of comments raising various issues regarding implementation of the authorization requirements. A majority of commenters said the authorization provisions of the Privacy Rule are too complex and confusing. Some commented that the sets of implementation specifications are not discrete, creating the potential for the implementation specifications for specific circumstances to conflict with the required core elements. Others expressed confusion generally about which authorization requirements they would be required to implement.

Commenters also have raised concerns about the revocation provisions in § 164.508(b)(5). The Privacy Rule provides an exception to the individual's right to revoke an authorization where the authorization is obtained as a condition of obtaining insurance coverage, or where other law provides the insurer the right to contest a claim under the policy. The Department intended this provision to permit insurers to obtain necessary protected health information during contestability periods under State law. For example, an individual may not revoke an authorization for the disclosure of protected health information to a life insurer for the purpose of investigating material misrepresentation if the individual's policy is still subject to the contestability period. However, commenters were concerned because other law also provides the insurer with the right to contest the policy itself, not just a claim under the policy, and the Privacy Rule does not provide an explicit exception to allow for this right.

Proposed Modifications

In response to these concerns, the Department is proposing modifications to the

Privacy Rule to simplify the authorization provisions, while preserving the provisions for ensuring that authorizing the use or disclosure of protected health information is a voluntary and informed decision. The Department proposes to consolidate the implementation specifications into a single set of criteria to simplify these provisions, prevent confusion, and eliminate the potential for conflicts between the authorization requirements.

Thus, under the proposed modifications, the specifications for the elements and requirements of an authorization would be consolidated under § 164.508(c). Paragraphs (d), (e), and (f) in this section would be eliminated. Paragraph (c)(1) would require all authorizations to contain the following core elements: (1) a description of the information to be used or disclosed, (2) the identification of the persons or class of persons authorized to make the use or disclosure of the protected health information, (3) the identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure, (4) a description of each purpose of the use or disclosure, (5) an expiration date or event, (6) the individual's signature and date, and (7) if signed by a personal representative, a description of his or her authority to act for the individual. The Department also proposes to add new language to clarify that when the individual initiates the authorization for his or her own purposes, the purpose may be described as "at the request of the individual." Thus, individuals would not have to reveal the purpose of the requested disclosure if they chose not to do so.

Paragraph (c)(2) would require authorizations to contain the following notifications: (1) a statement that the individual may revoke the authorization in writing,

and either a statement regarding the right to revoke, and instructions on how to exercise such right, or to the extent this information is included in the covered entity's notice, a reference to the notice, (2) a statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule, or, if conditioning is permitted by the Privacy Rule, a statement about the consequences of refusing to sign the authorization, and (3) a statement about the potential for the protected health information to be subject to redisclosure by the recipient. The Department also proposes to limit the requirement that a covered entity disclose any remuneration that will result from obtaining an authorization, to authorizations for marketing purposes. Therefore, the remuneration disclosure requirement appears only in the new § 164.508(a)(3) on marketing authorizations. These modifications would permit covered entities to use a single authorization form, and make it easier to use for the individual and the covered entity, as well as third parties.

The Department also proposes to add language to the revocation exceptions in § 164.508(b)(5)(ii) to include an exception with respect to the insurer's right to contest the policy under other law. This proposed modification would recognize, without expanding upon, an insurer's right to contest the policy under existing law.

Other proposed modifications concerning authorizations for research are discussed in section III.G of the preamble.

Finally, the Department proposes a number of technical conforming modifications throughout this section of the Privacy Rule to accommodate the modifications to this section, as well as the proposed modifications to the consent provision. Specifically, the

Department proposes to modify the exception to the minimum necessary standard in the Privacy Rule at § 164.502(b)(2), which exempts from the standard uses or disclosures made pursuant to an authorization under § 164.508, except for authorizations requested by the covered entity under § 164.508(d), (e), or (f). By simplifying the authorization requirements, the proposed modifications described above would eliminate the special authorizations required by § 164.508(d), (e), or (f) in the Privacy Rule. To be consistent with the proposed approach, the Department proposes to eliminate the reference to such authorizations in the exception at § 164.502(b)(2), thereby expanding the exception to exempt from the minimum necessary standard uses and disclosures made pursuant to an authorization for any purpose.

The Department also proposes modifications at §§ 164.508(a)(2)(i)(A), (B), and (C) to place limits on the use and disclosure of psychotherapy notes without authorization to carry out treatment, payment or health care operations. The modifications clarify that this information is not permitted to be used or disclosed without individual authorization for purposes of another entity.

The Department proposes to delete § 164.508(b)(4)(iii), relating to a health plan conditioning payment of a claim on the provision of an authorization, since this provision will be rendered moot under the proposed modifications to the consent provision. Additionally, the Department proposes to delete § 164.508(b)(2)(iv) of the Privacy Rule, because it is redundant with § 164.508(b)(1)(i), and to modify § 164.508(b)(1)(i) to clarify that an authorization is valid only if it meets the requirements of paragraphs (c)(1) and (c)(2). Modifications are also proposed at § 164.508(b)(1)(v) of the Privacy Rule (newly

designated as § 164.508(b)(2)(iv) in the proposed Rule) to clarify that an authorization that violates paragraph (b)(4) (prohibiting the conditioning of authorizations) is not a valid authorization.

These proposed modifications also expressly provide that an authorization is needed for purposes of marketing. See section III.G of the preamble for a detailed discussion of the proposed modifications regarding marketing.

I. De-Identification of Protected Health Information

At § 164.514(a)-(c), the Privacy Rule permits a covered entity to de-identify protected health information so that such information may be used and disclosed freely, without being subject to the Privacy Rule's protections. Health information is de-identified, or not individually identifiable, under the Privacy Rule, if it does not identify an individual and if the covered entity has no reasonable basis to believe that the information can be used to identify an individual. In order to meet this standard, the Privacy Rule provides two alternative methods for covered entities to de-identify protected health information.

First, a covered entity may demonstrate that it has met the standard if a person with appropriate knowledge and experience applying generally acceptable statistical and scientific principles and methods for rendering information not individually identifiable makes and documents a determination that there is a very small risk that the information could be used by others to identify a subject of the information. The preamble to the Privacy Rule refers to two government reports that provide guidance for applying these

principles and methods, including describing types of techniques intended to reduce the risk of disclosure that should be considered by a professional when de-identifying health information. These techniques include removing all direct identifiers, reducing the number of variables on which a match might be made, and limiting the distribution of records through a "data use agreement" or "restricted access agreement" in which the recipient agrees to limits on who can use or receive the data.

Alternatively, covered entities may choose to use the Privacy Rule's safe harbor method for de-identification. Under the safe harbor method, covered entities must remove all of a list of 18 enumerated identifiers and have no actual knowledge that the information remaining could be used alone or in combination to identify a subject of the information. The identifiers that must be removed include direct identifiers, such as name, street address, social security number, as well as other identifiers, such as birth date, admission and discharge dates, and five-digit zip code. The safe harbor does allow for the disclosure of all geographic subdivisions no smaller than a State, as well as the initial three digits of a zip code if the geographic unit formed by combining all zip codes with the same initial three digits contains more than 20,000 people. In addition, age, if less than 90, gender, ethnicity, and other demographic information not listed may remain in the information. The safe harbor is intended to provide covered entities with a simple, definitive method that does not require much judgment by the covered entity to determine if the information is adequately de-identified.

The Privacy Rule also allows for the covered entity to assign a code or other means of record identification to allow de-identified information to be re-identified by the

covered entity, if the code is not derived from or related to information about the subject of the information, e.g., derivation of the individual's social security number, and is not otherwise capable of being translated so as to identify the individual. The covered entity also may not use or disclose the code for any other purpose, and may not disclose the mechanism, e.g., algorithm or other tool, for re-identification.

The Department is cognizant of the increasing capabilities and sophistication of electronic data matching used to link data elements from various sources, and from which, therefore, individuals may be identified. Given this increasing risk to individuals' privacy, the Department included in the Privacy Rule the above stringent standards for determining when information may flow unprotected. The Department also wanted the standards to be flexible enough so the Privacy Rule would not be a disincentive for covered entities to use or disclose de-identified information wherever possible. The Privacy Rule, therefore, strives to balance an individuals' privacy interests with providing a sufficient level of information to make de-identified databases useful.

Public Comments

The Department heard a number of concerns from commenters regarding the de-identification standard in the Privacy Rule. These comments generally were raised in the context of using and disclosing information for research, public health purposes, or for certain health care operations. Commenters were concerned that the safe harbor method for de-identifying protected health information was so stringent that it required removal of many of the data elements that were essential to their analyses for these purposes. The

comments, however, demonstrated little consensus as to which data elements were needed for such analyses, with many commenters requesting elements, such as birth date, neighborhood, account numbers, medical record numbers, and device identifiers. In addition, commenters largely were silent with regard to the feasibility of using the Privacy Rule's alternative statistical method to de-identify information. The Department is aware, however, of a general view of covered entities that the statistical method is beyond their capabilities.

With regard to health care operations, a number of state hospital associations were concerned that the Privacy Rule will prevent them from collecting patient information from area hospitals in order to conduct and disseminate analyses that are useful for hospitals in making decisions about quality and efficiency improvements. These commenters explained that the Privacy Rule's stringent provisions for de-identification would not allow for the necessary data elements to be collected for such analyses. Specifically, commenters identified the following critical elements that would be restricted from disclosure by the Privacy Rule's de-identification standard: five-digit zip code, city, county or neighborhood; the dates on which the injury or illness was treated and the patient released from the hospital; and the month of birth (noted by commenters as especially important for very young children). In addition, commenters argued that the Privacy Rule's provisions for data aggregation by a business associate, while allowing for the collection and aggregation of identifiable data from multiple hospitals for quality and efficiency purposes, would not allow state hospital associations to disclose all the desired analyses back to the contributing hospitals because some identifiers would remain in the

data. These commenters emphasized the importance to hospitals to have access to information about community health care needs and the ability to compare their community to others in the state so that they may adequately respond to and fulfill such needs.

In addition, commenters identified a problem with hospitals themselves sharing aggregated information with other hospitals for health care operations purposes. The Privacy Rule prohibits covered entities from disclosing protected health information for the health care operations purposes of other covered entities. As described in section III.A.2 of the preamble regarding Uses and Disclosures for Treatment, Payment, and Health Care Operations, the Department is proposing to modify this restriction and allow covered entities to disclose protected health information for another covered entity's health care operations under some circumstances. However, two conditions on the sharing of individually identifiable information for health care operations may continue to pose a problem. The proposed modifications would condition the sharing on both entities being covered entities and both entities having a relationship with the individual. Hospitals wishing to exchange patient information with each other or with other community health care providers would not satisfy these conditions in all cases.

Many researchers expressed similar concerns, explaining that the Privacy Rule's de-identification safe harbor was so strict that it would result in more research being done on identifiable health information and, thereby, being subject to IRB review than is currently the case. Under the Common Rule, research that uses "identifiable private information" must undergo IRB review. However, there is no agreed-upon definition of

"identifiable private information" and IRBs determine on a case-by-case basis what constitutes "identifiable private information." Consistent with this variability, the comments did not demonstrate consensus on what identifiers should be permitted to be retained for research purposes.

In addition, commenters also expressed concerns with respect to public health reporting. For example, some product manufacturers subject to the jurisdiction of FDA were concerned that they would not be able to operate post-marketing surveillance registries, to which health care providers report problems. Commenters stated that even though they do not need information with direct identifiers, the Privacy Rule's strict de-identification standard would not allow the reporting of useful information into the registry. Additionally, a number of commenters described the de-identification standard as hampering many research and health care operations activities that also serve a public health purpose, e.g., the tracking of the emergence of disease that could be the result of bioterrorism.

The Department also heard from some consumer advocates who supported the elimination of barriers they believe are imposed by the de-identification standard to important medical research. In order to ensure privacy is protected, but at the same time not render impossible research using de-identified information, these commenters recommended that the Department permit the use of information for research that is facially de-identified, i.e., stripped of direct identifiers, so long as the research entity provides assurances that it will not use or disclose the information for purposes other than research and will not identify or contact the individuals who are the subjects of the