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# A Crosswalk Between the Final HIPAA Privacy Rule and Existing Federal Substance Abuse Confidentiality Requirements

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## BEHAVIORAL HEALTH ISSUE BRIEF SERIES

### Double Issue Brief #18-19

## A Crosswalk Between the Final HIPAA Privacy Rule and Existing Federal Substance Abuse Confidentiality Requirements

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## Introduction

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of Health and Human Services (HHS) to propose standards to protect the privacy of individually identifiable health information by August 21, 1997. On September 11, 1997, the Secretary submitted a report to Congress recommending that Congress pass comprehensive privacy legislation. Under HIPAA, Congress was given two years (until August 21, 1999) to enact privacy legislation. If Congress failed to act by that date, HIPAA directed the Secretary to finalize regulations containing proposed standards relating to the electronic transfer of medical information by February 21, 2000. Despite the statutory deadline, Congress was unable to reach consensus on the numerous privacy bills introduced. The Secretary of Health and Human Services then moved forward as required by HIPAA to promulgate regulations.

On November 3, 1999, HHS published a proposed rule in the *Federal Register* (64 Fed. Reg. 59918) that detailed standards for the privacy of electronically transmitted individually identifiable health information. The proposed regulation was narrower than the Secretary's 1997 legislative recommendations, but was nevertheless broad in scope, protecting electronically exchanged medical records and other personal health information maintained by health care providers, health plans, health insurers and health care clearinghouses.

The Department received over 52,000 comments on the proposed privacy rule, which demonstrated how significant these regulations were to those in the health care industry that use patient medical information for a variety of purposes. In addition, many individuals whose personal medical information is the subject of the rule filed comments on the proposed protections.

Given the magnitude of the response, the Department was unable to meet its statutory deadline under HIPAA to finalize regulations by February 21, 2000. On December 20, 2000, HHS released a comprehensive final regulation (the Privacy Rule).<sup>1</sup>

On February 26, 2001, the Department published a notice in the *Federal Register* postponing the effective date of the Privacy Rule until April 14, 2001.<sup>2</sup> The Department published another notice on February 28, 2001 announcing that public comments on the final regulation would be accepted for a limited period (until March 30, 2001) before the rule became effective.<sup>3</sup>

On April 14, 2001, the Privacy Rule became effective. Despite speculation that HHS would modify the rule prior to its effective date, the Bush Administration allowed the rule to take effect on schedule. HHS received approximately 11,000 new comments on the Privacy Rule during the comment period that ended on March 30, 2001.<sup>4</sup>

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<sup>1</sup> A fact sheet on the final regulation prepared by the U.S. Department of Health and Human Services can be found at <http://aspe.hhs.gov/admnsimp/final/pvcfact2.htm>. The regulation itself is available electronically at <http://aspe.hhs.gov/admnsimp>.

<sup>2</sup> 66 Fed. Reg. 12434 (Feb. 26, 2001).

<sup>3</sup> 66 Fed. Reg. 12738 (Feb. 28, 2001).

<sup>4</sup> HHS noted the number of comments in a July 6, 2001 press release, which can be found at <http://hhs.gov/news/press/2001pres/20010706a.html>.

On July 6, 2001, HHS issued its first guidance on the Privacy Rule.<sup>5</sup> The guidance addresses specific topics in both a brief question-and-answer and detailed comment format. The topics covered include patient consent, parental rights, marketing, medical research, and governmental access issues. Some of these topics (and others) are noted herein where relevant. The press release also noted that HHS “expects to propose appropriate changes to the rule in order to ensure that it does not adversely affect patients’ access to quality health care.”<sup>6</sup> The guidance notes that in order to make any changes, HHS must follow the notice-and-comment provisions of the Administrative Procedures Act.<sup>7</sup> These provisions require publication of the proposed changes in the *Federal Register* and a period of public comment.

This Issue Brief provides an overview of and crosswalk between the Privacy Rule and the federal Confidentiality of Alcohol and Drug Abuse Patient Records statute, 42 U.S.C. § 290dd-2, and its implementing regulations at 42 C.F.R. Part 2 (“42 C.F.R. Part 2”). The crosswalk is intended to highlight the differences between the requirements of the Privacy Rule and 42 C.F.R. Part 2. In addition, this Issue Brief addresses the Privacy Rule’s applicability to special populations and psychotherapy services provided by substance abuse paraprofessionals.

## **The Privacy Rule**

### *General Rule*

In general, the Privacy Rule can be summarized as follows: “Covered entities” may not use or disclose “protected health information” (PHI) except as authorized by the individual who is the subject of the information, or as explicitly required or permitted by the regulation.<sup>8</sup>

Even when the use or disclosure of PHI is permitted, in most circumstances, only the “minimum necessary” amount of information to accomplish the intended purpose of the use, disclosure or request may be provided.

The rules apply to all protected health information maintained, used or disclosed by a covered entity, regardless of the form it takes – electronic, written or oral. This information remains protected during the life of the individual, and information about a deceased individual must remain protected as long as the covered entity maintains the information.

### *Key Definitions*

#### *Covered entities*

“Covered entities” are broadly defined.<sup>9</sup> The term includes:

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<sup>5</sup> The guidance can be found at <http://aspe.hhs.gov/admsimp/final/pvcguide1.htm>. As an example of the changes HHS will propose, the press release cites “modifications to ensure that a pharmacist can fill a phoned-in prescription for a new patient, even when the pharmacist does not first have the patient’s signed consent on file.” *Id.*

<sup>6</sup> See the July 6, 2001 press release at <http://hhs.gov/news/press/2001pres/20010706a.html>.

<sup>7</sup> *Id.*

<sup>8</sup> 45 CFR § 164.502(a), 65 Fed. Reg. 82805 (Dec. 28, 2000).

<sup>9</sup> 45 CFR § 160.103, 65 Fed. Reg. 82799 (Dec. 28, 2000).

- A health plan;
- A health care clearinghouse; and
- A health care provider who transmits health information in electronic form in connection with transactions (i.e., exchanges of information) covered by HIPAA's administrative requirements

#### Health plan

A “health plan” means an individual or group plan that provides, or pays the cost of, medical care (as defined in §2791(a)(2) of the Public Health Service Act (PHSA)). Health plans include:<sup>10</sup>

- Virtually all group health plans (insured or self-insured) covered under the Employee Retirement Income Security Act of 1974 (ERISA) (i.e, those group health plans with 50 or more participants and plans of any size that are administered by other entities);
- Health insurance issuers (as defined by HIPAA to include an insurance company, insurance services, or insurance organization (including a health maintenance organization) that is licensed to engage in the business of insurance in a state and which is subject to state law regulating insurance (within the meaning of ERISA § 514(b)(2));
- HMOs;
- Medicare;
- Medicaid;
- Medicare-supplemental policy issuers;
- An employee welfare benefit plan or any other arrangement providing health benefits to employees of two or more employers;
- MEWAs (multiple employer welfare arrangements);
- Health care programs for active military personnel and veterans;
- CHAMPUS;
- The Indian Health Service;
- The Federal Employees Health Benefit Program;
- Approved SCHIP programs;
- Medicare +Choice plans; and
- State high-risk pools.

#### Health care clearinghouse<sup>11</sup>

“Health care clearinghouses” are public or private entities (including billing companies or community health management information systems) that either (1) process or facilitate processing of health information received from another entity in a nonstandard format into standard data elements or a standard transaction; or (2) receive a standard transaction from another entity and process or facilitate processing of health information into a nonstandard format or nonstandard data content for the receiving entity.

#### Health care provider<sup>12</sup>

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<sup>10</sup> *Id.*

<sup>11</sup> 45 C.F.R. § 160.103, 65 Fed. Reg. 82799 (Dec. 28, 2000).

“Health care providers” are providers of medical or health services and any other person or organization that furnishes, bills or is paid for health care in the normal course of business.

Health care<sup>13</sup>

“Health care” includes preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care. It also includes counseling, service, assessment, or other procedure with respect to the physical or mental condition (or functional status) of an individual or that affects the structure or function of the body.

Protected health information (PHI)<sup>14</sup>

“Protected health information (PHI)” means individually identifiable health information that is transmitted or maintained by electronic media or is transmitted or maintain in any other form or medium.

“Health information” is any information (whether oral or recorded in any form or medium) that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual or the past, present or future payment for the provision of health care to an individual.<sup>15</sup> This definition reflects the broad category of information governed by the administrative simplification provisions of HIPAA.

“Individually identifiable health information” is a subset of “health information.” It is health information that either actually identifies the individual or creates a reasonable basis to believe that the information would identify the individual.<sup>16</sup>

As defined above, PHI is a subset of individually identifiable health information. Note that the protections described below apply to data or information about an individual, not to any particular record. However, once the privacy protections attach to data, the transmitter and receiver of the data must protect every record (written, electronic or other) in which the data appears.

*Disclosure of Protected Health Information*

General rule

Under the Privacy Rule, covered entities may use or disclose PHI *only*:

- with the consent or authorization of the patient; or
- as explicitly permitted or required by the regulation.

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<sup>12</sup> 45 CFR § 160.103, 65 Fed. Reg. 82799 (Dec. 28, 2000).

<sup>13</sup> *Id.*

<sup>14</sup> 45 CFR § 164.501, 65 Fed. Reg. 82805 (Dec. 28, 2000).

<sup>15</sup> 45 CFR § 160.103, 65 Fed. Reg. 82799 (Dec. 28, 2000).

<sup>16</sup> 45 CFR § 164.501, 65 Fed. Reg. 82803 (Dec. 28, 2000).

In addition, individuals have certain rights to their own health information (described below).

### *Consent v. authorization*

Although most people use the terms “consent” and “authorization” interchangeably, the Privacy Rule makes an important distinction between them.<sup>17</sup>

As described in more detail below, “consent” refers to a broad general permission granted by the individual to a health care provider or other covered entity to use or disclose the individual’s PHI for treatment, payment or health care operations purposes.<sup>18</sup>

Different covered entities have different obligations regarding general consents. For example, providers are required to get a signed consent from the patient in order to release PHI to another covered entity or business partner for treatment, payment, and healthcare operations. Health insurers, however, are not required to obtain a general consent to release PHI to covered entities or business partners for such routine operations. A covered entity cannot use a general “consent” by an individual to share PHI with a non-covered entity or non-business partner.

In contrast, an “authorization” refers to a more specific and detailed permission given to a covered or non-covered entity or business partner by an individual to share an individual’s PHI about issues other than treatment, payment, and healthcare operations. All covered entities, including health insurers, providers, health care clearinghouses are required to obtain authorization for the disclosure of PHI for purposes other than routine operations.

In general, the Privacy Rule permits covered entities to use or disclose PHI for treatment, payment or health care operations. Each of these terms is discussed below. The rule contains some specific restrictions on those and other uses and disclosures of PHI.

For example, patient consent is necessary for providers to use or disclose PHI for treatment, payment or health care operations. In the case of other covered entities, disclosures are generally permitted for those uses without consent. A covered entity is only permitted to disclose PHI for other purposes with individual authorization.

### *Patient Consent for Uses or Disclosure of Routine Operations*

A covered health care provider must obtain the individual’s consent prior to using the individual’s PHI for treatment, payment or health care operations (each of these terms is described below). For example, consent is necessary unless the provider:

- has an indirect treatment relationship<sup>19</sup> with the individual,

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<sup>17</sup> The provisions governing “consent” are generally found in 45 CFR § 164.506 and the provisions governing “authorization” are generally found in 45 CFR § 164.508.

<sup>18</sup> For ease of reference, this analysis often refers to health care treatment, payment, and operations as “routine operations.” The terms “routine operations” and “treatment, payment, and operations” are interchangeable.



- is providing health care to an inmate,
- is in an emergency treatment situation (but then the provider must attempt to obtain consent as soon as practicable after the treatment is delivered),
- is required by law to obtain consent but unable to do so, or
- is unable to obtain consent because of substantial communication barriers.<sup>20</sup>

Patient Authorization for Disclosure of Non-Routine Operations

Unless otherwise specified under the regulation, a covered entity may only use or disclose PHI when it receives a valid authorization by an individual. Any use or disclosure of PHI must be consistent with the authorization.<sup>21</sup>

Except in certain circumstances, authorization is required for use or disclosure of psychotherapy notes, which will be discussed more fully below.<sup>22</sup>

Valid authorizations

To be valid, an authorization by the individual must:

- Describe the information to be used or disclosed in a specific and meaningful fashion;
- Name the person or class of persons authorized to make the disclosure or use;
- Name the person or class of persons to whom the disclosure may be made;
- Contain an expiration date that relates to the individual or to the purpose of the disclosure or use;
- Clearly state that the individual has a right to revoke the authorization in writing (and describe the procedure for doing so) as well as any exemptions to the right to revoke;
- Be signed by the individual (or the individual's personal representative) and dated.

The authorization must be written in plain language. In addition, if the proposed disclosure of PHI will be to a non-covered entity, the authorization must clearly state that the individual understands that disclosure to non-covered entities removes any privacy protections that had attached to the PHI.<sup>23</sup>

If a covered entity initiates the request for authorization for disclosure, rather than the individual, certain additional requirements are imposed beyond those described above.

Among the further requirements are:

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<sup>19</sup> An “indirect treatment relationship” means a relationship between an individual and a health care provider in which (1) the health care provider delivers health care to the individual based on the orders of another health care provider, and (2) the health care provider typically provides services, products or reports (e.g., diagnosis) directly to another health care provider who then provides the services or products or reports to the individual. 45 C.F.R. § 164.501; 65 Fed. Reg. 82804 (Dec. 28, 2000).

<sup>20</sup> 45 CFR § 164.506, 65 Fed. Reg. 82810 (Dec. 28, 2000).

<sup>21</sup> 45 CFR § 164.508, 65 Fed. Reg. 82811 (Dec. 28, 2000).

<sup>22</sup> 45 CFR § 164.508(a)(2), 65 Fed. Reg. 82811 (Dec. 28, 2000).

<sup>23</sup> 45 CFR § 164.508(c), 65 Fed. Reg. 82811-12 (Dec. 28, 2000).

1. the covered entity must specify the purposes for which the information is requested and how it will be used so that the individual can make an informed judgment whether or not to consent to the disclosure;
2. the request is subject to the “minimum necessary” requirements, described above;
3. individuals must be advised that they have a right to inspect and copy the information to be used or disclosed and that they have a right to refuse to authorize the requested use or disclosure;
4. treatment, payment, enrollment in the health plan, or eligibility for benefits cannot be conditioned on the individual’s authorization; and
5. if the covered entity will be receiving direct or indirect financial compensation in exchange for using or disclosing the PHI, the authorization must state that disclosure would result in such compensation to the covered entity.

The individual must be given a copy of the signed authorization.<sup>24</sup>

Note that general waivers of confidentiality of a patient’s medical information that often appear on enrollment or claims forms would no longer be valid under this regulation.

#### Required Disclosures/Disclosures Without Consent<sup>25</sup>

Covered entities are required to disclose PHI regarding an individual only in two instances: (1) to the individual who is the subject of the PHI when the individual requests it, and (2) to the Secretary of Health and Human Services when the Secretary is investigating a complaint or determining a covered entity’s compliance with the regulation. A description of the rights of access to PHI for individuals is found in §164.524 (45 Fed. Reg. 82823-24) and an individual’s right to an accounting of disclosures of PHI in §164.528 (45 Fed. Reg. 82826).

#### Permitted uses and disclosures<sup>26</sup>

The proposed regulations permit use or disclosure of PHI only in the following circumstances:

- To the patient (required disclosure if requested);
- Pursuant to a valid consent by the patient that meets the requirements of the regulation to carry out treatment, payment or health care operations;
- Pursuant to a valid authorization by the patient that meets the requirements of the regulation;
- Pursuant to an agreement under, or as otherwise permitted by, the regulation; or

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<sup>24</sup> 45 CFR § 164.508(d), 65 Fed. Reg. 82812 (Dec. 28, 2000).

<sup>25</sup> 45 CFR § 164.502(a)(2), 65 Fed. Reg. 82805 (Dec. 28, 2000).

<sup>26</sup> 45 CFR § 164.502(a)(1), 65 Fed. Reg. 82805 (Dec. 28, 2000).

- As explicitly permitted or required by the regulation (e.g., to the Secretary of HHS for purposes of determining compliance with the rule).

“Treatment” means the provision, coordination, or management of health care and related services by one or more health care providers. It also includes coordination or management of health care by a health provider and a third-party and consultation or referrals between one health care provider and another.<sup>27</sup>

“Payment” includes activities undertaken by a health plan or provider to obtain or provide reimbursement or premiums for the provision of health care and other activities, such as determinations of eligibility or coverage (including coordination of benefits), risk adjustments, billing, claims management, collections, medical necessity reviews, and utilization review.<sup>28</sup>

“Health care operations” includes certain services or activities necessary to carry out the covered functions of the covered entity with respect to treatment or payment, such as conducting quality assessment and improvement activities, outcomes evaluation and development of clinical guidelines (providing that obtaining generalizable knowledge is not the primary purpose of any studies resulting from these activities), population-based activities related to improving health or reducing health care costs, coordinating or managing care, evaluating provider performance, engaging in accreditation, certification or licensing activities, underwriting or premium rating for purposes of creation, renewal, or replacement of a contract of health insurance or health benefits, conducting or arranging for medical review, legal services, and auditing (including detection of fraud and abuse), business planning or development, management activities, customer service, resolution of internal plan grievances, and due diligence in connection with the sale or transfer of assets to a potential successor in interest.<sup>29</sup> Auditing claims and deciding claims appeals are two common plan functions that are included as part of health care operations.

In addition, §164.512 of the final regulation describes a number of situations in which covered entities may disclose the PHI of an individual without the individual’s written consent.<sup>30</sup> Unless a covered entity is specifically required to disclosure PHI without the individual’s consent (e.g., for health care oversight), however, the permission to disclose PHI without consent does not *require* such disclosure. For instance, these disclosures may be made:

- (1) to the extent that the disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of that law;<sup>31</sup>
- (2) for certain public health activities.<sup>32</sup> These might include disclosure to:
  - a public health authority authorized by law to collect information to prevent or control disease or conduct public health surveillance;

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<sup>27</sup> 45 CFR § 164.501, 65 Fed. Reg. 82805 (Dec. 28, 2000).

<sup>28</sup> 45 CFR § 164.501, 65 Fed. Reg. 82804-05 (Dec. 28, 2000).

<sup>29</sup> 45 CFR § 164.501, 65 Fed. Reg. 82803 (Dec. 28, 2000).

<sup>30</sup> 45 CFR § 164.512, 65 Fed. Reg. 82813-18 (Dec. 28, 2000).

<sup>31</sup> 45 CFR § 164.512(a), 65 Fed. Reg. 82813 (Dec. 28, 2000).

<sup>32</sup> 45 CFR § 164.512(b), 65 Fed. Reg. 82813-14 (Dec. 28, 2000).

- a public health authority empowered by law to receive reports of child abuse or neglect;
  - under certain circumstances, to a person subject to the jurisdiction of the Food and Drug Administration (FDA);
  - a person exposed to a communicable disease; or
  - in certain circumstances, an employer regarding workplace-related medical surveillance activities.
- (3) to a government authority authorized by law when the covered entity reasonably believes that an individual is a victim or abuse, neglect or domestic violence;<sup>33</sup>
  - (4) for health oversight activities authorized by law, including, for instance, fraud and abuse audits, investigations, and civil, administrative, or criminal proceedings (except if the investigation or other activities does not arise out of and is not directly related to the receipt of health care or qualification or receipt of public health benefits or services);<sup>34</sup>
  - (5) for judicial and administrative proceedings under certain circumstances;<sup>35</sup>
  - (6) for law enforcement purposes to a law enforcement official. However, under this exception, only limited information may be disclosed for identification and location purposes, such as information about an individual who is a victim of a crime when the victim has agreed to the disclosure or when reporting a crime in an emergency;<sup>36</sup>
  - (7) to organ procurement organizations regarding cadaver organs, eyes, or tissue for donation purposes;<sup>37</sup>
  - (8) for research purposes provided that an Institutional Review Board (IRB) or privacy board (as described in §164.512(i)(B) of the regulation) approves the waiver of individual authorization required under §164.508 of the regulation and certain other conditions are met;<sup>38</sup>
  - (9) to avert a serious threat to health or safety;<sup>39</sup>
  - (10) for specialized government functions, such as separation or discharge from the military, to determine eligibility for veterans' health benefits, or for protective services for the President and others;<sup>40</sup>

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<sup>33</sup> 45 CFR § 164.512(c), 65 Fed. Reg. 82814 (Dec. 28, 2000).

<sup>34</sup> 45 CFR § 164.512(d), 65 Fed. Reg. 82814 (Dec. 28, 2000).

<sup>35</sup> 45 CFR § 164.512(e), 65 Fed. Reg. 82814-15 (Dec. 28, 2000).

<sup>36</sup> 45 CFR § 164.512(f), 65 Fed. Reg. 82815-16 (Dec. 28, 2000).

<sup>37</sup> 45 CFR § 164.512(h), 65 Fed. Reg. 82816 (Dec. 28, 2000).

<sup>38</sup> 45 CFR § 164.512(i), 65 Fed. Reg. 82816-17 (Dec. 28, 2000).

<sup>39</sup> 45 CFR § 164.512(j), 65 Fed. Reg. 82817 (Dec. 28, 2000).

<sup>40</sup> 45 CFR § 164.512(k), 65 Fed. Reg. 82817-18 (Dec. 28, 2000).

- (11) to the extent necessary to comply with workers' compensation or other similar laws.<sup>41</sup> Note that the exception permitting disclosure applies only when providing the information is required under these laws, not when the laws simply permit disclosure.

#### Minimum Necessary<sup>42</sup>

Even if the covered entity is authorized to use or disclose PHI, it must make reasonable efforts to limit PHI to the minimum amount of PHI necessary to accomplish the intended purpose of the use or disclosure. The “minimum necessary” standard does not apply to:

- disclosures to or requests for information by a health care provider for treatment,
- certain disclosures made to an individual who is the subject of the PHI or to the Secretary of HHS,
- to uses or disclosures required by law, or
- to uses or disclosures that are required for compliance with the regulation.

As a practical matter, the “minimum necessary” determination should begin with an assessment of whether or not the intended use or purpose could be accomplished by de-identifying the data or using summary data, rather than assuming that all protected health information may be disclosed, and then attempting to narrowing the scope of disclosure of PHI to comply with the minimum necessary rule.

#### Disclosures to business associates

The Privacy Rules also applies to transactions between covered entities and their “business associates.” Business associates are defined as those who perform or assist in the performance by a covered entity of:

- (1) a function or activity involving the use or disclosure of individually identifiable health information (including claims processing or administration, data analysis, quality assurance, billing, benefit management);
- (2) a function or activity regulated by HIPAA.

Business associates are persons who provide certain services to or on behalf of the covered entity, including legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation or financial services.<sup>43</sup>

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<sup>41</sup> 45 CFR § 164.512(l), 65 Fed. Reg. 82818 (Dec. 28, 2000).

<sup>42</sup> 45 CFR § 164.502(b), 65 Fed. Reg. 82805 (Dec. 28, 2000).

<sup>43</sup> 45 CFR § 160.103, 65 Fed. Reg. 82798 (Dec. 28, 2000).

Generally speaking, covered entities may only share information with business associates pursuant to a contract that limits the use and disclosure of protected health information (PHI) under the same restrictions that apply to the covered entity.

A contract between a covered entity and its business associate(s) must meet the requirements of §164.504((e)(2) or (e)(3)).<sup>44</sup> Among other things, this contract must:

- (1) set out the permitted and required uses and disclosures of PHI by the business associate;
- (2) provide that the business associate will:
  - (a) not use or further disclose PHI except as permitted by the regulation;
  - (b) use appropriate safeguards to assure the proper use of PHI;
  - (c) report to the covered entity any inappropriate or non-contractually agreed upon use of PHI of which it becomes aware;
  - (d) ensure that its employees, agents, and subcontractors agree to the same restrictions that are imposed on the business associate; and
  - (e) permit the Secretary and the covered entity access for audit purposes to its internal practices, books and records relating to the use or disclosure of PHI.

If the covered entity and its business associate(s) are both governmental entities, these requirements can be satisfied through a Memorandum of Understanding, rather than a contract.<sup>45</sup>

### *Rights of Individuals*

The Privacy Rule affords new rights to individuals regarding access to their own PHI. For instance, individuals have a right to:

- inspect and obtain a copy of all PHI relating to the individual;<sup>46</sup>
- amend and/or correct that PHI;<sup>47</sup>
- with certain exceptions, an accounting of the uses and disclosure of their PHI (i.e., to know when and to whom disclosure has been made for purposes other than treatment, payment and health operations, including disclosures made by or

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<sup>44</sup> 45 CFR § 164.504(e)(1), 65 Fed. Reg. 82808 (Dec. 28, 2000).

<sup>45</sup> 45 CFR § 164.504(e)(3), 65 Fed. Reg. 82808 (Dec. 28, 2000).

<sup>46</sup> There are three exceptions to this rule. Individuals do not have a right of access to: (1) psychotherapy notes, (2) information compiled in reasonable anticipation of, or for use in, a civil, criminal or administrative action or proceeding, and (3) certain protected health information maintained by a covered entity that is subject to or exempted from the Clinical Laboratory Improvements Amendments of 1988 (CLIA). 45 CFR § 165.524(a), 65 Fed. Reg. 82823 (Dec. 28, 2000).

<sup>47</sup> 45 CFR § 164.526, 65 Fed. Reg. 82824-26 (Dec. 28, 2000).

to a business associate); this right applies to disclosures made in the six (6) year period prior to the request for an accounting;<sup>48</sup>

- notice<sup>49</sup> and a full description of the covered entity's use and disclosure practices (generally any use or disclosure of PHI not described in this notice is prohibited);<sup>50</sup> and
- challenge the covered entity's use or disclosure of PHI through complaints to (1) the privacy official designated by each covered entity and through the complaint process that must also be established or (2) to the Secretary of HHS through a process that the Secretary will establish.<sup>51</sup>

### *Preemption of State Privacy Laws*

The Privacy Rule does not save state statutes that would otherwise be preempted by ERISA, but the statute and rule do leave in place more stringent state privacy protections. The regulation specifically states that:

[O]ur reading of the statutes together is that the effect of section 264(c)(2) [of HIPAA] is only to leave in place state privacy protections that would otherwise apply and that are more stringent than the federal privacy protections.<sup>52</sup>

“More stringent” state laws are defined in the regulation as those that are more protective of an individual's right to privacy protection for his or her PHI, including those state laws providing for greater rights of access or amendment to individuals or prohibiting or restricting a disclosure or use under circumstances in which the Privacy Rule permits it.<sup>53</sup>

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<sup>48</sup> 45 CFR § 164.528, 65 Fed. Reg. 82826 (Dec. 28, 2000). Covered entities must provide this information within a reasonable time after the request is made, generally no later than 60 days following the receipt of the request, although under certain circumstances, extensions may be allowed.

<sup>49</sup> Individuals must be given a plain-language written notice of the covered entity's practices and procedures regarding PHI. Generally the notice must describe what is done with their PHI, how it is safeguarded, and what rights individuals have with respect to that information, including the right to inspect and copy PHI. The notice must also identify the covered entity's privacy officer and, if different, a contact person for registering complaints and obtaining additional information. The notice must be distributed by the compliance date of the final regulation or, if later, at enrollment. In addition, the notice must be distributed at least once every three years thereafter. If a covered entity materially changes its procedures, it must update the notice and redistribute it within 60 days of the change. 45 CFR § 164.520, 65 Fed. Reg. 82820-22 (Dec. 28, 2000).

<sup>50</sup> 45 CFR § 164.520, 65 Fed. Reg. 82820-22, and 45 CFR § 164.530(i), 65 Fed. Reg. 82827 (Dec. 28, 2000).

<sup>51</sup> 45 CFR § 164.530(d), 65 Fed. Reg. 82825 (complaints to covered entity) and 45 CFR § 160.306, 308, 310, and 312, 65 Fed. Reg. 82801-02 (complaints to the Secretary) (Dec. 28, 2000).

<sup>52</sup> Preamble, 65 Fed. Reg. 82483 (Dec. 28, 2000).

<sup>53</sup> 45 CFR § 160.202, 65 Fed. Reg. 82800-01 (Dec. 28, 2000).

*Applicability to Special Populations: Victims of Abuse, Neglect, or Domestic Violence*

The Privacy Rule allows covered entities to use or disclose PHI without consent or authorization if the covered entity reasonably believes the patient is a victim of abuse, neglect, or domestic violence.<sup>54</sup> The rule covers child abuse<sup>55</sup> and other victims of abuse, neglect or domestic violence (e.g., abuse of nursing home residents or residents of facilities for the mentally retarded).

Covered entities can make such disclosures only to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence.<sup>56</sup> The disclosure can be made only if:

- the disclosure is required by law and complies with and is limited to the relevant requirements of such law; or
- if the individual agrees to the disclosure; or
- to the extent the disclosure is expressly authorized by statute or regulation and
  1. the covered entity, in its professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or
  2. if the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the PHI sought is not intended for use against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.<sup>57</sup>

Once the covered entity discloses the PHI, it must promptly inform the individual that a report has been made, unless:

- the covered entity, in the exercise of professional judgment, believes that informing the individual would place the individual at risk of serious harm; or
- the covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing the representative would not be in the best interests of the individual.<sup>58</sup>

*Psychotherapy Services Provided by Substance Abuse Paraprofessionals*

The privacy rule treats psychotherapy notes as a distinct category of PHI. With a few exceptions, covered entities must obtain an individual's authorization to use or disclose

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<sup>54</sup> 45 C.F.R. § 164.512(c), 65 Fed. Reg. 82814 (Dec. 28, 2000).

<sup>55</sup> Disclosure of PHI regarding child abuse is covered at 45 C.F.R. §164.512(b), 65 Fed. Reg. 82813 (Dec. 28, 2000).

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*



psychotherapy notes to carry out treatment, payment, or health care operations.<sup>59</sup> As a practical matter, such authorizations will rarely be necessary, since, as the preamble to the rule points out, psychotherapy notes do not include information that covered entities typically need for treatment, payment, or other routine health care operations.<sup>60</sup>

A covered entity must obtain the patient's consent (but not authorization) for the person who created the psychotherapy notes to use the notes to carry out treatment and for the covered entity to use or disclose psychotherapy notes for conducting training programs in which students, trainees, or practitioners in mental health learn under supervision to improve their skills in counseling.<sup>61</sup>

A covered entity may also use psychotherapy notes to defend a legal action or other proceeding brought by the individual pursuant to a consent (but without a specific authorization). This would allow disclosure to the covered entity's attorney to defend against the action or proceeding, but disclosure to others during the judicial or administrative proceeding is governed by 45 C.F.R. § 164.512(e) (which describes court orders compelling discovery of the notes, etc.). The rule's preamble notes that disclosure to a covered entity's attorney only requires consent because the defense constitutes "health care operations" and the entity should be able to defend itself without seeking a specific authorization from the patient.<sup>62</sup>

The rule does not explicitly address psychotherapy paraprofessionals. The rule's broad definition, however, suggests that notes of paraprofessionals are treated similarly to those of any other provider who is a mental health professional:

*Psychotherapy Notes*<sup>63</sup>

Notes recorded (in any medium) by a *health care provider who is a mental health professional* documenting or analyzing the contents of a conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

***Enforcement and Compliance***

The Secretary of HHS delegated the enforcement of the Privacy Rule to HHS's Office of Civil Rights. Through that office, the Secretary of HHS can bring enforcement actions against covered entities. Under HIPAA, the Secretary may impose civil monetary penalties of not more than \$100 per person per violation and up to \$25,000 for violations of a single standard within a single calendar year. In addition, criminal penalties are established under HIPAA for wrongful

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<sup>59</sup> 45 C.F.R. § 164.508(a)(2); 65 Fed. Reg. 82811 (Dec. 28, 2000).

<sup>60</sup> 65 Fed. Reg. 82515 (Dec. 28, 2000).

<sup>61</sup> *Id.*

<sup>62</sup> 65 Fed. Reg. 82515 (Dec. 28, 2000).

<sup>63</sup> 65 Fed. Reg. 82805 (Dec. 28, 2000).

disclosures of PHI, which, upon conviction, could result in fines of not more than \$50,000 and/or imprisonment for not more than one year. Offenses committed with intent to sell, transfer or use PHI for commercial or personal gain or malicious harm are punishable by a fine not to exceed \$250,000 and/or 10-year imprisonment.

The Privacy Rule does not authorize private rights of action for wrongful disclosure violations. However, individuals may report violations to the Secretary so HHS can undertake appropriate investigation and enforcement activities on behalf of an aggrieved individual.<sup>64</sup>

Under the rule, providers have until April 14, 2003 to come into compliance (and small health plans with less than five million in revenues have an additional year).<sup>65</sup>

## **42 C.F.R. Part 2**

### *General Rule/History*

In general, the confidentiality of alcohol and drug abuse patient records is regulated under 42 C.F.R. Part 2. Because dependence on alcohol and drugs is not understood as a disease, there is a stigma associated with addiction and addiction recovery. People in recovery from addiction too often suffer degradation and discrimination. Many people in the public do not understand that individuals in recovery are managing a chronic, relapsing disease, much like diabetes, and are not “weak-willed” and “immoral.” Because of the stigma associated with seeking assistance through an alcohol and drug abuse prevention and treatment program, Congress passed the Confidentiality of Alcohol and Drug Abuse Patient Records statute to encourage people to seek out and remain in treatment and to protect the patient records of these individuals.

42 C.F.R. Part 2 prohibits the disclosure and use of drug and alcohol abuse records maintained in connection with the performance of any federally assisted substance abuse program unless certain conditions, addressed below, exist.<sup>66</sup>

Although 42 C.F.R. Part 2 permits disclosure in certain circumstances (with or without consent), it does not require disclosure under any circumstances (although a court order can require disclosure). 42 C.F.R. Part 2 is intended to ensure that a substance abuse patient in a federally assisted alcohol or drug abuse program is “not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.”<sup>67</sup>

In general, 42 C.F.R. Part 2 can be summarized as follows: the rule restricts the disclosure or use of any information, whether or not recorded, that would identify a patient as a substance abuse patient either directly, by reference to other publicly available information, or through verification of such identification by another person. The prohibition applies to information obtained by a

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<sup>64</sup> 45 CFR §§ 160.306 and 160.312, 65 Fed. Reg. 82801-02 (Dec. 28, 2000).

<sup>65</sup> 66 Fed. Reg. 12434 (Feb. 26, 2001).

<sup>66</sup> See 42 C.F.R. §2.3(a).

<sup>67</sup> 42 C.F.R. §2.3(b)(2).

federally assisted alcohol or drug abuse program for the purpose of treating alcohol or drug abuse, making a diagnosis for such treatment, or making a referral for such treatment.<sup>68</sup>

### *Key Definitions*

#### *Federally Assisted*<sup>69</sup>

An alcohol or substance abuse program is considered to be federally assisted under 42 C.F.R. Part 2 if it:

- receives Federal funds in any form (e.g., Medicare or Medicaid) for *any* purpose (including purposes not related to alcohol and drug treatment);
- holds Federal tax-exempt status, i.e., 501 3(c) tax-exempt status, or allows for tax deductions for contributions through the Internal Revenue Service.
- is conducted directly by the Federal government (e.g., an Federal agency's employee assistance program);
- a state or local government which receives Federal funds that may or may not necessarily be spent for alcohol or drug abuse programs;
- receives SAPT grant funds that may or may not be supplemented by State or local funds; and
- a program carried out under licensure, certification, registration or authorization by *any federal agency* (e.g., provider status under Medicare or registration to dispense controlled substances).

#### *Substance Abuse Program*<sup>70</sup>

Coverage includes, but is not limited to, treatment and rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners that hold themselves out as providing, and that do provide, alcohol or drug abuse diagnosis, treatment, or referral for treatment.

#### *Disclose or Disclosure*<sup>71</sup>

A communication of patient identifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

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<sup>68</sup> 42 C.F.R. §2.12(a)(i)-(ii).

<sup>69</sup> 42 C.F.R. §2.12(b).

<sup>70</sup> 42 C.F.R. §2.12(e)(1).

<sup>71</sup> 42 C.F.R. §2.11.

### Patient<sup>72</sup>

Any individual who has applied for, or has been given, a diagnosis for treatment for alcohol or drug abuse at a federally assisted program. This includes any individual who, after arrest on a criminal charge, is identified as an individual with a potential alcohol or drug abuse program in order to determine the individual's eligibility to participate in a treatment program.

### Patient Identifying Information<sup>73</sup>

The name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or with reference to other publicly available information. The term does *not* include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as social security, or driver's license number) that could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

### Qualified Service Organization<sup>74</sup>

A person or any entity (including corporations and government agencies) that provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analysis, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect that:

- (1) has entered into a written agreement with a program under which the person or entity:
  - acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the program, it is fully bound by 42 C.F.R. Part 2; and
  - if necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by 42 C.F.R. Part 2.

### Records<sup>75</sup>

Any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

### *Disclosure and Use of Substance Abuse Records*

Under 42 C.F.R. Part 2, substance abuse records may be disclosed or used only as permitted by the regulation (described below) and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority.<sup>76</sup>

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<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> 42 C.F.R. § 2.13(a).

The regulation applies whether or not the person holding the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement official or other official, or has a subpoena, or any other justification for a disclosure or use that is not permitted by 42 C.F.R. Part 2.<sup>77</sup>

In addition, a program may not respond to requests to acknowledge the presence of an identified patient in a facility or part of a facility that is publicly identified as a substance abuse facility unless the patient consents in writing to such acknowledgement or a court order compels such acknowledgement.<sup>78</sup> Responses to such requests for acknowledgement must be made in a manner that does not reveal whether an identified individual has been or is being treated for substance abuse.<sup>79</sup>

Permitted Disclosures With Patient Consent & Form of Consent<sup>80</sup>

A program may disclose a patient's records with the patient's written consent to any individual or organization named in the consent.<sup>81</sup>

A program may also disclose patient records to a central registry or to any detoxification or maintenance treatment program within 200 miles for the purpose of preventing multiple enrollment of the patient.<sup>82</sup> Such a disclosure requires a patient's written consent. The disclosure may be made when:

- (1) the disclosure is made when the patient is accepted for treatment;
- (2) the type or dosage of the drug is changed; or
- (3) the treatment is interrupted, resumed, or terminated.

Such a disclosure must be limited to the patient's identifying information, the type and dosage of the drug, and relevant dates. A central registry or detoxification program can use the information *only* for the purpose of preventing multiple enrollments, and cannot redisclose the information or use the information for any other purpose unless authorized by a court order.<sup>83</sup>

A program may also disclose information about a patient to elements of the criminal justice system that have referred patients to the program and made the patient's participation in the program a condition of the disposition of any criminal proceedings.<sup>84</sup> Such a disclosure can be made if (1) it is made only to the individuals within the criminal justice system that need the information in connection with their duty to monitor the patient's progress (e.g., probation or parole officers); and (2) the patient has signed a written consent for the disclosure.

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<sup>77</sup> *Id.*

<sup>78</sup> 42 C.F.R. § 2.13(b).

<sup>79</sup> *Id.*

<sup>80</sup> 42 C.F.R. § 2.33.

<sup>81</sup> Disclosures to central registries and in connection with criminal justice activities must meet the other requirements of the regulation. *See* 42 C.F.R. § 2.34 and § 2.35, respectively.

<sup>82</sup> 42 C.F.R. § 2.34.

<sup>83</sup> *Id.*

<sup>84</sup> 42 C.F.R. § 2.35.

Under 42 C.F.R. Part 2, a written consent to a disclosure under the regulation must include:

- (1) the specific name or general designation of the program or person permitted to make the disclosure;
- (2) the name or title of the individual or the name of the organization to which disclosure is made;
- (3) the name of the patient;
- (4) the purpose of the disclosure;
- (5) how much and what kind of information is to be disclosed;
- (6) the signature of the patient and, when required for a patient who is a minor, the signature of the person who is authorized to give consent; or, when the patient is incompetent or deceased, the signature of the person authorized to sign in lieu of the patient;
- (7) the date on which the consent is signed;
- (8) a statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it (including providing treatment services in reliance on a valid consent to disclose information to a third-party payer); and
- (9) the date, event, or condition on which the consent will expire if not revoked before (to ensure that the consent last no longer than reasonably necessary to serve the purpose for the disclosure).

The regulation provides a sample consent form at 42 C.F.R. § 2.31.

*Third party payers, administrative entities, and others*<sup>85</sup>

The restrictions of 42 C.F.R. Part 2 on disclosures apply to:

- (1) third party payers with regard to records disclosed to them by federally assisted substance abuse programs;
- (2) entities having direct administrative control over programs with regard to information communicated to them by the program; and
- (3) persons who receive patient records directly from a federally assisted substance abuse program and who are notified of the restrictions on redisclosure of the records.

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<sup>85</sup> 42 C.F.R. § 2.12(d)(2).

### Minors<sup>86</sup>

Under 42 C.F.R. Part 2, the term “minor” means a person that has not attained majority under the applicable state law (or, if no age of majority is specified in state law, eighteen years of age).

If a minor acting alone has the capacity under applicable state law to enter into a substance abuse program, then only the minor can give any written consent for disclosure under the regulation.<sup>87</sup>

Where state law requires consent of a parent, guardian, or other person for a minor to obtain substance abuse treatment, any written consent for disclosure must be given by *both* the minor and his or her parent, guardian, or other person authorized to act on the minor’s behalf.<sup>88</sup>

In addition, where state law requires parental consent to treatment, the fact that a minor has applied for treatment may be communicated to the minor’s parent, guardian, or other person authorized to act on the minor’s behalf only if:

- (1) the minor has given written consent to the disclosure; or
- (2) the minor lacks capacity to make a rational choice regarding such consent because of extreme youth or physical or mental condition, as judged by the program director.<sup>89</sup>

### Prohibition on Redisclosure<sup>90</sup>

Every disclosure made with a patient’s written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 C.F.R. Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R. Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

### Permitted Uses and Disclosures Without Consent<sup>91</sup>

42 C.F.R. Part 2 permits federally assisted substance abuse programs to use and disclose substance abuse records without a patient’s consent in the following situations:

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<sup>86</sup> 42 C.F.R. § 2.14.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> 42 C.F.R. § 2.32.

<sup>91</sup> 42 C.F.R. § 2.52.

- (1) to medical personnel In cases of medical emergencies;
- (2) to FDA medical personnel who assert a reason to believe that an individual may be harmed by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction (if the information is used solely to notify patients or physicians of potential dangers);
- (3) for medical research activities where the program director makes a determination that the recipient of the information:
  - is qualified to conduct the research;
  - has a research protocol under which the information will be secured and not redisclosed; and
  - has provided a written statement that a group of three or more independent individuals has reviewed the protocol and determined that the rights and welfare of the patients will be adequately protected and the risks of disclosure are outweighed by the potential benefits of the research.
- (4) to any person who conducts an audit or evaluation of the program on behalf of
  - any federal, state or local governmental agency that provides financial assistance to the program or is authorized to regulate the program;
  - third party payers covering patients in the program or peer review organizations performing a utilization or quality review; or
  - is determined by the director of the program to conduct audit or evaluation activities.<sup>92</sup> Records may not be copied or leave the premises unless the person removing the records agrees, in writing, to secure the records and destroy them upon completion of the audit or evaluation<sup>93</sup>; and
- (5) upon a court order compelling disclosure (see below).

Disclosure Under Court Order<sup>94</sup>

A substance abuse program may disclose a patient's substance abuse records without the patient's consent upon a court order accompanied by a subpoena or other legal mandate compelling disclosure.

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<sup>92</sup> 42 C.F.R. §2.53(a).

<sup>93</sup> 42 C.F.R. §2.53(b).

<sup>94</sup> 42 C.F.R. §2.61.



Court orders issued pursuant to 42 C.F.R. Part 2 are for a specific, limited purpose: to authorize a program to disclose or use patient information that would otherwise be prohibited under the rule.

42 C.F.R. Part 2 also provides that a court order may compel disclosure of a patient's confidential communications to a substance abuse program, but only if the disclosure is necessary to:

- (1) protect against an existing threat to life or of serious bodily injury (including child abuse and neglect);
- (2) investigate or prosecute an extremely serious crime (e.g., one that threatens life or serious bodily injury, homicide, rape, kidnapping, armed robbery, or child abuse and neglect); or
- (3) litigate in a proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.<sup>95</sup>

#### Disclosure Standard<sup>96</sup>

Like the Privacy Rule, 42 C.F.R. Part 2 limits the amount of information that may be disclosed. *Any* disclosure made under 42 C.F.R. Part 2 must be limited to the information “necessary to carry out the purpose of the disclosure.”

#### Exceptions<sup>97</sup>

42 C.F.R. Part 2 contains a number of exceptions to the general rule on substance abuse records. The rule does not apply to the following:

- (1) information on alcohol and drug abuse patients maintained in connection with the Veterans' Administration (VA) provision of hospital care, nursing home care, domiciliary care, and medical services (which are governed by separate VA regulations);
- (2) information obtained by any component of the armed forces during a period when the patient was subject to the Uniform Code of Military Justice that is exchanged within the armed forces or between the armed forces and components of the VA furnishing health care to veterans;<sup>98</sup>
- (3) communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of the diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

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<sup>95</sup> 42 C.F.R. §2.63.

<sup>96</sup> 42 C.F.R. §2.12(a).

<sup>97</sup> 42 C.F.R. § 2.12(c).

<sup>98</sup> The armed forces exception is limited to the exchanges noted (within the armed forces and between the armed forces and the VA). The regulations do apply to any other disclosure by the armed forces. *See* 42 C.F.R. §2.12(c)(2).

- within a program; or
  - between a program and an entity that has direct administrative control over the program.
- (4) communications between a program and a qualified service organization of information needed by the organization to provide services to the program;
  - (5) communications between program personnel and law enforcement officers that are
    - directly related to a patient’s commission of a crime on the premises or against program personnel (or the threat to commit such a crime); and
    - are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual’s name and address, and that individual’s last known whereabouts; and
  - (6) reporting under state law of incidents of suspected child abuse and neglect to the appropriate state or local authorities.
    - The restrictions of 42 C.F.R. Part 2 continue to apply to the original alcohol or drug abuse patient records maintained by the program, including their disclosure and use for civil or criminal proceedings that may arise out of the report of suspected child abuse and neglect.

In addition, the type of diagnosis a patient received affects whether or not 42 C.F.R. Part 2 applies to the patient’s record. The regulation covers any record of a diagnosis identifying a patient as an alcohol or drug abuse patient that is prepared in connection with the treatment or referral for treatment for alcohol or drug abuse.<sup>99</sup>

42 C.F.R. Part 2 *does not* cover:

- (1) a diagnosis made solely for the purpose of providing evidence for use by law enforcement authorities; or
- (2) a diagnosis of drug overdose or alcohol intoxication that clearly shows that the individual involved does not suffer from substance abuse (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).<sup>100</sup>

***Restriction on Use: Criminal Charges***

42 C.F.R. Part 2 allows the disclosure or use of a patient’s records to conduct a criminal investigation or initiate or substantiate criminal charges against a patient *only* if a court order compels such use or disclosure.<sup>101</sup> Without a court order, the restriction prohibits the introduction

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<sup>99</sup> 42 C.F.R. § 2.12(e)(4).

<sup>100</sup> *Id.*

<sup>101</sup> 42 C.F.R. § 2.12(a)(2).

of the records into evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime.<sup>102</sup>

Under the authorizing statute, a judge can issue a court order only for good cause, which requires a judge to balance the public interest and the need for disclosure against the injury to the patient, the physician-patient relationship, and to the treatment program.<sup>103</sup> The statute also requires a judge issuing such an order to impose appropriate safeguards to ensure against unauthorized disclosure of the information.<sup>104</sup>

The restriction applies to any person who obtains information about a patient for purposes of conducting a criminal investigation or initiating or substantiating criminal charges from a program, *regardless* of the status of the recipient or of whether the information was obtained in accordance with the regulation.<sup>105</sup> Information obtained by undercover agents or informants or through a patient's access to the records is subject to this restriction.<sup>106</sup>

### *Security Standards*

42 C.F.R. Part 2 requires programs to maintain substance abuse records subject to the regulation in a secure room, in a locked file cabinet, safe or other similar container when the records are not in use. In addition, the regulation requires programs to adopt written procedures to regulate access to and use of records subject to the regulation.<sup>107</sup>

These security standards are far easier to implement than the data security standards of the Privacy Rule, which are the subject of an entirely separate regulation under HIPAA.

### *Rights of Patients*

At the time a patient is admitted (or as soon after as the patient can communicate rationally), a program must inform the patient that federal law and regulations protect the confidentiality of alcohol and drug abuse patient records and provide a copy of the federal law and regulations to the patient.<sup>108</sup>

The notice to the patient must contain

- (1) a general description of the limited circumstances allowing disclosure;
- (2) a statement that violation of the law and regulations is a crime and that suspected violations may be reported to authorities;
- (3) a statement that information related to a patient's commission of a crime on the premises is not protected;

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<sup>102</sup> *Id.*

<sup>103</sup> 42 U.S.C. §290ee-3(b)(2)(c).

<sup>104</sup> *Id.*

<sup>105</sup> 42 C.F.R. § 2.12(d).

<sup>106</sup> *Id.*

<sup>107</sup> 42 C.F.R. § 2.16.

<sup>108</sup> 42 C.F.R. § 2.12.

- (4) a statement that reports of suspected child abuse and neglect made under state law to appropriate state or local authorities are not protected; and
- (5) a citation to the federal law and regulations.<sup>109</sup>

The regulation provides a sample notice at 42 C.F.R. § 2.23.

42 C.F.R. Part 2 allows (but does not require) a program to provide a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient.<sup>110</sup> The patient's consent or written authorization is not required.

This provision differs from the Privacy Rule, which requires that a patient be given access to his or her own PHI (except for psychotherapy notes).<sup>111</sup> Therefore, as a practical matter, substance abuse programs will have to comply with the Privacy Rule, which makes patient access to his or her own records a requirement rather than an option.

### *Relationship to State Laws*<sup>112</sup>

42 C.F.R. Part 2 does not preempt all state law regarding the confidentiality of substance abuse patient records. If a state law prohibits a disclosure permitted by 42 C.F.R. Part 2, neither the substance abuse confidentiality statute nor regulations authorize a violation of such a state law. Therefore, more strict state confidentiality laws remain in place. Similarly, no state law may authorize or compel any disclosure that 42 C.F.R. Part 2 prohibits.

### **Interaction of the Privacy Rule with Confidentiality of Alcohol and Drug Abuse Patient Record Rule**

The preamble to the Privacy Rule discusses the Rule's interaction with 42 C.F.R. Part 2.<sup>113</sup> In many cases, the two sets of rules treat disclosures similarly. For example, under either set of rules, the patient may have access to his or her medical records.

In other cases, either the Privacy Rule or 42 C.F.R. Part 2 is more stringent in terms of what disclosures are permitted. For example, the Privacy Rule permits disclosures without patient consent for public health activities and directory assistance. These disclosures would not be permissible under 42 C.F.R. Part 2.

In yet other cases, the Privacy Rule is more restrictive. For example, 42 C.F.R. Part 2 permits disclosure without patient consent to the FDA and for medical research activities.<sup>114</sup> The Privacy Rule restricts these types of disclosures and requires consent for them. Since neither set of rules requires disclosures that the other does not permit, there is no direct conflict between the Privacy Rule and 42 C.F.R. Part 2, although the requirements of each rule on any particular issue may not be obvious.

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<sup>109</sup> 42 C.F.R. § 2.22.

<sup>110</sup> 42 C.F.R. § 2.23.

<sup>111</sup> 45 CFR § 164.526, 65 Fed. Reg. 82824-26 (Dec. 28, 2000).

<sup>112</sup> 42 C.F.R. § 2.20.

<sup>113</sup> See 65 Fed. Reg. 82482, 82484 (Dec. 28, 2000).

<sup>114</sup> See 42 C.F.R. § 2.51.

Providers that fall under both sets of rules must follow the more stringent set of rules for any particular disclosure. This will make implementation of the rules challenging for most substance abuse providers.

## Crosswalk Between the Privacy Rule and 42 C.F.R. Part 2

The following chart highlights provisions of the Privacy Rule and 42 C.F.R. Part 2 and comments on the differences between the rules.

<i>Issue</i>	<i>Privacy Rule</i>	<i>42 C.F.R. Part 2</i>	<i>Commentary</i>
<b>General Rule</b>	“Covered entities” may not use or disclose “protected health information” (PHI) except as authorized by the individual who is the subject of the information, or as explicitly required or permitted by the regulation, noted below.	<p>The rule restricts the disclosure or use of any information, whether or not recorded, that would identify a patient as a substance abuse patient either directly, by reference to other publicly available information, or through verification of such identification by another person. Records may be disclosed only as permitted by the regulation (described below) and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority.</p> <p>The prohibition applies to information obtained by a federally assisted alcohol or drug abuse program for the purpose of treating alcohol or drug abuse, making a diagnosis for such treatment, or making a referral for such treatment.</p>	The Privacy Rule is much broader in its general rule and applicability. Whereas 42 C.F.R. Part 2 applies to substance abuse records of federally assisted substance abuse programs, the Privacy Rule applies to a broader class of information held by covered entities (which are defined below, but include providers and insurers and other entities that 42 C.F.R. does not specifically contemplate).
<b>Minimum Necessary Standard</b>	Even when the use or disclosure of PHI is permitted, in most circumstances, only the “minimum necessary” amount of information to accomplish the intended purpose of the use, disclosure or request may be provided.	42 C.F.R. Part 2 limits the amount of information that may be disclosed. <i>Any</i> disclosure made under 42 C.F.R. Part 2 must be limited to the information “necessary to carry out the purpose of the disclosure.”	<p>The provisions of the rules are similar.</p> <p>As a practical matter, the “minimum necessary” determination should begin with an assessment of whether or not the intended use or purpose could be accomplished by de-identifying the data or using summary data, rather than assuming that all protected health information may be disclosed, and then attempting to narrowing the scope of disclosure of PHI to comply with the minimum necessary rule.</p>
<b>Applicability and Duration</b>	The rule applies to all PHI maintained, used or disclosed by a covered entity, regardless of the form it takes – electronic, written or oral.	Applies to any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug	The Privacy Rule applies to a broader scope of information (all PHI) than 42 C.F.R. Part 2 (substance abuse records).

	<p>This information remains protected during the life of the individual, and information about a deceased individual must remain protected as long as the covered entity maintains the information.</p>	<p>program.</p> <p>The regulation applies whether or not the person holding the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement official or other official, or has a subpoena, or any other justification for a disclosure or use that is not permitted by 42 C.F.R. Part 2.</p> <p>A program may not respond to requests to acknowledge the presence of an identified patient in a facility or part of a facility that is publicly identified as a substance abuse facility unless the patient consents in writing to such acknowledgement or a court order compels such acknowledgement. Responses to such requests for acknowledgement must be made in a manner that does not reveal whether an identified individual has been or is being treated for substance abuse.</p> <p>42 C.F.R. does not prohibit the disclosure of patient identifying information related to cause of death for purposes of laws requiring or authorizing collection of vital statistics.</p>	
<p><b>Exceptions to Applicability</b></p>	<p>No specific exceptions like those contained in 42 C.F.R. Part 2, but the rule is limited to covered entities and allows for certain disclosures without a patient’s consent, noted below.</p>	<p>42 C.F.R. Part 2 contains a number of exceptions to the general rule on substance abuse records. The rule does not apply to the following:</p> <ul style="list-style-type: none"> <li>• information on alcohol and drug abuse patients maintained in connection with the Veterans’ Administration (VA) provision of hospital care, nursing home care, domiciliary care, and medical services (which are governed by separate VA regulations);</li> <li>• information obtained by any component</li> </ul>	<p>42 C.F.R. Part 2 provides more explicit exceptions than the Privacy Rule, which relies more on what is a covered entity and the types of disclosures permitted.</p> <p>42 C.F.R. Part 2’s exceptions related to treatment communications among personnel are similar to the Privacy Rule’s provisions on treatment, payment, and operations (TPO) for which consent is required. In that respect, the Privacy Rule is stricter than 42 C.F.R. Part 2.</p> <p>Similarly, 42 C.F.R. Part 2’s exceptions for qualified service organizations are more</p>

		<p>of the armed forces during a period when the patient was subject to the Uniform Code of Military Justice that is exchanged within the armed forces or between the armed forces and components of the VA furnishing health care to veterans;</p> <ul style="list-style-type: none"> <li>• communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of the diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are             <ol style="list-style-type: none"> <li>1. within a program; or</li> <li>2. between a program and an entity that has direct administrative control over the program.</li> </ol> </li> <li>• communications between a program and a qualified service organization of information needed by the organization to provide services to the program;</li> <li>• communications between program personnel and law enforcement officers that are             <ol style="list-style-type: none"> <li>1. directly related to a patient's commission of a crime on the premises or against program personnel (or the threat to commit such a crime); and</li> <li>2. are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts; and</li> </ol> </li> </ul>	<p>relaxed than the Privacy Rule's treatment of communications with "business associates."</p> <p>42 C.F.R. Part 2 makes exceptions to applicability for certain types of diagnosis. The Privacy Rule makes no distinctions based on type of diagnosis.</p>
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		<p>3. reporting under state law of incidents of suspected child abuse and neglect to the appropriate state or local authorities.</p> <p>In addition, the type of diagnosis a patient received affects whether or not 42 C.F.R. Part 2 applies to the patient’s record. The regulation covers any record of a diagnosis identifying a patient as an alcohol or drug abuse patient that is prepared in connection with the treatment or referral for treatment for alcohol or drug abuse.</p> <p>42 C.F.R. Part 2 <i>does not</i> cover:</p> <ul style="list-style-type: none"> <li>• a diagnosis made solely for the purpose of providing evidence for use by law enforcement authorities; or</li> <li>• a diagnosis of drug overdose or alcohol intoxication that clearly shows that the individual involved does not suffer from substance abuse (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).</li> </ul>	
<p><b>Key Definitions</b></p>	<p><u>Covered entities</u></p> <p>“Covered entities” are broadly defined. The term includes:</p> <ul style="list-style-type: none"> <li>• A health plan;</li> <li>• A health care clearinghouse; and</li> <li>• A health care provider who transmits health information in electronic form in connection with transactions (i.e., exchanges of information) covered by HIPAA’s administrative requirements</li> </ul>	<p><u>Federally Assisted</u></p> <p>An alcohol or substance abuse program is considered to be federally assisted under 42 C.F.R. Part 2 if it:</p> <ul style="list-style-type: none"> <li>• receives Federal funds in any form (e.g., Medicare or Medicaid) for <i>any</i> purpose (including purposes not related to alcohol and drug treatment);</li> <li>• holds Federal tax exempt status, 501 (c)(3) tax exempt status, or allows for tax deductions for contributions through the</li> </ul>	

	<p><u>Health plan</u></p> <p>A “health plan” means an individual or group plan that provides, or pays the cost of, medical care (as defined in §2791(a)(2) of the Public Health Service Act (PHSA)). Health plans include:</p> <ul style="list-style-type: none"> <li>• Virtually all group health plans (insured or self-insured) covered under the Employee Retirement Income Security Act of 1974 (ERISA) (i.e, those group health plans with 50 or more participants and plans of any size that are administered by other entities);</li> <li>• Health insurance issuers (as defined by HIPAA to include an insurance company, insurance services, or insurance organization (including a health maintenance organization) that is licensed to engage in the business of insurance in a state and which is subject to state law regulating insurance (within the meaning of ERISA § 514(b)(2));</li> <li>• HMOs;</li> <li>• Medicare;</li> <li>• Medicaid;</li> <li>• Medicare-supplemental policy issuers;</li> <li>• An employee welfare benefit plan or any other arrangement providing health benefits to employees of two or more employers;</li> <li>• MEWAs (multiple employer welfare arrangements);</li> <li>• Health care programs for active military personnel and veterans;</li> <li>• CHAMPUS;</li> <li>• The Indian Health Service;</li> <li>• The Federal Employees Health Benefit Program;</li> <li>• Approved SCHIP programs;</li> </ul>	<p>deductions for contributions through the Internal Revenue Service.</p> <ul style="list-style-type: none"> <li>• is conducted directly by the Federal government (e.g., an Federal agency’s employee assistance program);</li> <li>• a state or local government which receives Federal funds that may or may not necessarily be spent for alcohol or drug abuse programs;</li> <li>• receives SAPT grant funds that may or may not be supplemented by State or local funds; and</li> <li>• a program carried out under licensure, certification, registration or authorization by <i>any federal agency</i> (e.g., provider status under Medicare or registration to dispense controlled substances).</li> </ul> <p><u>Substance Abuse Program</u></p> <p>Coverage includes, but is not limited to, treatment and rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners that hold themselves out as providing, and that do provide, alcohol or drug abuse diagnosis, treatment, or referral for treatment.</p> <p><u>Disclose or Disclosure</u></p> <p>A communication of patient identifying information, the affirmative verification of another person’s communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.</p> <p><u>Patient</u></p>	
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	<ul style="list-style-type: none"> <li>• Medicare +Choice plans; and</li> <li>• State high-risk pools.</li> </ul> <p><u>Health care clearinghouse</u></p> <p>“Health care clearinghouses” are public or private entities (including billing companies or community health management information systems) that either (1) process or facilitate processing of health information received from another entity in a nonstandard format into standard data elements or a standard transaction; or (2) receive a standard transaction from another entity and process or facilitate processing of health information into a nonstandard format or nonstandard data content for the receiving entity.</p> <p><u>Health care provider</u></p> <p>“Health care providers” are providers of medical or health services and any other person or organization that furnishes, bills or is paid for health care in the normal course of business.</p> <p><u>Health care</u></p> <p>“Health care” includes preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care. It also includes counseling, service, assessment, or other procedure with respect to the physical or mental condition (or functional status) of an individual or that affects the structure or function of the body.</p> <p><u>Protected health information (PHI)</u></p> <p>“Protected health information (PHI)” means individually identifiable health information that is transmitted or maintained by electronic</p>	<p>Any individual who has applied for, or has been given, a diagnosis for treatment for alcohol or drug abuse at a federally assisted program. This includes any individual who, after arrest on a criminal charge, is identified as an individual with a potential alcohol or drug abuse program in order to determine the individual’s eligibility to participate in a treatment program.</p> <p><u>Qualified Service Organization</u></p> <p>A person or any entity (including corporations and government agencies) that provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analysis, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect that:</p> <ol style="list-style-type: none"> <li>1. has entered into a written agreement with a program under which the person or entity: <ul style="list-style-type: none"> <li>• acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the program, it is fully bound by 42 C.F.R. Part 2; and if necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by 42 C.F.R. Part 2.</li> </ul> </li> </ol> <p><u>Records</u></p> <p>Any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.</p>	
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	<p>media or is transmitted or maintain in any other form or medium.</p> <p>“Health information” is any information (whether oral or recorded in any form or medium) that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual or the past, present or future payment for the provision of health care to an individual. This definition reflects the broad category of information governed by the administrative simplification provisions of HIPAA.</p> <p>“Individually identifiable health information” is a subset of “health information.” It is health information that either actually identifies the individual or creates a reasonable basis to believe that the information would identify the individual.</p> <p>As defined above, PHI is a subset of individually identifiable health information. Note that the protections described below apply to data or information about an individual, not to any particular record. However, once the privacy protections attach to data, the transmitter and receiver of the data must protect every record (written, electronic or other) in which the data appears.</p>	<p><u>Patient Identifying Information</u></p> <p>The name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or with reference to other publicly available information. The term does <i>not</i> include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as social security, or driver’s license number) that could be used to identify a patient with reasonable accuracy and speed from sources external to the program.</p>	
<p><b>General Rule Regarding Disclosure</b></p>	<p><u>Permitted uses and disclosures</u></p> <p>The rule permits use or disclosure of PHI only in the following circumstances:</p> <ul style="list-style-type: none"> <li>• To the patient (required disclosure if</li> </ul>	<p><u>Permitted Disclosures With Patient Consent &amp; Form of Consent</u></p> <p>A program may disclose a patient’s records with the patient’s written consent to any individual or organization named in the</p>	<p>The Privacy Rule permits disclosures without patient consent in several instances, such as public health activities and directory assistance, that would not be permissible under 42 C.F.R. Part 2.</p>

	<p>requested);</p> <ul style="list-style-type: none"> <li>• Pursuant to a valid consent by the patient that meets the requirements of the regulation to carry out treatment, payment or health care operations;</li> <li>• Pursuant to a valid authorization by the patient that meets the requirements of the regulation;</li> <li>• Pursuant to an agreement under, or as otherwise permitted by, the regulation; or</li> <li>• As explicitly permitted or required by the regulation (e.g., to the Secretary of HHS for purposes of determining compliance with the rule).</li> </ul>	<p>consent.</p> <p>A program may also disclose patient records to a central registry or to any detoxification or maintenance treatment program within 200 miles for the purpose of preventing multiple enrollment of the patient. Such a disclosure requires a patient’s written consent. The disclosure may be made when:</p> <ol style="list-style-type: none"> <li>1. the disclosure is made when the patient is accepted for treatment;</li> <li>2. the type or dosage of the drug is changed; or</li> <li>3. the treatment is interrupted, resumed, or terminated.</li> </ol> <p>Such a disclosure must be limited to the patient’s identifying information, the type and dosage of the drug, and relevant dates. A central registry or detoxification program can use the information <i>only</i> for the purpose of preventing multiple enrollments, and cannot redisclose the information or use the information for any other purpose unless authorized by a court order.</p> <p>A program may also disclose information about a patient to elements of the criminal justice system that have referred patients to the program and made the patient’s participation in the program a condition of the disposition of any criminal proceedings. Such a disclosure can be made if (1) it is made only to the individuals within the criminal justice system that need the information in connection with their duty to monitor the patient’s progress (e.g., probation or parole officers); and (2) the patient has signed a written consent for the disclosure.</p>	<p>In other cases, the Privacy Rule is more restrictive. 42 C.F.R. Part 2 permits disclosure without patient consent to the FDA and for medical research activities. The Privacy Rule restricts these types of disclosures and requires consent for them.</p> <p>Since neither set of rules <u>requires</u> disclosures that the other does not permit, there is no direct conflict between the Privacy Rule and 42 C.F.R. Part 2, although the requirements of each rule on any particular issue may not be obvious.</p> <p>An exhaustive list of each rule’s treatment of every potential disclosure is beyond the scope of this chart. As a practical matter, however, whenever a particular disclosure is in question, a provider should check both sets of rules to determine which is more stringent, and follow the requirements of the stricter rule.</p>
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<p><b>Form of Consent Required</b></p>	<p>The Privacy Rule allows a consent document to be “brief and may be written in general terms. It must be written in plain language, inform the individual that the information may be used and disclosed for TPO, state the patient’s rights to review the providers’ privacy notice, to request restrictions and to revoke consent, and be dated and signed by the individual (or his or her representative).”</p> <p>The Privacy Rule’s requirement for an authorization is more specific. To be valid, an authorization by the individual must:</p> <ul style="list-style-type: none"> <li>• Describe the information to be used or disclosed in a specific and meaningful fashion;</li> <li>• Name the person or class of persons authorized to make the disclosure or use;</li> <li>• Name the person or class of persons to whom the disclosure may be made;</li> <li>• Contain an expiration date that relates to the individual or to the purpose of the disclosure or use;</li> <li>• Clearly state that the individual has a right to revoke the authorization in writing (and describe the procedure for doing so) as well as any exemptions to the right to revoke;</li> <li>• Be signed by the individual (or the individual’s personal representative) and dated.</li> </ul> <p>The individual must be given a copy of the signed authorization.</p> <p>If a covered entity initiates the request for authorization or disclosure (rather than the individual), additional requirements apply.</p>	<p>Under 42 C.F.R. Part 2, a written consent to a disclosure under the regulation must include:</p> <p>(10) specific name or general designation of the program or person permitted to make the disclosure;</p> <p>(11) name or title of the individual or the name of the organization to which disclosure is made;</p> <p>(12) name of the patient;</p> <p>(13) purpose of the disclosure;</p> <p>(14) how much and what kind of information is to be disclosed;</p> <p>(15) signature of the patient and, when required for a patient who is a minor, the signature of the person who is authorized to give consent; or, when the patient is incompetent or deceased, the signature of the person authorized to sign in lieu of the patient;</p> <p>(16) the date on which the consent is signed;</p> <p>(17) a statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it (including providing treatment services in reliance on a valid consent to disclose information to a third-party payer); and</p> <p>(18) the date, event, or condition on</p>	<p>42 C.F.R. provides more detailed guidance on what a valid consent must require, although the Privacy Rule’s authorization requirements are quite specific.</p> <p>42 C.F.R. Part 2 also provides a sample consent form (the Privacy Rule does not provide any example).</p> <p>As a practical matter, providers should develop consent and authorization forms that comply with both requirements simultaneously, which is possible because the form of consent/authorization under either rule is similar and does not conflict with the other.</p>
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		<p>which the consent will expire if not revoked before (to ensure that the consent last no longer than reasonably necessary to serve the purpose for the disclosure).</p> <p>The regulation provides a sample consent form at 42 C.F.R. § 2.31.</p>	
<p><b>Consent v. Authorization</b></p>	<p>“Consent” refers to a broad general permission granted by the individual to a health care provider or other covered entity to use or disclose the individual’s PHI for treatment, payment or health care operations purposes.</p> <p>In contrast, an “authorization” refers to a more specific and detailed permission given to</p>	<p>No distinction.</p>	<p>The Privacy Rule draws a distinction between consent and authorization that is not contained in 42 C.F.R. Part 2 because the privacy rule contemplates different uses (such as TPO) that 42 C.F.R. either addresses as exceptions or allows only with consent. The broad nature of “consent” under the Privacy Rule and the narrow nature of “authorization” are collapsed into singular treatment as</p>

	<p>a covered or non-covered entity or business partner by an individual to share an individual's PHI about issues other than treatment, payment, and healthcare operations.</p> <p>All covered entities, including health insurers, providers, health care clearinghouses are required to obtain authorization for the disclosure of PHI for purposes other than routine operations.</p>		consent by 42 C.F.R. Part 2.
<b>Prohibition on Redisclosure</b>	The Privacy Rule applies to recipients of PHI,	<p>Every disclosure made with a patient's written consent must be accompanied by the following written statement:</p> <p>This information has been disclosed to you from records protected by Federal confidentiality rules (42 C.F.R. Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R. Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.</p>	The Privacy Rule does not require any written statement on redisclosure like the one required by 42 C.F.R. Part 2 (although the Privacy Rule does require certain language in business associate agreements, noted below).
<b>Use or Disclosure for Treatment, Payment, or Health Care Operations (TPO)</b>	<p>Permits covered entities to use or disclose PHI for TPO.</p> <p>Consent required before a covered health provider that has a direct treatment relationship can use or disclose PHI for TPO.</p>	42 C.F.R. Part 2 makes an exception for certain treatment, payment, and operations communications (see applicability, above)	The Privacy Rule is stricter in its requirement that an initial consent be given for TPO. 42 C.F.R. Part 2 provides for an exception that allows use or disclosure for certain treatment, payment, or operations purposes without patient consent.
<b>Exceptions to Consent Requirement for TPO</b>	<p>Consent is necessary for use or disclosure for TPO unless the provider:</p> <ul style="list-style-type: none"> <li>• has an indirect treatment relationship with the individual,</li> <li>• is providing health care to an inmate,</li> </ul>	42 C.F.R. Part 2 contains exceptions for certain treatment, payment, and operations purposes (see applicability/exceptions above).	See 42 C.F.R. Part 2's exceptions for certain treatment, payment, and operations purposes.



	<ul style="list-style-type: none"> <li>is in an emergency treatment situation (but then the provider must attempt to obtain consent as soon as practicable after the treatment is delivered), is required by law to obtain consent but unable to do so, or is unable to obtain consent because of substantial communication barriers</li> </ul>		
<b>Patient Authorization for Disclosure of Non-Routine Operations</b>	Unless otherwise specified under the regulation, a covered entity may only use or disclose PHI when it receives a valid authorization by an individual. Any use or disclosure of PHI must be consistent with the authorization.	Covered by general consent requirements.	42 C.F.R. does not make the “non-routine operations” distinction. 42 C.F.R. Part 2 allows disclosure pursuant to a valid consent to any entity.
<b>Required Disclosures</b>	Covered entities are required to disclose PHI regarding an individual only in two instances: (1) to the individual who is the subject of the PHI when the individual requests it, and (2) to the Secretary of Health and Human Services when the Secretary is investigating a complaint or determining a covered entity’s compliance with the regulation.	None, unless by court order.	The Privacy Rule provides greater patient protection by requiring disclosure to the patient (42 C.F.R. Part 2 permits, but does not require, such disclosure).
<b>Disclosures Permitted Without Patient Consent</b>	<p>The Privacy Rule permits disclosure without patient consent:</p> <p>(1) to the extent that the disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of that law;</p> <p>(2) for certain public health activities. These might include disclosure to:</p> <ul style="list-style-type: none"> <li>a public health authority authorized by law to collect information to prevent or control disease or conduct public health surveillance;</li> <li>a public health authority empowered by law to receive reports of child abuse or neglect;</li> <li>under certain circumstances, to a person subject to the jurisdiction of</li> </ul>	<p>42 C.F.R. Part 2 permits federally assisted substance abuse programs to use and disclose substance abuse records without a patient’s consent in the following situations:</p> <p>(6) to medical personnel In cases of medical emergencies;</p> <p>(7) to FDA medical personnel who assert a reason to believe that an individual may be harmed by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction (if the information is used solely to notify patients or physicians of potential dangers);</p> <p>(8) for medical research activities where the program director makes a determination that the recipient of</p>	<p>As noted above, the Privacy Rule permits certain disclosures (e.g., for public health activities) that 42 C.F.R. Part 2 does not permit. Providers must check any potential disclosure against the requirements of each rule.</p> <p>42 C.F.R. Part 2 is more explicit in detailing disclosures under court order than the Privacy Rule. As a practical matter, providers faced with a subpoena or court order compelling disclosure should check the order and purposes for the disclosure against each rule. 42 C.F.R. Part 2 is likely to be stricter on disclosure under these circumstances.</p>

	<p>the Food and Drug Administration (FDA);</p> <ul style="list-style-type: none"> <li>• a person exposed to a communicable disease; or</li> <li>• in certain circumstances, an employer regarding workplace-related medical surveillance activities.</li> </ul> <p>(3) to a government authority authorized by law when the covered entity reasonably believes that an individual is a victim or abuse, neglect or domestic violence;</p> <p>(4) for health oversight activities authorized by law, including, for instance, fraud and abuse audits, investigations, and civil, administrative, or criminal proceedings (except if the investigation or other activities does not arise out of and is not directly related to the receipt of health care or qualification or receipt of public health benefits or services);</p> <p>(5) for judicial and administrative proceedings under certain circumstances;</p> <p>(6) for law enforcement purposes to a law enforcement official. However, under this exception, only limited information may be disclosed for identification and location purposes, such as information about an individual who is a victim of a crime when the victim has agreed to the disclosure or when reporting a crime in an emergency;</p>	<p>the information:</p> <ul style="list-style-type: none"> <li>• is qualified to conduct the research;</li> <li>• has a research protocol under which the information will be secured and not redisclosed; and</li> <li>• has provided a written statement that a group of three or more independent individuals has reviewed the protocol and determined that the rights and welfare of the patients will be adequately protected and the risks of disclosure are outweighed by the potential benefits of the research.</li> </ul> <p>(9) to any person who conducts an audit or evaluation of the program on behalf of</p> <ul style="list-style-type: none"> <li>• any federal, state or local governmental agency that provides financial assistance to the program or is authorized to regulate the program;</li> <li>• third party payers covering patients in the program or peer review organizations performing a utilization or quality review; or</li> <li>• is determined by the director of the program to conduct audit or evaluation activities. Records may not be copied or leave the premises unless the person removing the records agrees, in writing, to secure the records and destroy them upon completion of the audit or evaluation; and</li> </ul> <p>(10) upon a court order compelling</p>	
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	<p>(7) to organ procurement organizations regarding cadaver organs, eyes, or tissue for donation purposes;</p> <p>(8) for research purposes provided that an Institutional Review Board (IRB) or privacy board (as described in §164.512(i)(B) of the regulation) approves the waiver of individual authorization required under §164.508 of the regulation and certain other conditions are met;</p> <p>(9) to avert a serious threat to health or safety;</p> <p>(10) for specialized government functions, such as separation or discharge from the military, to determine eligibility for veterans' health benefits, or for protective services for the President and others;</p> <p>(11) to the extent necessary to comply with workers' compensation or other similar laws. Note that the exception permitting disclosure applies only when providing the information is <u>required</u> under these laws, not when the laws simply permit disclosure.</p>	<p>disclosure (see below).</p> <p><i>Disclosure Under Court Order</i></p> <p>A substance abuse program may disclose a patient's substance abuse records without the patient's consent upon a court order accompanied by a subpoena or other legal mandate compelling disclosure.</p> <p>Court orders issued pursuant to 42 C.F.R. Part 2 are for a specific, limited purpose: to authorize a program to disclose or use patient information that would otherwise be prohibited under the rule.</p> <p>42 C.F.R. Part 2 also provides that a court order may compel disclosure of a patient's confidential communications to a substance abuse program, but only if the disclosure is necessary to:</p> <p>(4) protect against an existing threat to life or of serious bodily injury (including child abuse and neglect);</p> <p>(5) investigate or prosecute an extremely serious crime (e.g., one that threatens life or serious bodily injury, homicide, rape, kidnapping, armed robbery, or child abuse and neglect); or</p> <p>(6) litigate in a proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.</p>	
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<p><b>Business Associates</b></p>	<p>The Privacy Rule also applies to transactions between covered entities and their “business associates.” Business associates are defined as those who perform or assist in the performance by a covered entity of:</p> <p>(3) a function or activity involving the use or disclosure of individually identifiable health information (including claims processing or administration, data analysis, quality assurance, billing, benefit management);</p> <p>(4) a function or activity regulated by HIPAA.</p> <p>Business associates are persons who provide certain services to or on behalf of the covered entity, including legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation or financial services.</p> <p>Generally speaking, covered entities may only share information with business associates pursuant to a contract that limits the use and disclosure of protected health information (PHI) under the same restrictions that apply to the covered entity.</p> <p>A contract between a covered entity and its business associate(s) must meet the requirements of §164.504(e)(2) or (e)(3). Among other things, this contract must:</p> <p>(3) set out the permitted and required uses and disclosures of PHI by the business associate;</p> <p>(4) provide that the business associate will:</p>	<p>42 C.F.R. Part 2 also applies to “qualified service organizations,” the definition of which is repeated here:</p> <p><u>Qualified Service Organization</u></p> <p>A person or any entity (including corporations and government agencies) that provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analysis, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect that:</p> <ol style="list-style-type: none"> <li>1. has entered into a written agreement with a program under which the person or entity: <ul style="list-style-type: none"> <li>• acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the program, it is fully bound by 42 C.F.R. Part 2; and if necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by 42 C.F.R. Part 2.</li> </ul> </li> </ol> <p><u>Third party payers, administrative entities, and others</u></p> <p>The restrictions of 42 C.F.R. Part 2 on disclosures apply to:</p> <ol style="list-style-type: none"> <li>1. third party payers with regard to records disclosed to them by federally assisted substance abuse programs;</li> <li>2. entities having direct administrative control over programs with regard to information communicated to them by the program; and</li> </ol>	<p>The rules are similar in coverage of organizations that provide services to “covered entities” (Privacy Rule) or substance abuse programs (42 C.F.R. Part 2).</p> <p>As a practical matter, providers and covered entities must review the relationships they have with entities with which they share information, to ensure compliance with both sets of rules.</p>
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	<p>(f) not use or further disclose PHI except as permitted by the regulation;</p> <p>(g) use appropriate safeguards to assure the proper use of PHI;</p> <p>(h) report to the covered entity any inappropriate or non-contractually agreed upon use of PHI of which it becomes aware;</p> <p>(i) ensure that its employees, agents, and subcontractors agree to the same restrictions that are imposed on the business associate; and</p> <p>(j) permit the Secretary and the covered entity access for audit purposes to its internal practices, books and records relating to the use or disclosure of PHI.</p> <p>If the covered entity and its business associate(s) are both governmental entities, these requirements can be satisfied through a Memorandum of Understanding, rather than a contract.</p>	<p>3. persons who receive patient records directly from a federally assisted substance abuse program and who are notified of the restrictions on redisclosure of the records.</p>	
<p><b>Rights of Individuals</b></p>	<p>The Privacy Rule affords new rights to individuals regarding access to their own PHI. For instance, individuals have a right to:</p> <ul style="list-style-type: none"> <li>• inspect and obtain a copy of all PHI relating to the individual;</li> <li>• amend and/or correct that PHI;</li> <li>• with certain exceptions, an accounting of the uses and disclosure of their PHI (i.e., to know when and to whom disclosure has been made for purposes other than treatment, payment and health operations, including disclosures made by or to a business associate); this right applies to disclosures made in the six (6) year period</li> </ul>	<p>At the time a patient is admitted (or as soon after as the patient can communicate rationally), a program must inform the patient that federal law and regulations protect the confidentiality of alcohol and drug abuse patient records and provide a copy of the federal law and regulations to the patient.</p> <p>The notice to the patient must contain</p> <ul style="list-style-type: none"> <li>(6) a general description of the limited circumstances allowing disclosure;</li> <li>(7) a statement that violation of the law and regulations is a</li> </ul>	<p>42 C.F.R. Part 2 and the Privacy Rule differ on a patient's access to his or her own records. 42 C.F.R. Part 2 allows, but does not require, that the patient be given access. In contrast, the Privacy Rule requires that a patient be given access to his or her own PHI (except for psychotherapy notes).</p> <p>Therefore, as a practical matter, substance abuse programs will have to comply with the Privacy Rule, which makes patient access to his or her own records a requirement rather than an option.</p>

	<ul style="list-style-type: none"> <li>• prior to the request for an accounting; notice and a full description of the covered entity’s use and disclosure practices (generally any use or disclosure of PHI not described in this notice is prohibited); and</li> <li>• challenge the covered entity’s use or disclosure of PHI through complaints to (1) the privacy official designated by each covered entity and through the complaint process that must also be established or (2) to the Secretary of HHS through a process that the Secretary will establish.</li> </ul>	<p>crime and that suspected violations may be reported to authorities;</p> <p>(8) a statement that information related to a patient’s commission of a crime on the premises is not protected;</p> <p>(9) a statement that reports of suspected child abuse and neglect made under state law to appropriate state or local authorities are not protected; and</p> <p>(10) a citation to the federal law and regulations.</p> <p>The regulation provides a sample notice at 42 C.F.R. § 2.23.</p> <p>42 C.F.R. Part 2 allows (but does not require) a program to provide a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The patient’s consent or written authorization is not required.</p>	
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<p><b>Preemption of State Privacy Laws</b></p>	<p>Does not preempt state statutes that have more stringent privacy protections.</p> <p>“More stringent” state laws are defined in the regulation as those that are more protective of an individual’s right to privacy protection for his or her PHI, including those state laws providing for greater rights of access or amendment to individuals or prohibiting or restricting a disclosure or use under circumstances in which the Privacy Rule permits it.</p>	<p>42 C.F.R. Part 2 does not preempt all state law regarding the confidentiality of substance abuse patient records. If a state law prohibits a disclosure permitted by 42 C.F.R. Part 2, neither the substance abuse confidentiality statute nor regulations authorize a violation of such a state law. Therefore, more strict state confidentiality laws remain in place. Similarly, no state law may authorize or compel any disclosure that 42 C.F.R. Part 2 prohibits.</p>	<p>The preemption provisions in each rule are similar.</p>
<p><b>Applicability to Special Populations: Victims of Abuse, Neglect, or Domestic Violence</b></p>	<p>The Privacy Rule allows covered entities to use or disclose PHI without consent or authorization if the covered entity reasonably believes the patient is a victim of abuse, neglect, or domestic violence. The rule covers child abuse and other victims of abuse, neglect or domestic violence (e.g., abuse of nursing home residents or residents of facilities for the mentally retarded).</p> <p>Covered entities can make such disclosures only to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence. The disclosure can be made only if:</p> <ul style="list-style-type: none"> <li>• the disclosure is required by law and complies with and is limited to the relevant requirements of such law; or</li> <li>• if the individual agrees to the disclosure; or</li> <li>• to the extent the disclosure is expressly</li> </ul>		

	<p>authorized by statute or regulation and</p> <ol style="list-style-type: none"> <li>3. the covered entity, in its professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or</li> <li>4. if the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the PHI sought is not intended for use against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.</li> </ol> <p>Once the covered entity discloses the PHI, it must promptly inform the individual that a report has been made, unless:</p> <ul style="list-style-type: none"> <li>• the covered entity, in the exercise of professional judgment, believes that informing the individual would place the individual at risk of serious harm; or</li> <li>• the covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing the representative would not be in the best interests of the individual.</li> </ul>		
<p><b>Applicability to Minors</b></p>	<p>HHS's guidance on the Privacy Rule indicates that a parent with authority to make health care decisions for the minor is generally a "personal representative" of his or her minor child under the Rule and has the right to obtain access to health information about his or her minor child.</p>	<p><u>Minors</u></p> <p>Under 42 C.F.R. Part 2, the term "minor" means a person that has not attained majority under the applicable state law (or, if no age of majority is specified in state law, eighteen years of age).</p>	<p>Although the provisions are generally similar and depend on provisions of state or other law, the Privacy Rule affords more discretion in confidential treatment relationships between minors and providers. 42 C.F.R. Part 2's treatment depends solely on whether state law requires parental consent, but the Privacy Rule</p>



	<p>There are exceptions to this general rule, in which a parent might not be the “personal representative” with respect to certain health information. In the following situations, the rule defers to determinations under other law that the parent does not control the minor’s health care decisions and, thus, does not control the PHI related to that care:</p> <ol style="list-style-type: none"> <li>1. When state or other law does not require consent of a parent or other person before a minor can obtain a particular health care services, and the minor consents to the health care services, the parent is not the minor’s personal representative under the Privacy Rule. For example, when a state law provides an adolescent the right to consent to mental health treatment without the consent of his or her parent, and the adolescent obtains such treatment without the consent of the parent, the parent is not the personal representative of the minor under the Privacy Rule for that treatment. The minor may choose to involve a parent in the treatment decisions without giving up his or her right to control the PHI related to the treatment.</li> <li>2. When a court determines or other law authorizes someone other than the parent to make treatment decisions for a minor, the parent is not the personal representative of the minor for the relevant services.</li> </ol> <p>For example, the Privacy Rule “reflects current professional practice” in determining that the parent is not the minor’s personal representative with respect to the relevant PHI:</p>	<p>If a minor acting alone has the capacity under applicable state law to enter into a substance abuse program, then only the minor can give any written consent for disclosure under the regulation.</p> <p>Where state law requires consent of a parent, guardian, or other person for a minor to obtain substance abuse treatment, any written consent for disclosure must be given by <i>both</i> the minor and his or her parent, guardian, or other person authorized to act on the minor’s behalf.</p> <p>In addition, where state law requires parental consent to treatment, the fact that a minor has applied for treatment may be communicated to the minor’s parent, guardian, or other person authorized to act on the minor’s behalf only if:</p> <ol style="list-style-type: none"> <li>1. the minor has given written consent to the disclosure; or</li> <li>2. the minor lacks capacity to make a rational choice regarding such consent because of extreme youth or physical or mental condition, as judged by the program director.</li> </ol>	<p>allows for additional protections for minors.</p>
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	<ol style="list-style-type: none"> <li>1. When a parent agrees to a confidential relationship between a minor and a physician, the parent does not have access to the PHI related to that relationship.</li> <li>2. When a physician or other covered entity reasonably believes that the child has been or may be subjected to abuse or neglect, or that treating the parent as the child's personal representative could endanger the child, the covered entity may choose not to treat the parent as the minor's personal representative.</li> </ol>		
<p><b>Restriction: Criminal Charges</b></p>	<p>The Privacy Rule permits disclosures without consent to law enforcement officials.</p>	<p>42 C.F.R. Part 2 allows the disclosure or use of a patient's records to conduct a criminal investigation or initiate or substantiate criminal charges against a patient <i>only</i> if a court order compels such use or disclosure. Without a court order, the restriction prohibits the introduction of the records into evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime.</p> <p>Under the authorizing statute, a judge can issue a court order only for good cause, which requires a judge to balance the public interest and the need for disclosure against the injury to the patient, the physician-patient relationship, and to the treatment program. The statute also requires a judge issuing such an order to impose appropriate safeguards to ensure against unauthorized disclosure of the information.</p> <p>The restriction applies to any person who obtains information about a patient for purposes of conducting a criminal investigation or initiating or substantiating criminal charges from a program, <i>regardless of</i></p>	<p>The provisions of 42 C.F.R. Part 2 are stricter.</p>

		the status of the recipient or of whether the information was obtained in accordance with the regulation. Information obtained by undercover agents or informants or through a patient's access to the records is subject to this restriction.	
<b>Psychotherapy Services Provided by Substance Abuse Paraprofessionals</b>	<p>The privacy rule treats psychotherapy notes as a distinct category of PHI. With a few exceptions, covered entities must obtain an individual's authorization to use or disclose psychotherapy notes to carry out treatment, payment, or health care operations. As a practical matter, such authorizations will rarely be necessary, since, as the preamble to the rule points out, psychotherapy notes do not include information that covered entities typically need for treatment, payment, or other routine health care operations.</p> <p>A covered entity must obtain the patient's consent (but not authorization) for the person who created the psychotherapy notes to use the notes to carry out treatment and for the covered entity to use or disclose psychotherapy notes for conducting training programs in which students, trainees, or practitioners in mental health learn under supervision to improve their skills in counseling.</p> <p>A covered entity may also use psychotherapy notes to defend a legal action or other proceeding brought by the individual pursuant to a consent (but without a specific authorization). This would allow disclosure to the covered entity's attorney to defend against the action or proceeding, but disclosure to others during the judicial or administrative proceeding is governed by 45 C.F.R. § 164.512(e) (which describes court orders compelling discovery of the notes, etc.). The</p>	42 C.F.R. Part 2 does not specifically address substance abuse paraprofessionals, but if they worked as part of a substance abuse program covered by the rule, they would be subject to its requirements.	

	<p>rule’s preamble notes that disclosure to a covered entity’s attorney only requires consent because the defense constitutes “health care operations” and the entity should be able to defend itself without seeking a specific authorization from the patient.</p> <p>The rule does not explicitly address psychotherapy paraprofessionals. The rule’s broad definition, however, suggests that notes of paraprofessionals are treated similarly to those of any other provider who is a mental health professional:</p> <p>Notes recorded (in any medium) by a <i>health care provider who is a mental health professional</i> documenting or analyzing the contents of a conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual’s medical record. <i>Psychotherapy notes</i> excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.</p>		
<b>Data Security Standards</b>	As part of HIPAA’s administrative simplification, HHS promulgated extensive electronic security standards. <i>See</i> 65 Fed. Reg. 50311 (Aug. 17, 2000)/	42 C.F.R. Part 2 requires programs to maintain substance abuse records subject to the regulation in a secure room, in a locked file cabinet, safe or other similar container when the records are not in use. In addition, the regulation requires programs to adopt written procedures to regulate access to and use of records subject to the regulation.	2 C.F.R. Part 2’s security standards are far easier to implement than the data security standards of the Privacy Rule, which are the subject of an entirely separate regulation under HIPAA.
<b>Enforcement and</b>	The Secretary of HHS delegated the	Any person violating 42 C.F.R. Part 2 or its	The penalties for violation of the Privacy Rule

<p><b>Compliance</b></p>	<p>enforcement of the Privacy Rule to HHS's Office of Civil Rights. Through that office, the Secretary of HHS can bring enforcement actions against covered entities. Under HIPAA, the Secretary may impose civil monetary penalties of not more than \$100 per person per violation and up to \$25,000 for violations of a single standard within a single calendar year. In addition, criminal penalties are established under HIPAA for wrongful disclosures of PHI, which, upon conviction, could result in fines of not more than \$50,000 and/or imprisonment for not more than one year. Offenses committed with intent to sell, transfer or use PHI for commercial or personal gain or malicious harm are punishable by a fine not to exceed \$250,000 and/or 10-year imprisonment.</p> <p>The Privacy Rule does not authorize private rights of action for wrongful disclosure violations. However, individuals may report violations to the Secretary so HHS can undertake appropriate investigation and enforcement activities on behalf of an aggrieved individual.</p> <p>Under the rule, providers have until April 14, 2003 to come into compliance (and small health plans with less than five million in revenues have an additional year).</p>	<p>implementing statutes can be fined up to \$500 for the first offense, and up to \$5,000 for each subsequent offense.</p>	<p>are more severe (higher monetary penalties and potential jail time) than the penalties for violating 42 C.F.R. Part 2.</p>
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