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- A statement, prominently displayed stating: "THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY;"
- A description in sufficient detail of the types of uses and disclosures that the program may make without the patient's consent or authorization.[19] For substance abuse treatment programs, these would include uses and disclosures:
    - In connection with treatment, payment or health care operations (include at least one example of each);
    - To qualified service organizations or business associates who provide services to the program's treatment, payment or health care operations;
    - In medical emergencies;
    - Authorized by court order;
    - To auditors and evaluators;
    - To researchers if the information will be protected as required by Federal regulations;
    - To report suspected child abuse or neglect; and
    - To report a crime or a threat to commit a crime on program premises or against program personnel.
- A statement that other disclosures will be made only with the patient's written consent or authorization which can be revoked, unless the program has taken action in reliance on the consent or authorization. ;[20]
- A statement that the program may contact the patient to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the patient;[21]
- A statement that it is required by law to maintain the privacy of PHI and to notify patients of its legal duties and privacy practices, including any changes to its policies;
- A statement that the program must abide by the terms of the notice currently in effect; a statement that the program reserves the right to change the terms of its notice and to make the new notice provisions effective for all information it maintains;[22] and a statement describing how it will provide patients with a revised notice of its practices;

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[19] The Privacy Rule also requires that the notice contain information about any more restrictive law. For example, if State law further limits disclosure of HIV-related information, that restriction should also appear in the notice.

[20] Programs often need to provide PHI to criminal justice agencies that mandate patients into treatment. Under Part 2, such disclosures may be made pursuant to a non-revocable consent that complies with 42 CFR §2.35. Under the Privacy Rule, such disclosures may be made pursuant to an authorization or pursuant to a court order. In order to comply with both rules, programs may find it helpful to ask the court in such a situation to issue an order that the program disclose necessary information to the court and other law enforcement personnel.

[21] A substance abuse treatment program engaging in these kinds of activities must be careful in contacting the patient that it does not make any patient-identifying disclosures to others. If the program does not intend to contact the patient, they do not need to include this statement.

[22] This is also voluntary. However, if this statement is not included, any changes in privacy practices described in the notice will apply only to PHI the program created or received after issuing a revised notice reflecting such changes. 45 CFR §164.520(b)(1)(v)(C).

- The name or title and telephone number of a person or office the patient can contact for further information;
- A statement of the patient's rights with respect to PHI and a brief description of how the patient may exercise those rights, including:
    - The right to request restrictions on certain uses and disclosures of PHI, including the statement that the program is not required to agree with requested restrictions;
    - The right to receive confidential communications of PHI (such as having mail and telephone calls be limited to home or office location);
    - The right to access and amend PHI;
    - The right to receive an accounting of the program's disclosures of PHI;
    - The right to complain—free from retaliation—to the program and to the Secretary of Health and Human Services (HHS) about violations of privacy rights, and information on how to file a complaint with the program; and
    - The right to obtain a paper copy of the notice upon request.
- The effective date of the notice.

See 45 CFR §164.520(b).

2. Distribution of the Notice

Part 2 requires that programs provide the notice at the time of admission or as soon thereafter as the patient is capable of rational communication. See 42 CFR §2.22(a). The Privacy Rule requires that the substance abuse treatment program must provide the notice to a patient on the date of the first service delivery, including service delivered electronically, after April 14, 2003.[23] The program must also have the notice available on site for patients to request to take with them and posted in a clear and prominent location where it is reasonable to expect patients to be able to read it. Whenever there is a material change to the notice, the notice must be promptly revised, made available upon request, and re-posted as previously referenced. See 45 CFR §§164.520(c)(2); 164.530(i)(4)(i)(C).

The program must make a good faith effort to obtain patients' written acknowledgment of receipt of the notice, except in an emergency treatment situation, on the date of the first service delivery. If written acknowledgment is not obtained, the program must document its efforts and the reason it was not able to obtain the acknowledgement. See 45 CFR §164.520(c)(2)(ii).

Any program that maintains a web site that provides information about its services or benefits must prominently post its notice on the site and make it available electronically through the site. When patients agree, the program can provide the notice by e-mail. See 45 CFR §164.520(c)(3).

[23] There is an exception in emergency situations. If treatment is provided on an emergency basis, the program must provide the notice as soon as practicable after the emergency is resolved. See 45 CFR §164.520(c)(2)(i)(B).

B. Patient rights

The Privacy Rule provides patients with new Federal privacy rights, including the right to request restrictions of uses and disclosures of PHI, and the right to access, amend, and receive an accounting of disclosures of PHI. See 45 CFR §§164.522, 164.524, 164.526,164.528.

1. Right to request a restriction of uses and disclosures

The Privacy Rule requires that programs allow patients to request that the program restrict uses or disclosures of PHI for the purpose of treatment, payment or health care operations and for involvement in the patient's care and notification under 45 CFR §164.510(b). The program is not required to agree to a requested restriction. If, however, a program agrees to a restriction, the program may not then violate the agreed-upon restriction, except for emergency treatment purposes, so long as the program requests that the emergency treatment provider not further use or disclose the PHI. A covered entity may terminate the agreement to a restriction, effective after the patient has been informed of the termination. See 45 CFR §164.522(a).

The Privacy Rule gives the individual the right to request that communication of PHI be done by alternative means or to alternative locations (confidential communications). See 45 CFR §164.522(b)(1)(i). This might include the right to request that mail and telephone calls be limited to home or office location. The Privacy Rule requires programs to accommodate reasonable requests.

2. Right to access PHI

Neither Part 2 nor the Privacy Rule requires programs to obtain written consent from individuals before permitting them to see their own records. Likewise, neither rule prohibits a program from giving 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. 42 CFR §2.23. However, the Privacy Rule permits programs to require that such requests be in writing. See 45 CFR §164.524(b)(1). The Privacy Rule provides patients with a right of access to inspect and obtain a copy of their PHI. See 45 CFR §164.524(a)(1).[24] Certain information, however, is exempt from this right of access:

[24] The Privacy Rule requires access to information in a designated record set for as long as the PHI is maintained in the designated record set. "Designated record set" is defined as "[a] group of records maintained by or for a covered entity that is: (i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals." 45 CFR §164.501. The program must document the designated record sets that are subject to access and the titles of the persons or offices responsible for receiving and processing requests for access (45 CFR §164.524(e)). It must retain the documentation for six (6) years from the date it was last effective, whichever is later (45 CFR §164.530(j)). Under Part 2, the information need not be contained in a designated record set. Thus, programs could permit access to all disclosable patient records.

- Psychotherapy notes;[25]
- Information compiled in reasonable anticipation of or for use in a civil, criminal, or administrative action or proceeding; and
- Information that may be subject to or exempt from certain Clinical Laboratory Improvement Amendment (CLIA) provisions.

See 45 CFR §164.524(a)(1).

The Privacy Rule requires that programs respond to a patient's request for access within 30 days after receipt of the request (within 60 days if the information is not maintained or accessible on-site). The program may extend the deadline once by not more than 30 days, if within 30 days of the receipt of the request (or 60 days of receipt if the information is not on-site), the patient is provided with a written statement containing the reasons for the delay and the date by which it will permit access. See 45 CFR §164.524(b). If the program does not maintain the requested information, but knows where the requested information is maintained, it must inform the patient where to direct his or her request. See 45 CFR §164.524(d)(3).

If a program grants the patient's request for access to his or her records, it can charge the patient a reasonable, cost-based fee, consistent with the restrictions on fees as provided in the Privacy Rule. See 45 CFR §164.524(c)(4).[26]

Denial of Access

The Privacy Rule allows a program to deny a patient access without providing an opportunity for review of the denial, on the following grounds:

- The information is specifically exempted from the right of access by the Privacy Rule. See 45 CFR §164.524(a)(1);
- The program is a correctional institution or a provider acting under the direction of the correctional institution and denies in whole or in part an inmate's request to obtain a copy of his or her records if doing so would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of an officer, employee or other person at the correctional institution or responsible for transporting the inmate. See §164.524(a)(2)(ii));
- The requested information was created or obtained by a program in the course of research that includes treatment. The individual's access to such information

[25] The Privacy Rule defines "psychotherapy notes" as "notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session 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." 45 CFR §164.501.

[26] Information obtained by patient access to his or her own record is subject to Part 2's restriction on use of the information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient. See 42 CFR §2.23(b).

may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research and the program has informed him or her that the right of access will be reinstated upon completion of the research. See 45 CFR §164.524(a)(2)(iii);
- The requested information is subject to the Privacy Act and would be denied under the access provisions of the Privacy Act, 5 USC §522a. See 45 CFR §164.524(a)(2)(iv); or
- The requested information was obtained under a promise of confidentiality from someone other than a health care provider and such access would be likely to reveal the source of the information. See 45 CFR §164.524(a)(2)(v).

The Privacy Rule permits a program to deny patient access, provided that the patient is given the right to have such a denial reviewed, on the following grounds:

- A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the patient or another person;
- The information makes reference to another person (other than a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access is reasonably likely to cause substantial harm to such other person; or
- The request for access is made by the patient's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the patient or another person.

See 45 CFR §164.524(a)(3).

If the program's denial is based on one of the last three reasons, the patient has the right to have that denial reviewed by a licensed health care professional who is designated by the program to act as a reviewing official and who did not participate in the original decision to deny access. See 45 CFR §164.524(a)(4).

If the program denies a patient access to all or parts of his or her PHI, it must give the patient a timely denial written in plain language containing:

- The basis for the denial;
- If applicable, a statement of the patient's review rights, including a description of how the patient may exercise those rights; and
- A description of how the patient may complain to the program or to the Secretary of HHS. The description must include information regarding how the patient may complain to the program pursuant to the program's complaint procedures or to the Secretary, and must include the name or title, and telephone number of the contact person or office designated by the program to receive complaints.

See 45 CFR §164.524(d)(2).

A program that denies a patient access in part must give the patient access to any other PHI requested after excluding the information to which the program had reason to deny access. See 45 CFR §164.524(d)(1).

3. The right to amend PHI

The Privacy Rule gives patients the right to have the program amend their PHI or a record about the patient in a designated record set. See 45 CFR §164.526. The program must act on a patient's request for amendment within 60 days after it receives the request. The program may extend the deadline once by not more than 30 days if, within the 60 days, the patient is provided with a written statement of the reasons for the delay and the date by which it will respond. See 45 CFR §164.526(b)(2).

A program that accepts a patient's request to amend PHI must:

- Timely inform the patient of its decision to accept the amendment;
- Make the appropriate amendment by identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment; and
- If the patient agrees, make reasonable efforts to notify and provide the amendment within a reasonable period of time to:
    - Persons identified by the patient as having received the patient's PHI and needing the amendment; and
    - Persons, including business associates, that the program knows to have received the PHI that is the subject of the amendment and that may have relied, or could foreseeably rely on such information to the detriment of the patient.

See 45 CFR §164.526(c).

A program must obtain patient consent on forms that comply with 42 CFR §2.31 before it provides any copies of the amendment to other persons or organizations.

Denial of Amendment

A program may deny a patient's request for amendment if it determines that:

- It did not create the information, unless the patient provides a reasonable basis to believe that the originator of the PHI is no longer available to act on the requested amendment;
- The information or record is accurate and complete; or

- The information that is the subject of the request is not part of a designated record set or would not otherwise be available for inspection under the Privacy Rule's request for access provisions.

See 45 CFR §164.526(a)(2).

If a program denies a patient's request to amend records, it must give him or her a timely denial, written in plain language, and contain:

- The basis for the denial;
- Notice of the patient's right to file a written statement of disagreement with the denial and how the patient may file such a statement;
- Notice that, if the patient does not submit a statement of disagreement, the patient may request that the program include his or her request for amendment and its denial with any future disclosures of the PHI that is subject to the amendment; and
- A description of how the patient may complain about the program's actions to the program or to the Secretary of HHS. The description must include information regarding how the individual may complain to the program pursuant to its complaint procedures or to the Secretary, and must include the name or title, and telephone number of the contact person or office designated by the program to receive complaints.

See 45 CFR §164.526(d)(1).

The program may prepare a written rebuttal to the patient's statement of disagreement. If it prepares such a rebuttal, it must provide a copy to the patient who submitted the statement of disagreement. This information (e.g. the statement of disagreement and rebuttal), or in some cases, a summary, must all be included in any subsequent disclosures of the information to which the disagreement relates as provided in 45 CFR §164.526(d)(3), (4), and (5).

The program must document the titles of the persons or offices responsible for receiving and processing requests for amendment. It must retain the documentation for six (6) years from the date it was created or last effective, whichever is later. See 45 CFR §164.526(f).

4. Right to an accounting of disclosures of PHI

The Privacy Rule provides individuals with the right to obtain an accounting of certain disclosures of PHI made by a program during the six (6) years prior to the request. See 45 CFR §164.528(a).

A program does not have to provide an accounting for any disclosures that were made:

- For treatment, payment, and health care operations as provided in 45 CFR §164.506;
- To the patient as provided in 45 CFR §164.502;
- Incident to a use or disclosure that is otherwise permitted as provided in 45 CFR §164.502;
- Pursuant to the patient's written consent (an "authorization" meeting the Privacy Rule's requirements at 45 CFR §164.508);
- For the facility's directory or to persons involved in the patient's care or other notification purposes as set forth by the rule at 45 CFR §164.510;
- For national security or intelligence purposes as provided by the rule at 45 CFR §164.512(k)(2);
- To correctional institutions or law enforcement officials having custody of an inmate or individual and as specified under 45 CFR §164.512(k)(5);
- As part of a limited data set in accordance with the rule at 45 CFR §164.514(e); and
- Before April 14, 2003.

See 45 CFR §164.528(a)(1). In addition, a program must temporarily suspend a patient's right to receive an accounting of disclosures to a health oversight agency or law enforcement official if the program receives notification that it would be reasonably likely to impede the activities of the agency or official. See 45 CFR §164.528(a)(2).

The accounting must be in writing[27] and include:

- The date of each disclosure;
- The name and address (if known) of the entity or person who received the PHI;
- A brief description of the PHI disclosed; and
- A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of a written request for disclosure, if any.

See 45 CFR §164.528(b)(2).

For substance abuse treatment programs, the following disclosures are typically made without patient consent and must therefore be included in an accounting of disclosures:

- Disclosures to health oversight agencies;
- Disclosures to researchers that include patient-identifying information;[28]
- Disclosures to public health authorities;[29]

[27] There are special provisions under the Privacy Rule that are applicable to accounting for recurrent disclosures and certain research disclosures. See 45 CFR §§164.528(b)(3) and (b)(4).
[28] There are special provisions under the Privacy Rule that are applicable to accounting for research. See 45 CFR §164.528(b)(4)).
[29] When a program authorizes access to an entire universe of records, e.g., for public health surveillance activities, the Privacy Rule's accounting requirement can be met without the program having to make a

- Court-ordered disclosures;
- Reports of patient crimes on program premises or against program personnel; and
- Child abuse and neglect reports.

Programs should establish mechanisms to document all disclosures for which they must account.

The accounting must be made within 60 days of the program's receipt of the request. The program may extend the deadline once by not more than 30 days if, within the 60 days, the patient is provided with a written statement of the reasons for the delay and the date by which it will provide the accounting. A program must respond to a patient's request for one accounting within any 12-month period without charge. For any subsequent request within a 12-month period, it may charge a patient a reasonable, cost-based fee. If the program imposes a fee, it must inform the patient of the fee in advance and give the patient an opportunity to withdraw or modify the request. See 45 CFR §164.528(c).

The program must also document the following:

- The information it was required to provide the patient;
- The written accounting it provided the patient; and
- The titles of the persons or offices responsible for receiving and processing requests for an accounting.

This documentation must be retained for six (6) years from the date created or last effective, which ever is later. See 45 CFR §164.528(d).

C. Administrative Requirements

1. Complaints about the program's privacy practices

Part 2 allows violations of those regulations to be reported to the United States Attorney for the judicial district in which the violation occurs. See 42 CFR §2.5.

The Privacy Rule establishes a process for individuals to file a complaint with the Secretary of HHS if they believe a program violated the Privacy Rule. The complaint must be written, either on paper or electronically, and filed with HHS' Office for Civil Rights within 180 days of when the complainant knew, or should have known, that the act or omission complained of occurred, unless a waiver is granted. The complaint must name the program and describe the violation of the Privacy Rule. See 45 CFR §160.306. Programs must also establish a process for individuals to make complaints about the program's privacy policies and procedures or the program's compliance with

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notation in each medical record that has been accessed by public health authorities. See Office for Civil Rights, Frequently Asked Questions, http://www.hhs.gov/ocr/hipaa.

such policies and procedures or with the requirements of the Privacy Rule. See 45 CFR §164.530(d).

2. Other administrative requirements

Programs subject to the Privacy Rule are required to meet administrative requirements including:

- Designate a privacy official who is responsible for the development and implementation of its policies and procedures and a contact person or office responsible for receiving complaints and able to provide further information. See 45 CFR §164.530(a).
- Train all members of the workforce on the program's policies and procedures. Each new member of the workforce must receive training within a reasonable period of time after s/he joins the workforce. Whenever a workforce member's functions are affected by a material change in privacy policies or procedures, that person must receive additional training within a reasonable period of time after the material change becomes effective. The program must document all training and retain the records for a period of six (6) years after the training. See 45 CFR §164.530(b).
- Have in place appropriate administrative, technical, and physical safeguards to protect the privacy of PHI. See 45 CFR §164.530(c).
- Establish written policies and procedures that identify the staff persons or classes of persons who need access to patients' PHI, the categories of PHI they need access to, and any conditions appropriate to such access. The program must make reasonable efforts to limit access based on these determinations. See 45 CFR §164.514(d)(2).
- Establish policies and procedures to ensure that, for disclosures of information that occur on a routine and recurring basis, reasonable efforts are made to limit disclosures to the minimum necessary to accomplish the intended purpose of the disclosure. See 45 CFR §§164.502(b) and 164.514(d)(3)(i). For "all other disclosures," the program must develop criteria designed to limit the information it discloses to the information reasonably necessary to accomplish the purpose for which disclosure is sought and review requests for disclosure on an individual basis in accordance with those criteria. See 45 CFR §164.514(d)(3)(ii). Programs must also develop policies, procedures and criteria to ensure that requests to other entities subject to the Privacy Rule for PHI are limited to information "which is reasonably necessary to accomplish the purpose for which the request is made." See 45 CFR §164.514(d)(4). The written polices and procedures must be retained for six (6) years after the last time they were effective. See 45 CFR §164.530(j).
- Establish and apply appropriate sanctions against members of its workforce who fail to comply with its privacy policies and procedures. See 45 CFR §164.530(e).

- Mitigate, to the extent practicable, any harmful effect that is known to the program that results from a use or disclosure in violation of its policies and procedures. See 45 CFR §164.530(f).
- Refrain from taking intimidating, threatening, coercing, discriminating, or other retaliatory action against any individual who exercises rights under the Privacy Rule, including filing a complaint, assisting in an investigation, compliance review, proceeding or hearing pursuant to the Privacy Rule, as well as any individual who opposes any act or practice made unlawful by the Privacy Rule, provided that he or she has a good faith belief that the practice is unlawful and the manner of opposition is reasonable and does not invoke an impermissible disclosure of PHI. See 45 CFR §164.530(g).
- Not require patients to waive their rights to complain to the Secretary of HHS or their other rights under the Privacy Rule as a condition of treatment, payment, enrollment in a health plan, or eligibility for benefits. See 45 CFR §164.530(h).
- Implement policies and procedures regarding PHI that are designed to comply with the standards, implementation specifications, and other requirements of the Privacy Rule, and maintain the policies and procedures in written or electronic form for six years from the date the document was created, or last effective, whichever is later. See 45 CFR §164.530(i) and (j).

D. Security of information

Part 2 requires programs to maintain patient written records in a secure room, locked file cabinet, safe or other similar container. The regulations also require programs to adopt written procedures to regulate access to patients' records. See 42 CFR §2.16.

Section 164.530(c) of the Privacy Rule requires programs to maintain reasonable and appropriate administrative, technical and physical safeguards to protect the privacy of PHI. The issue of security has been addressed in more detail through a separate Security Rule issued by HHS on February 20, 2003 that established the physical and technical security standards required to guard the integrity, confidentiality and availability of confidential information that is electronically stored, maintained or transmitted. See 68 Federal Register 8334. Covered entities must be in compliance with the Security Rule by April 20, 2005, except small health plans which have until April 20, 2006.

Conclusion

Compliance with Part 2 has given the substance abuse treatment programs extensive experience with protecting patient confidentiality. Although substance abuse programs will need to make some changes to their business practices, they have a good starting point to work from in achieving compliance with the HIPAA Privacy Rule. Substance abuse treatment programs should contact their respective State substance abuse agencies and/or provider organizations, as well as legal counsel for assistance in implementing practices that will comply with both Part 2 and the Privacy Rule.