

## Summary of the HIPAA Privacy Rule

### Summary of the HIPAA Privacy Rule

---



This is a summary of key elements of the Privacy Rule including who is covered, what information is protected, and how protected health information can be used and disclosed. Because it is an overview of the Privacy Rule, it does not address every detail of each provision.

For more information visit:

<http://www.hhs.gov/ocr/privacy/>

## Introduction

The *Standards for Privacy of Individually Identifiable Health Information* (“Privacy Rule”) establishes, for the first time, a set of national standards for the protection of certain health information. The U.S. Department of Health and Human Services (“HHS”) issued the Privacy Rule to implement the requirement of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).<sup>1</sup> The Privacy Rule standards address the use and disclosure of individuals’ health information—called “protected health information” by organizations subject to the Privacy Rule — called “covered entities,” as well as standards for individuals’ privacy rights to understand and control how their health information is used. Within HHS, the Office for Civil Rights (“OCR”) has responsibility for implementing and enforcing the Privacy Rule with respect to voluntary compliance activities and civil money penalties.

A major goal of the Privacy Rule is to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public’s health and well being. The Rule strikes a balance that permits important uses of information, while protecting the privacy of people who seek care and healing. Given that the health care marketplace is diverse, the Rule is designed to be flexible and comprehensive to cover the variety of uses and disclosures that need to be addressed.

This is a summary of key elements of the Privacy Rule and not a complete or comprehensive guide to compliance. Entities regulated by the Rule are obligated to comply with all of its applicable requirements and should not rely on this summary as a source of legal information or advice. To make it easier for entities to review the complete requirements of the Rule, provisions of the Rule referenced in this summary are cited in the [end notes](#). Visit our [Privacy Rule](#) section to view the entire Rule, and for other additional helpful information about how the Rule applies. In the event of a conflict between this summary and the Rule, the Rule governs.

### **Statutory and Regulatory Background**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, was enacted on August 21, 1996. Sections 261 through 264 of HIPAA require the Secretary of HHS to publicize standards for the electronic exchange, privacy and security of health information. Collectively these are known as the *Administrative Simplification* provisions.

HIPAA required the Secretary to issue privacy regulations governing individually identifiable health information, if Congress did not enact privacy legislation within three years of the passage of HIPAA. Because Congress did not enact privacy legislation, HHS developed a proposed rule and released it for public comment on November 3, 1999. The Department received over 52,000 public comments. The final regulation, the Privacy Rule, was published December 28, 2000.<sup>2</sup>

In March 2002, the Department proposed and released for public comment modifications to the Privacy Rule. The Department received over 11,000 comments. The final modifications were published in final form on August 14, 2002.<sup>3</sup> A text combining the final regulation and the modifications can be found at 45 CFR [Part 160](#) and [Part 164](#), Subparts A and E.

## Who is Covered by the Privacy Rule

The Privacy Rule, as well as all the Administrative Simplification rules, apply to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA (the “covered entities”). [For help in determining whether you are covered, use CMS's decision tool.](#)

**Health Plans.** Individual and group plans that provide or pay the cost of medical care are covered entities.<sup>4</sup> Health plans include health, dental, vision, and prescription drug insurers, health maintenance organizations (“HMOs”), Medicare, Medicaid, Medicare+Choice and Medicare supplement insurers, and long-term care insurers (excluding nursing home fixed-indemnity policies). Health plans also include employer-sponsored group health plans, government and church-sponsored health plans, and multi-employer health plans. There are exceptions—a group health plan with less than 50 participants that is administered solely by the employer that established and maintains the plan is not a covered entity. Two types of government-funded programs are not health plans: (1) those whose principal purpose is not providing or paying the cost of health care, such as the food stamps program; and (2) those programs whose principal activity is directly providing health care, such as a community health center,<sup>5</sup> or the making of grants to fund the direct provision of health care. Certain types of insurance entities are also not health plans, including entities providing only workers’ compensation, automobile insurance, and property and casualty insurance. If an insurance entity has separable lines of business, one of which is a health plan, the HIPAA regulations apply to the entity with respect to the health plan line of business.

**Health Care Providers.** Every health care provider, regardless of size, who electronically transmits health information in connection with certain transactions, is a covered entity. These transactions include claims, benefit eligibility inquiries, referral authorization requests, or other transactions for which HHS has established standards under the HIPAA Transactions Rule.<sup>6</sup> Using electronic technology, such as email, does not mean a health care provider is a covered entity; the transmission must be in connection with a standard transaction. The Privacy Rule covers a health care provider whether it electronically transmits these transactions directly or uses a billing service or other third party to do so on its behalf. Health care providers include all “providers of services” (e.g., institutional providers such as hospitals) and “providers of medical or health services” (e.g., non-institutional providers such as physicians, dentists and other practitioners) as defined by Medicare, and any other person or organization that furnishes, bills, or is paid for health care.

**Health Care Clearinghouses.** *Health care clearinghouses* are entities that process nonstandard information they receive from another entity into a standard (i.e., standard format or data content), or vice versa.<sup>7</sup> In most instances, health care clearinghouses will receive individually identifiable health information only when they are providing these processing services to a health plan or health care provider as a business associate. In such instances, only certain provisions of the Privacy Rule are applicable to the health care clearinghouse’s uses and disclosures of protected health information.<sup>8</sup> Health care clearinghouses include billing services, repricing companies, community health management information systems, and value-added networks and switches if these entities perform clearinghouse functions.

## **Business Associates**

**Business Associate Defined.** In general, a business associate is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. Business associate functions or activities on behalf of a covered entity include claims processing, data analysis, utilization review, and billing.<sup>9</sup> Business associate services to a covered entity are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services. However, persons or organizations are not considered business associates if their functions or services do not involve the use or disclosure of protected health information, and where any access to protected health information by such persons would be incidental, if at all. A covered entity can be the business associate of another covered entity.

**Business Associate Contract.** When a covered entity uses a contractor or other non-workforce member to perform "*business associate*" services or activities, the Rule requires that the covered entity include certain protections for the information in a business associate agreement (in certain circumstances governmental entities may use alternative means to achieve the same protections). In the business associate contract, a covered entity must impose specified written safeguards on the individually identifiable health information used or disclosed by its business associates.<sup>10</sup> Moreover, a covered entity may not contractually authorize its business associate to make any use or disclosure of protected health information that would violate the Rule. Covered entities that had an existing written contract or agreement with business associates prior to October 15, 2002, which was not renewed or modified prior to April 14, 2003, were permitted to continue to operate under that contract until they renewed the contract or April 14, 2004, whichever was first.<sup>11</sup> See additional guidance on [Business Associates](#) and [sample business associate contract language](#).

## What Information is Protected

**Protected Health Information.** The Privacy Rule protects all "*individually identifiable health information*" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information (PHI)."<sup>12</sup>

"Individually identifiable health information" is information, including demographic data, that relates to: the individual's past, present or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.<sup>13</sup> Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

The Privacy Rule excludes from protected health information employment records that a covered entity maintains in its capacity as an employer and education and certain other records subject to, or defined in, the Family Educational Rights and Privacy Act, 20 U.S.C. §1232g.

**De-Identified Health Information.** There are no restrictions on the use or disclosure of de-identified health information.<sup>14</sup> De-identified health information neither identifies nor provides a reasonable basis to identify an individual. There are two ways to de-identify information; either: (1) a formal determination by a qualified statistician; or (2) the removal of specified identifiers of the individual and of the individual's relatives, household members, and employers is required, and is adequate only if the covered entity has no actual knowledge that the remaining information could be used to identify the individual.<sup>15</sup>

### **General Principle for Uses and Disclosures**

**Basic Principle.** A major purpose of the Privacy Rule is to define and limit the circumstances in which an individual's protected health information may be used or disclosed by covered entities. A covered entity may not use or disclose protected health information, except either: (1) as the Privacy Rule permits or requires; or (2) as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing.<sup>16</sup>

**Required Disclosures.** A covered entity must disclose protected health information in only two situations: (a) to individuals (or their personal representatives) specifically when they request access to, or an accounting of disclosures of, their protected health information; and (b) to HHS when it is undertaking a compliance investigation or review or enforcement action.<sup>17</sup> See additional guidance on [Government Access](#).

## Permitted Uses and Disclosures

**Permitted Uses and Disclosures.** A covered entity is permitted, but not required, to use and disclose protected health information, without an individual’s authorization, for the following purposes or situations: (1) To the Individual (unless required for access or accounting of disclosures); (2) Treatment, Payment, and Health Care Operations; (3) Opportunity to Agree or Object; (4) Incident to an otherwise permitted use and disclosure; (5) Public Interest and Benefit Activities; and (6) Limited Data Set for the purposes of research, public health or health care operations.<sup>18</sup> Covered entities may rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make.

**(1) To the Individual.** A covered entity may disclose protected health information to the individual who is the subject of the information.

**(2) Treatment, Payment, Health Care Operations.** A covered entity may use and disclose protected health information for its own treatment, payment, and health care operations activities.<sup>19</sup> A covered entity also may disclose protected health information for the treatment activities of any health care provider, the payment activities of another covered entity and of any health care provider, or the health care operations of another covered entity involving either quality or competency assurance activities or fraud and abuse detection and compliance activities, if both covered entities have or had a relationship with the individual and the protected health information pertains to the relationship. See additional guidance on [Treatment, Payment, & Health Care Operations](#).

**Treatment** is the provision, coordination, or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another.<sup>20</sup>

**Payment** encompasses activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits, and furnish or obtain reimbursement for health care delivered to an individual<sup>21</sup> and activities of a health care provider to obtain payment or be reimbursed for the provision of health care to an individual.

**Health care operations** are any of the following activities: (a) quality assessment and improvement activities, including case management and care coordination; (b) competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation; (c) conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; (d) specified insurance functions, such as underwriting, risk rating, and reinsuring risk; (e) business planning, development, management, and administration; and (f) business management and general administrative activities of the entity, including but not limited to: de-identifying protected health information, creating a limited data set, and certain fundraising for the benefit of the covered entity.<sup>22</sup>

Most uses and disclosures of psychotherapy notes for treatment, payment, and health care operations purposes require an authorization as described below.<sup>23</sup> Obtaining “consent” (written permission from individuals to use and disclose their protected health information for treatment, payment, and health care operations) is optional under the Privacy Rule for all covered entities.<sup>24</sup> The content of a consent form, and the process for obtaining consent, are at the discretion of the covered entity electing to seek consent.

## Limiting Uses and Disclosures to the Minimum Necessary

**Minimum Necessary.** A central aspect of the Privacy Rule is the principle of “minimum necessary” use and disclosure. A covered entity must make reasonable efforts to use, disclose, and request only the minimum amount of protected health information needed to accomplish the intended purpose of the use, disclosure, or request.<sup>50</sup> A covered entity must develop and implement policies and procedures to reasonably limit uses and disclosures to the minimum necessary. When the minimum necessary standard applies to a use or disclosure, a covered entity may not use, disclose, or request the entire medical record for a particular purpose, unless it can specifically justify the whole record as the amount reasonably needed for the purpose. See additional guidance on [Minimum Necessary](#). The minimum necessary requirement is not imposed in any of the following circumstances: (a) disclosure to or a request by a health care provider for treatment; (b) disclosure to an individual who is the subject of the information, or the individual’s personal representative; (c) use or disclosure made pursuant to an authorization; (d) disclosure to HHS for complaint investigation, compliance review or enforcement; (e) use or disclosure that is required by law; or (f) use or disclosure required for compliance with the HIPAA Transactions Rule or other HIPAA Administrative Simplification Rules.

**Access and Uses.** For internal uses, a covered entity must develop and implement policies and procedures that restrict access and uses of protected health information based on the specific roles of the members of their workforce. These policies and procedures must identify the persons, or classes of persons, in the workforce who need access to protected health information to carry out their duties, the categories of protected health information to which access is needed, and any conditions under which they need the information to do their jobs.

**Disclosures and Requests for Disclosures.** Covered entities must establish and implement policies and procedures (which may be standard protocols) for *routine, recurring disclosures, or requests for disclosures*, that limits the protected health information disclosed to that which is the minimum amount reasonably necessary to achieve the purpose of the disclosure. Individual review of each disclosure is not required. For non-routine, non-recurring disclosures, or requests for disclosures that it makes, covered entities must develop criteria designed to limit disclosures to the information reasonably necessary to accomplish the purpose of the disclosure and review each of these requests individually in accordance with the established criteria.

**Reasonable Reliance.** If another covered entity makes a request for protected health information, a covered entity may rely, if reasonable under the circumstances, on the request as complying with this minimum necessary standard. Similarly, a covered entity may rely upon requests as being the minimum necessary protected health information from: (a) a public official, (b) a professional (such as an attorney or accountant) who is the covered entity’s business associate, seeking the information to provide services to or for the covered entity; or (c) a researcher who provides the documentation or representation required by the Privacy Rule for research.

## Notice and Other Individual Rights

**Privacy Practices Notice.** Each covered entity, with certain exceptions, must provide a notice of its privacy practices.<sup>51</sup> The Privacy Rule requires that the notice contain certain elements. The notice must describe the ways in which the covered entity may use and disclose protected health information. The notice must state the covered entity's duties to protect privacy, provide a notice of privacy practices, and abide by the terms of the current notice. The notice must describe individuals' rights, including the right to complain to HHS and to the covered entity if they believe their privacy rights have been violated. The notice must include a point of contact for further information and for making complaints to the covered entity. Covered entities must act in accordance with their notices. The Rule also contains specific distribution requirements for direct treatment providers, all other health care providers, and health plans. See additional guidance on [Notice](#).

**Notice Distribution.** A covered health care provider with a *direct treatment* relationship with individuals must have delivered a privacy practices notice to patients starting April 14, 2003 as follows:

- Not later than the first service encounter by personal delivery (for patient visits), by automatic and contemporaneous electronic response (for electronic service delivery), and by prompt mailing (for telephonic service delivery);

- By posting the notice at each service delivery site in a clear and prominent place where people seeking service may reasonably be expected to be able to read the notice; and

- In emergency treatment situations, the provider must furnish its notice as soon as practicable after the emergency abates.

Covered entities, whether direct treatment providers or indirect treatment providers (such as laboratories) or health plans must supply notice to anyone on request.<sup>52</sup> A covered entity must also make its notice electronically available on any web site it maintains for customer service or benefits information.

The covered entities in an organized health care arrangement may use a joint privacy practices notice, as long as each agrees to abide by the notice content with respect to the protected health information created or received in connection with participation in the arrangement.<sup>53</sup> Distribution of a joint notice by any covered entity participating in the organized health care arrangement at the first point that an OHCA member has an obligation to provide notice satisfies the distribution obligation of the other participants in the organized health care arrangement.

A health plan must distribute its privacy practices notice to each of its enrollees by its Privacy Rule compliance date. Thereafter, the health plan must give its notice to each new enrollee at enrollment, and send a reminder to every enrollee at least once every three years that the notice is available upon request. A health plan satisfies its distribution obligation by furnishing the notice to the "named insured," that is, the subscriber for coverage that also applies to spouses and dependents.

## **Administrative Requirements**

HHS recognizes that covered entities range from the smallest provider to the largest, multi-state health plan. Therefore the flexibility and scalability of the Rule are intended to allow covered entities to analyze their own needs and implement solutions appropriate for their own environment. What is appropriate for a particular covered entity will depend on the nature of the covered entity's business, as well as the covered entity's size and resources.

**Privacy Policies and Procedures.** A covered entity must develop and implement written privacy policies and procedures that are consistent with the Privacy Rule.<sup>64</sup>

**Privacy Personnel.** A covered entity must designate a privacy official responsible for developing and implementing its privacy policies and procedures, and a contact person or contact office responsible for receiving complaints and providing individuals with information on the covered entity's privacy practices.<sup>65</sup>

**Workforce Training and Management.** Workforce members include employees, volunteers, trainees, and may also include other persons whose conduct is under the direct control of the entity (whether or not they are paid by the entity).<sup>66</sup> A covered entity must train all workforce members on its privacy policies and procedures, as necessary and appropriate for them to carry out their functions.<sup>67</sup> A covered entity must have and apply appropriate sanctions against workforce members who violate its privacy policies and procedures or the Privacy Rule.<sup>68</sup>

**Mitigation.** A covered entity must mitigate, to the extent practicable, any harmful effect it learns was caused by use or disclosure of protected health information by its workforce or its business associates in violation of its privacy policies and procedures or the Privacy Rule.<sup>69</sup>

**Data Safeguards.** A covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of protected health information in violation of the Privacy Rule and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure.<sup>70</sup> For example, such safeguards might include shredding documents containing protected health information before discarding them, securing medical records with lock and key or pass code, and limiting access to keys or pass codes. See additional guidance on [Incidental Uses and Disclosures](#).

**Complaints.** A covered entity must have procedures for individuals to complain about its compliance with its privacy policies and procedures and the Privacy Rule.<sup>71</sup> The covered entity must explain those procedures in its privacy practices notice.<sup>72</sup>

Among other things, the covered entity must identify to whom individuals can submit complaints to at the covered entity and advise that complaints also can be submitted to the Secretary of HHS.

**Retaliation and Waiver.** A covered entity may not retaliate against a person for exercising rights provided by the Privacy Rule, for assisting in an investigation by HHS or another appropriate authority, or for opposing an act or practice that the person believes in good faith violates the Privacy Rule.<sup>73</sup> A covered entity may not require an individual to waive any right under the Privacy Rule as a condition for obtaining treatment, payment, and enrollment or benefits eligibility.<sup>74</sup>

**Documentation and Record Retention.** A covered entity must maintain, until six years after the later of the date of their creation or last effective date, its privacy policies and procedures, its privacy practices notices, disposition of complaints, and other actions, activities, and designations that the Privacy Rule requires to be documented.<sup>75</sup>

**Fully-Insured Group Health Plan Exception.** The only administrative obligations with which a fully-insured group health plan that has no more than enrollment data and summary health information is required to comply are the (1) ban on retaliatory acts and waiver of individual rights, and (2) documentation requirements with respect to plan documents if such documents are amended to provide for the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO that services the group health plan.<sup>76</sup>

## Organizational Options

The Rule contains provisions that address a variety of organizational issues that may affect the operation of the privacy protections.

**Hybrid Entity.** The Privacy Rule permits a covered entity that is a single legal entity and that conducts both covered and non-covered functions to elect to be a “hybrid entity.”<sup>77</sup> (The activities that make a person or organization a covered entity are its “covered functions.”<sup>78</sup>) To be a hybrid entity, the covered entity must designate in writing its operations that perform covered functions as one or more “health care components.” After making this designation, most of the requirements of the Privacy Rule will apply only to the health care components. A covered entity that does not make this designation is subject in its entirety to the Privacy Rule.

**Affiliated Covered Entity.** Legally separate covered entities that are affiliated by common ownership or control may designate themselves (including their health care components) as a single covered entity for Privacy Rule compliance.<sup>79</sup> The designation must be in writing. An affiliated covered entity that performs multiple covered functions must operate its different covered functions in compliance with the Privacy Rule provisions applicable to those covered functions.

**Organized Health Care Arrangement.** The Privacy Rule identifies relationships in which participating covered entities share protected health information to manage and benefit their common enterprise as “organized health care arrangements.”<sup>80</sup> Covered entities in an organized health care arrangement can share protected health information with each other for the arrangement’s joint health care operations.<sup>81</sup>

**Covered Entities With Multiple Covered Functions.** A covered entity that performs multiple covered functions must operate its different covered functions in compliance with the Privacy Rule provisions applicable to those covered functions.<sup>82</sup> The covered entity may not use or disclose the protected health information of an individual who receives services from one covered function (e.g., health care provider) for another covered function (e.g., health plan) if the individual is not involved with the other function.

**Group Health Plan disclosures to Plan Sponsors.** A group health plan and the health insurer or HMO offered by the plan may disclose the following protected health information to the “plan sponsor”—the employer, union, or other employee organization that sponsors and maintains the group health plan<sup>83</sup>:

Enrollment or disenrollment information with respect to the group health plan or a health insurer or HMO offered by the plan. If requested by the plan sponsor, summary health information for the plan sponsor to use to obtain premium bids for providing health insurance coverage through the group health plan, or to modify, amend, or terminate the group health plan. “Summary health information” is information that summarizes claims history, claims expenses, or types of claims experience of the individuals for whom the plan sponsor has provided health benefits through the group health plan, and that is stripped of all individual identifiers other than five digit zip code (though it need not qualify as de-identified protected health information).

Protected health information of the group health plan’s enrollees for the plan sponsor to perform plan administration functions. The plan must receive certification from the plan sponsor that the group health plan document has been amended to impose restrictions on the plan sponsor’s use and disclosure of the protected health information. These restrictions must include the representation that the plan sponsor will not use or disclose the protected health information for any employment-related action or decision or in connection with any other benefit plan.

### **Other Provisions: Personal Representatives and Minors**

**Personal Representatives.** The Privacy Rule requires a covered entity to treat a "*personal representative*" the same as the individual, with respect to uses and disclosures of the individual's protected health information, as well as the individual's rights under the Rule.<sup>84</sup> A personal representative is a person legally authorized to make health care decisions on an individual's behalf or to act for a deceased individual or the estate. The Privacy Rule permits an exception when a covered entity has a reasonable belief that the personal representative may be abusing or neglecting the individual, or that treating the person as the personal representative could otherwise endanger the individual.

**Special Case: Minors.** In most cases, parents are the personal representatives for their minor children. Therefore, in most cases, parents can exercise individual rights, such as access to the medical record, on behalf of their minor children. In certain exceptional cases, the parent is not considered the personal representative. In these situations, the Privacy Rule defers to State and other law to determine the rights of parents to access and control the protected health information of their minor children. If State and other law is silent concerning parental access to the minor's protected health information, a covered entity has discretion to provide or deny a parent access to the minor's health information, provided the decision is made by a licensed health care professional in the exercise of professional judgment. See additional guidance on [Personal Representatives](#).

## State Law

**Preemption.** In general, State laws that are contrary to the Privacy Rule are preempted by the federal requirements, which means that the federal requirements will apply.<sup>85</sup> “Contrary” means that it would be impossible for a covered entity to comply with both the State and federal requirements, or that the provision of State law is an obstacle to accomplishing the full purposes and objectives of the Administrative Simplification provisions of HIPAA.<sup>86</sup> The Privacy Rule provides exceptions to the general rule of federal preemption for contrary State laws that (1) relate to the privacy of individually identifiable health information and provide greater privacy protections or privacy rights with respect to such information, (2) provide for the reporting of disease or injury, child abuse, birth, or death, or for public health surveillance, investigation, or intervention, or (3) require certain health plan reporting, such as for management or financial audits.

**Exception Determination.** In addition, preemption of a contrary State law will not occur if HHS determines, in response to a request from a State or other entity or person, that the State law:

Is necessary to prevent fraud and abuse related to the provision of or payment for health care,

Is necessary to ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation,

Is necessary for State reporting on health care delivery or costs,

Is necessary for purposes of serving a compelling public health, safety, or welfare need, and, if a Privacy Rule provision is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

### **Enforcement and Penalties for Noncompliance**

**Compliance.** The Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) establishes a set of national standards for the use and disclosure of an individual's health information – called protected health information – by covered entities, as well as standards for providing individuals with privacy rights to understand and control how their health information is used. The Department of Health and Human Services, Office for Civil Rights (OCR) is responsible for administering and enforcing these standards and may conduct complaint investigations and compliance reviews.

Consistent with the principles for achieving compliance provided in the Privacy Rule, OCR will seek the cooperation of covered entities and may provide technical assistance to help them comply voluntarily with the Privacy Rule. Covered entities that fail to comply voluntarily with the standards may be subject to civil money penalties. In addition, certain violations of the Privacy Rule may be subject to criminal prosecution. These penalty provisions are explained below.

**Civil Money Penalties.** OCR may impose a penalty on a covered entity for a failure to comply with a requirement of the Privacy Rule. Penalties will vary significantly depending on factors such as the date of the violation, whether the covered entity knew or should have known of the failure to comply, or whether the covered entity's failure to comply was due to willful neglect. Penalties may not exceed a calendar year cap for multiple violations of the same requirement.

### **Compliance Dates**

**Compliance Schedule.** All covered entities, except “small health plans,” must have been compliant with the Privacy Rule by April 14, 2003.<sup>90</sup> Small health plans, however, had until April 14, 2004 to comply.

**Small Health Plans.** A health plan with annual receipts of not more than \$5 million is a small health plan.<sup>91</sup> Health plans that file certain federal tax returns and report receipts on those returns should use the guidance provided by the Small Business Administration at 13 Code of Federal Regulations (CFR) 121.104 to calculate annual receipts. Health plans that do not report receipts to the Internal Revenue Service (IRS), for example, group health plans regulated by the Employee Retirement Income Security Act 1974 (ERISA) that are exempt from filing income tax returns, should use proxy measures to determine their annual receipts.<sup>92</sup> See What constitutes a small health plan?