HIPAA AdminSimp -- Compliance Day Is Here
Dispassionate Enforcement or Compassionate Persecution?

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April 14, 2003

The Administrative Simplification Subtitle of the Health Insurance Portability and Accountability Act of 1996, known as HIPAA, will revolutionize how health information is, and patients are, treated privacy-wise, security-wise, and otherwise. The transactions and data codes sets rule requirements under HIPAA, as well as privacy and security, will be included in the enforcement part of HIPAA. Because of the many changes in health care delivery that HIPAA will require, lots of anxiety has been created about penalties. Certainly few areas of the HIPAA law are more important than the enforcement provisions.

Covered entities will need to address their de facto enforcement obligations with respect to business associates in order to avoid governmental enforcement against covered entities. But a careful reading of the law should provide comfort and encouragement that notwithstanding the hype, the enforcement procedure likely will not be so bad after all. Covered entities and business associates who study and learn can be prepared to meet the challenges of the HIPAA law. Note also that not discussed further below are possible state law enforcement activities based upon HIPAA and the new national standard set by HIPAA and likely to be embraced by state Attorneys General and judges in state courts in evaluating privacy and security compliance in health care with respect to breach of contract, negligence and class action litigation.

In fact, the civil enforcement provisions of the HIPAA law evidence a Congressional mandate that civil sanctions – that is, monetary fines -- under HIPAA should be imposed leniently and in a way that will encourage compliance and not make covered entities feel as if they are being persecuted for inadvertent violations of the HIPAA law.

Although the Office for Civil Rights, to which the Department of Health and Human Services delegated the privacy enforcement responsibility, has not promulgated a proposed

enforcement rule, the HIPAA law provides a clear indication of Congressional intent regarding how enforcement should proceed. It can therefore be expected that the OCR enforcement rule will mirror the HIPAA law enforcement provisions and the enforcement language already set forth in the HIPAA final privacy rule. CMS will enforce the transactions and security rules.

These civil penalty enforcement provisions of the HIPAA law begin as follows:

"GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS

SEC. 1176. (a) GENERAL PENALTY.--
(1) IN GENERAL.--Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part a penalty of not more than $100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed $25,000.
"(2) PROCEDURES.--The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1128A."

Thus the magnitude of a penalty assessment surely can add up, particularly for repeated transactional defaults. But Congress provided a generous and unusual opportunity in HIPAA to prevent, to deflect and possibly to avoid any penalty (***emphasis supplied***):

"(b) LIMITATIONS.--
"(1) OFFENSES OTHERWISE PUNISHABLE.--A penalty may ***not*** be imposed under subsection (a) with respect to an act if the act constitutes an offense punishable under section 1177 [namely, "HIPAA For Crooks": the criminal provisions].
(2) NONCOMPLIANCE NOT DISCOVERED.--A penalty may ***not*** be imposed under subsection (a) with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did ***not*** know, and by exercising reasonable diligence would ***not*** have known, that such person violated the provision."

So, if a covered entity is able to satisfy the Office for Civil Rights that the covered entity did not know, and by exercising reasonable diligence would not have known, of a violation of the HIPAA law, no penalty may be imposed under (a).

And even if the covered entity did know, or by exercising reasonable diligence would have known that the covered entity would be a violator (***emphasis supplied***), the possibility of deflecting a penalty would still exist:

"(3) FAILURES DUE TO REASONABLE CAUSE.--
(A) IN GENERAL.--Except as provided in subparagraph (B), a penalty may ***not*** be imposed under subsection (a) if--
"(i) the failure to comply was due to reasonable cause and ***not*** to willful neglect; and
"(ii) the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred."

Accordingly, no penalty would be imposed if a failure to comply with the HIPAA law – which failure a covered entity knew would be a failure – was due to reasonable cause and not to willful neglect, and the failure is corrected within thirty days after the first date on which the covered entity knew, or by exercising reasonable diligence could have known (whether or not, it appears, there was actual knowledge on the part of the covered entity) that the failure occurred. So, after receiving a complaint from the Office for Civil Rights, the possibility exists that a covered entity could promptly correct the problem and thereby avoid any penalties.

And more opportunities will exist to have penalties abated (***emphasis supplied***):

"(B) EXTENSION OF PERIOD.--
(i) NO PENALTY.--The period referred to in subparagraph (A)(ii) ***may be extended*** as determined appropriate by the Secretary based on the nature and extent of the failure to comply.
(ii) ASSISTANCE.--If the Secretary determines that a person failed to comply because the person was ***unable*** to comply, the Secretary may provide ***technical assistance*** to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary."

So, the thirty-day correction and cure period could be extended by the Office for Civil Rights and during that additional period, the Office for Civil Rights could provide technical assistance. This could mean that the violation would be able to be corrected without any penalty being imposed by the OCR.

And finally, a penalty may be reduced (***emphasis supplied***):

"(4) REDUCTION.--In the case of a failure to comply which is due to ***reasonable cause*** and ***not*** to willful neglect, any penalty under subsection (a) that is ***not*** entirely waived under paragraph (3) ***may be waived*** to the extent that the payment of such penalty would be excessive relative to the compliance failure involved."

Thus even if is a penalty was going to be imposed, the Office for Civil Rights could reduce the penalty if deemed to be "excessive." As this review of the enforcement part of the HIPAA law indicates, Congress would seem to have intended the civil enforcement procedure to

be a conciliatory and encouraging process and not a process of persecution, because there are so many avenues for "mercy" to be shown by OCR and CMS (but not for the Department of Justice).

Although we have not yet seen the preliminary rules that are being prepared by the Office for Civil Rights and CMS now, we can hope that those working on the enforcement rules adhere to what Congress said in HIPAA. And regardless, the courts are bound to respect the HIPAA law.

We don't know what will be done regarding the criminal penalties under HIPAA. Perhaps the Department of Justice will offer some guidance regarding what "knowingly" and what "intent" will be viewed by the DOJ as meaning, under the HIPAA law, when HIPAA criminal prosecutions occur. In any event, the criminal part of HIPAA penalties follows:

"WRONGFUL DISCLOSURE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

SEC. 1177. (a) OFFENSE.--A person who knowingly and in violation of this part--
(1) uses or causes to be used a unique health identifier;
(2) obtains individually identifiable health information relating to an individual; or
(3) discloses individually identifiable health information to another person,
shall be punished as provided in subsection (b).
(b) PENALTIES.--A person described in subsection (a) shall--
(1) be fined not more than $50,000, imprisoned not more than 1 year, or both;
(2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; and
(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than $250,000, imprisoned not more than 10 years, or both."

Questions raised by "HIPAA for crooks" include what "knowingly" will be found to mean under HIPAA; what "intent" will be found to mean under HIPAA; whether the confusion that arose under the anti-fraud and anti-kickback laws in health care relative to "the sole purpose" or "only one of several purposes" will find its way into HIPAA criminal enforcement; how the law of false claims, conspiracy and obstruction of justice and other such laws will relate to HIPAA enforcement; and how the Office for Civil Rights, CMS and federal prosecutors will determine which alleged violations are treated as civil violations and which alleged violations are treated as criminal violations. Surely all covered entities will want to have corporate compliance programs established and maintained in a manner consistent with the Federal Sentencing Guidelines, in order to endeavor either to avoid or to reduce the severity of criminal penalties.

With all the foregoing in mind, certainly the sooner covered entities begin the process of getting ready for HIPAA enforcement, the better. The key to avoiding penalties will be having

policies and procedures in place that evidence a good faith intention to endeavor to comply with the HIPAA law. A summary of what to do to endeavor to avoid civil HIPAA penalties follows:

- Use reasonable diligence to know as much as you can about HIPAA
- Establish policies that evidence a reasonable approach to prevention
- Don't be neglectful, willfully or otherwise, or reckless
- Try to cure breaches within 30 days
- Ask for an extension if necessary
- Seek technical advice if necessary
- Be sure to document everything done in furtherance of HIPAA corporate compliance, preparation, implementation, and education and training.

Ignorance will not be bliss, and avoidance will not be blissful. Instead, the only way to prepare for HIPAA is the old fashioned way: study it and learn it. Patients will expect no less, and covered entities surely will want to do even more to assure that their patients receive both quality care and the privacy and security protections, and the benefits of the transactions and data code sets standardization, that patients deserve and, under the law, are going to be required.

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"GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS

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"(2) PROCEDURES.--The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1128A.

"(b) LIMITATIONS.--

"(1) OFFENSES OTHERWISE PUNISHABLE.--A penalty may not be imposed under subsection (a) with respect to an act if the act constitutes an offense punishable under section 1177.

"(2) NONCOMPLIANCE NOT DISCOVERED.--A penalty may not be imposed under subsection (a) with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision.

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"(4) REDUCTION.--In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

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"(b) PENALTIES.--A person described in subsection (a) shall--

"(1) be fined not more than $50,000, imprisoned not more than 1 year, or both;

"(2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; and
"(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than $250,000, imprisoned not more than 10 years, or both.

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) 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.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

§ 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

(1) The State law for which the exception is requested;

(2) The particular standard, requirement, or implementation specification for which the exception is requested;

(3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;

(4) How health care providers, health plans, and other entities would be affected by the exception;

(5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and

(6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the Federal Register. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met.

§ 160.205 Duration of effectiveness of exception determinations.

An exception granted under this subpart remains in effect until:

(a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or

(b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

Subpart C - Compliance and Enforcement

§ 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, and others with respect to ascertaining the compliance by covered entities with and the enforcement of the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

§ 160.302 Definitions.

As used in this subpart, terms defined in § 164.501 of this subchapter have the same meanings given to them in that section.

§ 160.304 Principles for achieving compliance.

(a) *Cooperation.* The Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(b) *Assistance.* The Secretary may provide technical assistance to covered entities to help them comply voluntarily with the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

§ 160.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes a covered entity is not complying with the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter may file a complaint with the Secretary.

(b) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the entity that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the Federal Register.

(c) *Investigation.* The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the covered entity and of the circumstances regarding any alleged acts or omissions concerning compliance.

§ 160.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether covered entities are complying with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

§ 160.310 Responsibilities of covered entities.

(a) *Provide records and compliance reports.* A covered entity must keep such records and submit such compliance reports, in such time and manner and containing such

information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(b) *Cooperate with complaint investigations and compliance reviews.* A covered entity must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of a covered entity to determine whether it is complying with the applicable requirements of this part 160 and the standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(c) *Permit access to information.*

(1) A covered entity must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter, or if otherwise required by law.

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution where noncompliance is indicated.*

(1) If an investigation pursuant to § 160.306 or a compliance review pursuant to § 160.308 indicates a failure to comply, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing and attempt to resolve the matter by informal means whenever possible.

(2) If the Secretary finds the covered entity is not in compliance and determines that the matter cannot be resolved by informal means, the Secretary may issue to the covered entity and, if the matter arose from a complaint, to the complainant written findings documenting the non-compliance.

(b) *Resolution when no violation is found.* If, after an investigation or compliance review, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant in writing.

PART 164 – SECURITY AND PRIVACY

Subpart A – General Provisions

Subparts B-D – [Reserved]

Subpart E – Privacy of Individually Identifiable Health Information

Authority: 42 U.S.C. 1320d-2 and 1320d-4, sec. 264 of Pub. L. No. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note)).

Subpart A--General Provisions

§ 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation specifications under part C of title XI of the Act and section 264 of Public Law 104-191.

§ 164.104 Applicability.

Except as otherwise provided, the provisions of this part apply to covered entities: health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with any transaction referred to in section 1173(a)(1) of the Act.

§ 164.106 Relationship to other parts.

In complying with the requirements of this part, covered entities are required to comply with the applicable provisions of parts 160 and 162 of this subchapter.

Subpart B-D--[Reserved]

Subpart E - Privacy of Individually Identifiable Health Information

§ 164.500 Applicability.

(a) Except as otherwise provided herein, the standards, requirements, and implementation specifications of this subpart apply to covered entities with respect to protected health information.

(b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows:

(1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with:

(i) Section 164.500 relating to applicability;

(ii) Section 164.501 relating to definitions;

(iii) Section 164.502 relating to uses and disclosures of protected health information, except that a clearinghouse is prohibited from

Programs

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HIPAA Electronic Health Care Transactions and Sets Complaint Submission Form

You may use this form to file a HIPAA complaint. This form is for the sul of complaints about covered entities that are not compliant with the HIP electronic health care transactions and code set standards. This form sh be used to file complaints regarding the privacy of health information.

If you prefer to submit a paper-based form, you may download an Adob based complaint form. (PDF, 80KB)

All fields marked with a * are mandatory.

Section A: Your Contact Information (Person or Entity Filing The Compl

*First Name Middle Initial *Last Name
*Title
*Organization
*Street Address Line 1
Street Address Line 2
*City *State *ZIP
*Telephone Number ( ) - extension
Email Address

Section B: Information About The Entity For Which You Are Filing A Co

*Entity Name
Tax Identification Number
Medicare Identification Number
*Type of covered entity (Click all that apply)
- Health Care Clearinghouse
- Health Plan
- Health Care Provider

Covered Entity Contact Person:
First Name Middle Initial Last Name
Title

*Street Address Line 1

Street Address Line 2

*City *State *ZIP

Telephone Number ( ) - extension

Section C: Specific Complaint.

* Type of Complaint (Check all that apply)

Transactions

- Health claims and equivalent encounter information
- Enrollment and disenrollment in a health plan
- Eligibility for a health plan
- Health care payment and remittance advice
- Health plan premium payments
- Health claim status
- Referral certification and authorization
- Coordination of benefits

Code Sets

- ICD-9 diagnosis
- ICD-9 procedure
- HCPCS
- CPT-4
- Dental
- NDC

*Provide comments in the area below:

Submit Clear This Page

Note: Some of the files on this page are available only in Adobe Acrobat - Portable Document Format (PDF). To view PDF files, you must have the Adobe Acrobat Reader (minimum version 4, version 5 suggested). You can check here to see if you have the Acrobat Reader installed on your computer. If you do not already have the Acrobat Reader installed, please go to Adobe's Acrobat download page now.

Last Modified on Friday, January 31, 200

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Centers for Medicare & Medicaid Services
7500 Security Boulevard, Baltimore MD 21244-1850
CMS Telephone Numbers

Department of Health and Human Services
Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Electronic Health Care Transactions and Code Sets Complaint Submission Form

You may use this form to file a HIPAA complaint. This form is for the submission of complaints about covered entities that are not compliant with the HIPAA electronic health care transactions and code set standards. This form should not be used to file complaints regarding the privacy of health information.

If you choose, you can now file on-line at http://cms.hhs.gov/hipaa/hipaa2/default.asp. Or you may mail your complaint to the following address:

HIPAA Complaint
7500 Security Blvd., C5-24-04
Baltimore, MD 21244

Section A: Your Contact Information (person or entity filing the complaint)

First Name: _____ Middle Initial: ____ Last Name: _____

Title: _____ Organization: _____

Street Address Line 1: _____

Street Address Line 2: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: _____ Extension: _____

Email Address: _____

Section B: Information about the Entity that you are filing a complaint about

Name of Covered Entity: _____

Tax Identification Number: _____ Medicare Identification Number: _____

Type of Covered Entity (Check one)

____ Health Care Clearinghouse
____ Health Plan
____ Health Care Provider (choose one)
- O *Dentist*
- O *DME Supplier*
- O *Home Health Agency*
- O *Hospice*
- O *Hospital*
- O *Nursing Home*
- O *Pharmacy*
- O *Physician/Group Practice*
- O *Other*

Covered Entity Contact Person:

First Name: _____ Middle Initial: ____ Last Name: _____

Title: _____

Street Address Line 1: _____

Street Address Line 2: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: _____ Extension: _____

Section C: Specific Complaint

Type of Complaint:

____ Transactions (check all that apply)

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- O *Coordination of benefits*

____ Code Sets (check all that apply)

- O *ICD-9 diagnosis*
- O *ICD-9 procedure*
- O *HCPCS*
- O *CPT-4*
- O *Dental*
- O *NDC*

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Baltimore, MD 21244

Skip Navigation

United States Department of Health & Human Services

News Release

FOR IMMEDIATE RELEASE
October 15, 2002

Contact: CMS Press Office
(202) 690-6145

CMS NAMED TO ENFORCE HIPAA TRANSACTION AND CODE SET STANDARDS
HHS Office for Civil Rights To Continue To Enforce Privacy Standards

HHS Secretary Tommy G. Thompson announced today that the Centers for Medicare & Medicaid Services (CMS) will be responsible for enforcing the transaction and code set standards that are part of the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

"HIPAA administrative simplification is going to streamline and standardize the electronic filing and processing of health insurance claims, save money and provide better service for providers, insurers and patients," Thompson said.

"To accomplish this will require an enforcement operation that will assure compliance and provide support for those who file and process health care claims and other transactions," Thompson said. "CMS is the agency best able to do this."

CMS will continue to enforce the insurance portability requirements of HIPAA. The HHS Office for Civil Rights (OCR) will enforce the HIPAA privacy standards. CMS and OCR will work together on outreach and enforcement and on issues that touch on the responsibilities of both organizations - such as application of security standards or exception determinations.

Ruben J. King-Shaw Jr., CMS deputy administrator and chief operating officer, said CMS will create a new office to bring together its responsibilities under HIPAA, including enforcement.

"Concentrating these CMS responsibilities in a new office with a single mission will give us the most efficient operation possible, while providing strong support for all our partners in the health care community," King-Shaw said.

The new CMS office will establish and operate enforcement processes and develop regulations related to the HIPAA standards for which CMS is responsible. These standards include transactions and code sets, security, and identifiers for providers, insurers and employers for use in electronic transactions. The office will report directly to the deputy administrator.

The office also will conduct outreach activities to HIPAA covered entities such as health care providers and insurers to make sure they are aware of the requirements and to help them comply.

Federal law requires most health plans, clearing houses, and those providers that conduct certain transactions electronically to be compliant with the HIPAA transactions standards by Oct. 16, 2002, unless they file on or before Oct. 15 for a one-year extension. Those who are not compliant and have not filed for the extension may be subject to statutory penalties. (The law gives certain small health plans until Oct. 16, 2003 to comply).

Enforcement activities will focus on obtaining voluntary compliance through technical assistance. The process will be primarily complaint driven and will consist of progressive steps that will provide opportunities to demonstrate compliance or submit a corrective action plan.

A fact sheet summarizing the administrative simplification standards required by HIPAA is available at http://www.hhs.gov/news/press/2002pres/hipaa.html. More detailed information about the standards is available at http://www.cms.hhs.gov/hipaa.

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Note: All HHS press releases, fact sheets and other press materials are available at *http://www.hhs.gov/news*.

Last Revised: October 15, 2002

Fact Sheets Discrimination Complaint Form Title VI of The Civil Rights Act of 1964 Fact Sheet

HOW TO FILE A COMPLAINT WITH OCR

If you believe you have been discriminated against because of your race, color or national origin, you may file a complaint with OCR within 180 days from the date of the alleged discriminatory act. (OCR may extend the 180-day period if good cause is shown.) Include the following information in your written complaint, or request a Discrimination Complaint Form from OCR:

- *Your name, address and telephone number*. You must sign your name. (If you file a complaint on someone's behalf, include your name, address, telephone number, and state- ment of your relationship to that person--e.g., spouse, attorney, friend, etc.)
- Name and address of the institution or agency you believe discriminated against you.
- How, why and when you believe you were discriminated against.
- Any other relevant information.

Send the complaint to the OCR regional office below or to the Washington, D.C. headquarters' address on the front of this Fact Sheet.

Once a complaint is filed with OCR, the law prohibits the alleged discriminating party from taking any retaliatory actions against a complainant or any person who provides information to OCR regarding a complaint. OCR should be notified immediately in the event of retaliatory action.

Upon receipt of your complaint, OCR staff will review the issues to determine coverage by Title Vl. If your complaint raises covered issues, an investigation will be initiated. If discrimination is found, OCR will negotiate with the institution or organization to voluntarily correct the discriminatory action. If negotiations are unsuccessful, enforcement proceedings may be instituted to suspend or terminate Federal funding.

If we determine your complaint is not within our jurisdiction, OCR may forward it to an appropriate agency that may be able to help you.

Additional information about the rights of persons under Title Vl, as well as information on other laws enforced by OCR, may be obtained by contacting an OCR office. For circumstances where you require a quick answer regarding a civil rights problem, you may call us at the following Hotlines:

Voice: 1-800-368- 1019; TDD: 1-800-537-7697

The Office for Civil Rights employees will make every effort to provide prompt service.

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OCR Home Page Return to OCR Home Page

Aug. 1990
ocrmail@hhs.gov

the back of each piece of glass. The first layer applied to the glass is a tin solution, which is an adhesion promoter so that the silver will bond to the glass. After the tin solution, a silver solution is applied, which creates a metal film on the glass surface, giving the mirror its reflective surface. The third step is to apply a copper solution, which helps keep the silver from oxidizing and creates a surface to which the mirror backing paint will adhere. Finally, the mirror backing paint is applied. This adds a hard coating that protects the solutions from becoming scratched or damaged and further protects the silver solution from corrosion.

Both Lilly and Valspar produce all of the components, other than glass, necessary to make a mirror. The United States mirror solutions and mirror backing paint markets are highly concentrated, and the proposed acquisition would produce a firm controlling over 90% of the mirror solutions markets and over 60% of the mirror backing paint market. Both companies have frequently competed against each other for customers. By eliminating competition between the two most significant competitors in these highly concentrated markets, the proposed acquisition would allow the combined firm to exercise market power unilaterally, thereby increasing the likelihood that purchasers of mirror solutions as well as mirror backing paint would be forced to pay higher prices and that innovation and service levels in these markets would decrease.

Significant impediments to new entry exist in the mirror solutions and mirror backing paint markets. A new entrant into any of these markets would need to undertake the difficult, expensive and time-consuming process of developing a competitive product, establishing reliable U.S. distribution and technical support, and developing a reputation among mirror manufacturers for consistently producing a high-quality product. Because of the difficulty of accomplishing these tasks, new entry into either the mirror solutions markets or the mirror backing paint market could not be accomplished in a timely manner. Additionally, new entry into any one of these markets is made more unlikely because of the limited sales opportunities available to new entrants.

The Consent Agreement effectively remedies the acquisition's anticompetitive effects in the United States mirror solutions and mirror backing paint markets by requiring Valspar to divest its mirror coatings business. Pursuant to the Consent Agreement, Valspar is required to divest its mirror coatings business to Spraylat Corporation within ten days of the date the Commission places the Order on the public record. Should Valspar fail to do so, the Commission may appoint a trustee to divest the business.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed buyer of divested assets must not itself present competitive problems. The Commission is satisfied that Spraylat is a well-qualified acquirer of the divested assets. Based in Mount Vernon, New York, Spraylat is a family owned company that manufactures and sells specialty paints and coatings for industrial uses. Spraylat possesses the necessary industry expertise to replace the competition that existed prior to the proposed acquisition. Furthermore, Spraylat poses no separate competitive issues as the acquirer of the divested assets.

The Consent Agreement includes a number of provisions that are designed to ensure that the transfer of Valspar's mirror coatings business to the acquirer is successful. The Consent Agreement requires Valspar to provide incentives to certain key employees to accept employment, and remain employed, by the acquirer. Valspar is also prohibited from inducing key customers from terminating their contracts with the acquirer for a period of one year. Finally, Valspar employees involved with its mirror coating business are prohibited from disclosing any confidential information to employees involved with the Lilly business.

In order to ensure that the Commission remains informed about the status of the Valspar mirror coatings business pending divestiture, and about efforts being made to accomplish the divestiture, the Consent Agreement requires Valspar to report to the Commission within 30 days, and every thirty days thereafter until the divestiture is accomplished. In addition, Valspar is required to report to the Commission every 60 days regarding its obligations to provide transitional services and facilities management.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the Consent Agreement or to modify in any way its terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 00–33028 Filed 12–27–00; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office for Civil Rights; Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Director, Office for Civil Rights (OCR), with authority to redelegate, the following authorities vested in the Secretary of Health and Human Services:

1. The authority under section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, as amended, to the extent that these actions pertain to the Standards for the Privacy of Individually Identifiable Health Information, to:

A. impose civil monetary penalties, under section 1176 of the Social Security Act, for a covered entity's failure to comply with certain requirements and standards;

B. make exception determinations, under section 1178(a)(2)(A) of the Social Security Act, concerning when provisions of State laws that are contrary to the federal standards are not preempted by the federal provisions; and

2. The authority under section 264 of HIPAA, as amended, to administer the regulations, ''Standards for the Privacy of Individually Identifiable Health Information,'' 45 CFR Part 164, and General Administrative Requirements, 45 CFR Part 160, as these requirements pertain to Part 164, and to make decisions regarding the interpretation, implementation and enforcement of these Standards and General Administrative Requirements.

I hereby affirm and ratify any actions taken by the Director of OCR, or any subordinates, involving the exercise of the authorities delegated herein prior to the effective date of this delegation. This Delegation of Authority is effective concurrent with the effective date of the regulations, 45 CFR Parts 160 through 164.

Dated: December 20, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–33039 Filed 12–27–00; 8:45 am]

BILLING CODE 4153–01–M

HIPAA ADMINISTRATIVE SIMPLIFICATION PRIVACY RULE CONTRARY & MORE STRINGENT STATE LAW PROJECT

The Health Law Section's eHealth and Privacy Interest Group is embarking on a new project and is looking for interested volunteers. The Interest Group is looking for volunteers to help compile a nationwide database of state privacy laws. The database will be available to anyone who needs the information to determine whether such laws are contrary to and/or more stringent than HIPAA's final privacy rule.

This project is necessary because under the Administrative Simplification Subtitle of the Health Insurance Portability and Accountability Act of 1996, and more particularly, Section 264(c)(2), stating: (2) PREEMPTION — A [privacy] regulation promulgated under paragraph (1) shall not supersede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation...," it will be necessary for "Covered Entities" and "Business Associates" and others to determine whether HIPAA privacy rule standards and requirements are contrary to and/or more stringent than applicable State law.

This need for state law determinations creates an enormous task and will require constant monitoring, analysis, and application of judgment. But perhaps the most difficult part of this task will be determining what the relevant State law (which includes constitutional, statutory and common law) will be for any analysis. It is here that our Project can be helpful. Unfortunately, we understand that the federal government does not have the resources available now to engage in such a project.

So, the Interest Group's approach will be to enlist the aid and support of lawyer-members of the American Bar Association's Health Law Section, as well as members of other Sections (such as the Science and Technology Section and the Business Law Section) interested in HIPAA. At least one volunteer, and more likely many volunteers, will be assigned for every state and in the four additional jurisdictions (the District of Columbia, the Commonwealth of Puerto Rico, Guam, and the U.S. Virgin Islands) for which such determinations must be made, in order to participate in preparing, maintaining and updating a database of relevant constitutional, statutory and common law.

The project intends to make maximum use of existing resources so that such database projects already underway by others for certain States and jurisdictions can be shared and enhanced. A leadership team of several lawyers would be appointed to serve as the liaison between each State and jurisdiction, and the leadership of our Interest Group project. The Interest Group intends to complete the project not later than the end of this year.

If you are looking for a way to make a professional contribution to how health care privacy will be maintained and enhanced by HIPAA and otherwise as part of your public service commitment as a member of the bar, this project is worthy of your consideration. There is a paucity of resources otherwise available for the information that the project will produce and maintain, and therefore this surely is an area in which the American Bar Association can assist our government, over two hundred eighty million patients, and those involved in the health care delivery system, in furtherance of the public interest.

For more information or to volunteer to be a part the project, contact Section Director Jill Peña at 312/988-5548 or e-mail her at jillpena@staff.abanet.org.

NOMINATION COMMITTEE

The Nominating Committee for the Section has been appointed. The Committee will consider nominees for Vice Chair, Secretary, Finance Officer, Delegate to the ABA House of Delegates, and two Council Members. The Nominating Committee will submit a report to Council. Elections will be held at the ABA Annual Meeting in August. The report of the Nominating Committee will be published on the Section web site (www.abanet.org/health) no later than June 21, 2002. The members of the Nominating Committee are:

- Robert L. Roth, Crowell & Moring, Washington, DC
- Patricia T. Meador, Kennedy Covington Lobdell & Hickman, Research Triangle Park, NC
- Christina M. Mireles, Crowell & Moring, Washington, DC

Contact Section Director Jill Peña at 312/988-5548 or jillpena@staff.abanet.org is you have any questions or comments.

contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: March 7, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–5953 Filed 3–7–03; 3:20 pm]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

Office of Management Services

Cancellation of an Optional Form by the U.S. Office of Personnel Management

AGENCY: Office of Management Services, GSA.

ACTION: Notice.

SUMMARY: The U.S. Office of Personnel Management cancelled the following Optional Form because of low usage:

OF 299, Request by Employee for Action on Allotment of Pay

DATES: Effective March 11, 2003.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Beth Smith-Toomey, U.S. Office of Personnel Management, (202) 606–8358.

Dated: February 28, 2003.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer, General Services Administration.

[FR Doc. 03–5667 Filed 3–10–03; 8:45 am]

BILLING CODE 6820–34–M

GENERAL SERVICES ADMINISTRATION

Interagency Committee for Medical Records (ICMR); Cancellation of Medical Standard Forms

AGENCY: General Services Administration.

ACTION: Notice

SUMMARY: Standard Form 556, Medical Record—Immunohematology is cancelled. The Federal medical community no longer uses this form.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

DATES: Effective March 11, 2003.

Dated: March 3, 2003.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer, General Services Administration.

[FR Doc. 03–5668 Filed 3–10–03; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

Notice of Address for Submission of Requests for Preemption Exception Determinations

AGENCY: Office for Civil Rights, HHS.

ACTION: Notification of address for submission of requests for preemption exception determinations.

SUMMARY: This notice advises that, in accordance with the requirements of 45 CFR 160.204(b), a request to except a provision of State law from preemption by a federal standard, requirement, or implementation specification adopted under the Administrative Simplification title of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, must be submitted in writing to the Director, Office for Civil Rights, Department of Health and Human Services, Mail Stop Room 506F, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. The requirements for submission of a request for an exception determination are described in the Supplemental Information below, and can be found at 45 CFR 160.203–205.

EFFECTIVE DATES: Requests for preemption exception determinations may be submitted a the designated address upon publication of this notice.

SUPPLEMENTAL INFORMATION: Section 1178(a)(1) of the Social Security Act (the Act), as added by section 262 of HIPAA, Public Law 104–191, establishes a general rule that State law provisions which are contrary to the standards, requirements, or implementation specifications adopted or established by the Secretary of Health and Human Services pursuant to the Administrative Simplification title of HIPAA are preempted by the Federal requirements. The Act, as amended, at sections 1178(a)(2), 1178(b) and 1178(c) provides for certain exceptions to this general rule. Regulations implementing the preemption rule and its exceptions are codified at 45 CFR part 160, subpart B. This notice pertains to section 1178(a)(2)(A) of the Act, which sets forth the circumstances under which the Secretary of Health and Human Services, or his designee, may make a determination that a contrary provision of State law will not be preempted by the Administrative Simplification title of HIPAA.[1]

Section 1178(a)(2)(A) of the Act provides that requests may be made for an exception to the general rule of Federal preemption, where the Secretary determines that a contrary provision of State law meets certain criteria. These criteria for a Secretarial exception determination are set forth at 45 CFR 160.203(a), as follows:

''(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) 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.''

In addition, only State laws that are ''contrary'' to the Federal requirements are subject to preemption, and thus eligible for an exception determination. *See* 45 CFR 160.203. As defined at 45

[1] The Secretary does not have the legal authority to make determinations with respect to the exceptions to preemption in section 1178(a)(2)(B), 1178(b) and 1178(c) of the Act. Thus, the Secretary will not make exception determinations with respect to section 1178(a)(2)(B), which excepts from preemption contrary provisions of State law that relate to the privacy of individually identifiable health information and, under section 264(c)(2) of HIPAA, are ''more stringent'' than the federal requirements. Similarly, the Secretary does not have the legal authority to make determinations with respect to State laws that are excepted from preemption under sections 1178(b), concerning certain State laws providing for public health reporting, surveillance, investigation, or intervention, or 1178(c), concerning State laws requiring a health plan to report or provide access to information concerning management audits, financial audits, program monitoring or evaluation, or licensure or certificaiton of facilities or individuals.

CFR 160.202, ''contrary'' means that it would be impossible for a covered entity to comply with both the State and Federal requirements, or that the State law is an obstacle to accomplishing the full purposes and objectives of the Administration Simplification provisions of HIPAA.

The regulations also provide that a request to except a provision of State law from preemption under 45 CFR 160.203(a) must be submitted to the Secretary in writing. If the request is from a State, it must be submitted through its chief elected official, or his or her designee. The request must: (1) Identify the provision of State law for which the exception is requested; (2) identify the particular standard, requirement, or implementation specification for which the exception is requested; (3) specify the part of the standard or other provision that will not be implemented if the exception determination is made or the additional data to be collected based on the exception, as appropriate; (4) state how the exception determination would affect health care providers, health plans and other entities; and (5) the reasons why the State law should not be preempted, including how the contrary State law meets one or more of the specific criteria in 45 CFR 160.203(a). The Secretary may also request additional information that may be necessary for him to make the exception determination. *See* 45 CFR 160.204.

This notice establishes that, for the purposes of 45 CFR 160.204, exception determination requests should be addressed to the Director, Office for Civil Rights, Department of Health and Human Services, Mail Stop Room 506F, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.[2] To expedite handling, the envelope should also state: ''ATTN: Exception Determination Request.''

The Federal standard, requirement, or implementation specification remains in effect until an exception determination is made. When such determinations are made, we will promptly inform the public through publication of notice in the **Federal Register** and on the Department's websites, including the OCR Web site at *www.hhs.gov/ocr/hipaa/.*

[2] This notice identifies the address where all exception determinations should be submitted. The Secretary delegated to the Director of the Office for Civil Rights (OCR) the authority to make exception determinations as they may relate to the Privacy Rule. *See* 65 FR 82381. The Secretary, or his designee, shall make exception determinations with respect to requests concerning the other Administrative Simplification Rules.

The OCR Web site and the Web site for the Centers for Medicare and Medicaid Services, *http://www.cms.hhs.gov/hipaa/,* may also be consulted for more information about the Administrative Simplification provisions (including the Privacy Rule). In addition, answers to frequently asked questions about preemption and exception determinations will be available on the OCR website soon.

FOR FURTHER INFORMATION CONTACT: Susan McAndrew, Office for Civil Rights, Department of Health and Human Services, Mail Stop Room 506F, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Telephone number: (202) 205–8725.

Dated: January 29, 2003.

Richard M. Campanelli,

Director, Office for Civil Rights.

[FR Doc. 03–5774 Filed 3–10–03; 8:45 am]

BILLING CODE 4153–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Budget, Technology and Finance; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended as follows: Chapter AM, Office of Budget, Technology and Finance, as last amended at 66 FR 55666–55678, dated October 26, 2001. This reorganization will help streamline Office functions and better support the Office's ability to meet the goals of the President's Management Agenda.

The changes are as follows:

1. Under Part A, ''Office of the Secretary,'' delete Chapter AM in its entirety and replace with the following:

A. Chapter (AM) Office of Budget, Technology and Finance

Section AM.00 Mission. The mission of the Office of Budget, Technology and Finance (OBTF) is to provide advice and guidance to the Secretary on budget, financial management, and information technology, and to provide for the direction and coordination of these activities throughout the Department.

Section AM.10 Organization: The Office of Budget, Technology, and Finance is headed by the Assistant Secretary for Budget, Technology and Finance (ASBTF). The Assistant Secretary for Budget, Technology, and Finance is the Departmental Chief Financial Officer (CFO), and reports to the Secretary. The office consists of the following components:

- Immediate Office of the ASBTF (AM)
- Office of Budget (AML)
- Office of Information Resources Management (AMM)
- Office of Finance (AMS)

Section AM.20. Functions

1. *Immediate Office of the Assistant Secretary for Budget, Technology, and Finance/Chief Financial Officer (AM).* Provides executive direction to OBTF components. The ASBTF is the principal adviser to the Secretary on all aspects of budgetary and financial management and information technology. By delegation from the Secretary, the ASBTF/CFO exercises full Department-wide authority of the Secretary in the assigned areas of responsibility to include all responsibilities provided by the Chief Financial Officers Act of 1990. This includes the approval of the job descriptions and skill requirements, and the selection of OPDIV CFOs as well as participation with the OPDIV Head in the annual performance plan/evaluation of the OPDIV CFO. In addition, the ASBTF/CFO provides Department-wide policy guidance on the qualifications, recruitment, performance, training, and retention of all financial management personnel. The ASBTF manages the Chief Information Officer (CIO) and the CIO's fulfillment of all functional responsibilities included in the Clinger-Cohen Act.

2. *Office of Budget (AML).* The Office of Budget is headed by a Deputy Assistant Secretary for Budget. The Office: (1) Advises and supports the Secretary and the Assistant Secretary for Budget, Technology and Finance/CFO and oversees the preparation of the Departmental budget estimates and forecasts resources required to support programs and activities of the Department; (2) analyzes budgetary and financial management implications of new or proposed legislation, programs or activities; (3) appraises program activities and operations in terms of policies, goals and objectives of the Department; (4) operates HHS' integrated funding system; (5) recommends and administers policies and procedures for allocation and control of employment ceilings; (6) develops and executes Department-wide procedures relating to implementation and management of the Government Performance and Results Act (GPRA); (7) responsible for the Office of the

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ABA Health Law Section

(THIS WEBSITE IS STILL UNDER CONSTRUCTION & WILL BE UPDATED AS SO INFORMATION BECOMES AVAILABLE)

Health Law Section Health Insurance Portabi Accountability Act of 1996 Administrati Simplification Subtitle Privacy Rule Contra and More Stringent Than Project

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The purpose of this web site is to share preliminary information provided by members o Law Section of the American Bar Association and others, relative to the Health Law Se Insurance Portability and Accountability Act of 1996 - Administrative Simplification Subt Rule "contrary to and more stringent than" Project.

Under the Administrative Simplification Subtitle of the Health Insurance Portability and Act of 1996, and more particularly, Section264(c)(2), stating: (2) PREEMPTION.--A reg promulgated under paragraph (1) shall not supercede a contrary provision of State law, provision of State law imposes requirements, standards, or implementation specificatio more stringent than the requirements, standards, or implementations specifications imp the regulation...," it will be necessary for "Covered Entities" and "Business Associates" determine whether HIPAA privacy rule standards and requirements are, or are likely to by some as, contrary and more stringent than applicable State law. This is an enormou require constant monitoring, analysis, and application of professional judgment fortified enhanced knowledge of applicable local law.
But perhaps the most difficult part of this task will be determining what the relevant Stat includes constitutional, statutory and common law) will be for any analysis. It is here tha can be particularly helpful. Our approach is enlist the aid and support of lawyer-membe American Bar Association Health Law Section, as well as members of other interested every state and in the four additional jurisdictions (the District of Columbia, the Commo Puerto Rico, Guam, and the U. S. Virgin Islands), in preparing a data base of relevant S are making maximum use of existing resources, so that similar projects already underw for certain States and jurisdictions could be a part of the Project results.

Initially, we propose to focus on constitutional, statutory and regulatory law. Eventually, to include judicial decisions and administrative and other law.

A leadership team of several lawyers has been appointed in many States and jurisdictio as the liaison between each State and jurisdiction and the leadership of our Project. Aft information and data is accumulated, we will post interim results on this web site, for ea and updating. A list of leadership and volunteer members of our Project appears on this along with the names of our ABA staff who provide support for our Project, with contact

We are not be attempting to make decisions that only legal counsel retained in connect advice applicable to particular facts and circumstances should be making. Therefore we providing legal advise or legal opinions. Instead, our goal is to provide readily accessibl

and current information and data resources, including citations, textual material, and the
the legal work involved in making decisions and judgments, and rendering opinions, co
simplified and expedited. In addition, we will provide information regarding and links to
information of others, relating to the subject of our Project and believed to be useful.

All who visit this web site are invited to provide comments and suggestions regarding c
approach. Volunteer lawyers are still needed, and expressions of interest in participatin
Project are invited. Contact Kim Jensen at jensenk@staff.abanet.org.

DISCLAIMER

The materials and advice provides at this web site, and in conn
with this Project, reflect the views of the individuals that prepa
and do not represent the position of the American Bar Associa
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services. The professional services of competent legal counse
be retained for legal advice regarding particular facts and
circumstances.

Completed states are indicated by an asterisk (*)

Alabama	Kentucky	*Ohio
Alaska	Louisiana	Oklahoma
Arizona	*Maine	Oregon
Arkansas	Maryland	Pennsylvania
*California	Massachusetts	*Puerto Rico
Colorado	Michigan	Rhode Island
*Connecticut	Minnesota	South Carolina
Delaware	Mississippi	South Dakota
*District of Columbia	Missouri	*Tennessee
*Florida	Montana	*Texas
Georgia	Nebraska	Utah
Guam	Nevada	*Vermont
Hawaii	New Hampshire	Virgin Islands
Idaho	New Jersey	Virginia
Illinois	New Mexico	Washington

Indiana	New York	West Virginia
Iowa	North Carolina	Wyoming
*Kansas	North Dakota	

Alan S. Goldberg's Law, Technology & Change Home Page SM

Last Updated April 11, 2003

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Welcome from Alan S. Goldberg, Webmaster

Internet Email

For information about *The Webmaster*

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The Webmaster is a member of *Goulston & Storrs - A Professional Corporation*

(888) 777-0566

1717 Pennsylvania Av., NW, Washington, DC 20006

Voice (202) 721-1137 -- Fax (617) 574-7583

Note: the Webmaster is a member of the bars of the District of Columbia, the Commonwealth of Massachusetts, & the State of Florida

The Webmaster has served on the adjunct faculty of
University of Maryland School of Law
&
Boston College Law School **&**
Suffolk University Law School

400 Atlantic Av., Boston, MA 02110
Voice (617) 482-1776 -- Fax (617) 574-7583

60 Lombard Street, London EC3V 9EA, United Kingdom
Voice 011-44-207-464-8467

Please read our *Year 2000 Readiness Disclosure* for this Web site

By entering this Web site, you agree to our *Disclaimer*

Please read our *Privacy Policy*

>***Citizens for Health et al. vs. Tommy G. Thompson, Complaint for Declaratory and Injunctive Relief April 10, 2003 USDC ED PA***

The Webmaster's LeadingLinks **(sm)**

>***Letters dated 12/09/02 to OCR & 4/01/03 from OCR about state board of pharmacy inspections & HIPAA AdminSimp accountings for disclosures***

>***Review of Protected Health Information and Applicability of Business Associate Agreements Under the Health Insurance Portability and Accountability Act (HIPAA) for the Purposes of Survey and Certification***

"DATE: March 14, 2003 FROM:

Director Survey and Certification Group SUBJECT: Review of Protected Health Information and Applicability of Business Associate Agreements Under the Health Insurance Portability and Accountability Act (HIPAA) for the Purposes of Survey and Certification TO: Survey and Certification Regional Office Management (G-5) State Survey Agency Directors The purpose of this letter is to provide guidance regarding the appropriateness of executing business associate agreements between the state survey agencies (SAs) and providers, and the provision of individually identifiable health care information during surveys under the HIPAA Privacy Rule. Several SAs have received requests from providers to enter into business associate agreements, which were addressed in the "Standards for Privacy of Individually Identifiable Health Information" (HIPAA Privacy Rule) published December 28, 2000, and most recently amended August 14, 2002 (65 Fed. Reg. 82462, as modified by 67 Fed. Reg. 53182). Additionally, several providers have expressed concern over the release of protected health information (PHI) to surveyors under the HIPAA Privacy Rule...."

"In summary, to the extent that the information sought by an SA is PHI for survey and certification work that is either 1) required by law or 2) for health care oversight activities, the surveyed entity does not need to receive an authorization prior to releasing the necessary PHI to the SA. Furthermore, surveyed entities do not need to execute a business associate agreement with SAs prior to releasing PHI as SAs are not business associates of the surveyed entities under the HIPAA Privacy Rule definition of "business associate." SAs do not conduct a function or activity of the surveyed entity on the surveyed entity's behalf. (See 45 CFR 160.103). We have attached a suggested template for use by the SAs in response to requests to take part in business associate agreements with providers, and to address provider's concerns over the release of PHI for oversight activities." Effective Date: April 14, 2003

>***Medicare Fee for Service Contractor Guidance on the HIPAA Privacy Rule***

Program Memorandum Department of Health & Human Services (DHHS) Intermediaries/Carriers Centers for Medicare & Medicaid Services (CMS) Transmittal AB-03-034 Date: FEBRUARY 28, 2003 CHANGE REQUEST 2484 SUBJECT: Medicare Fee for Service Contractor Guidance on the HIPAA Privacy Rule

"The purpose of this Program Memorandum (PM) is to provide guidance in describing the roles of Medicare FFS contractors (i.e., fiscal intermediaries, carriers, DMERC and Program Safeguard Contractors) and the Centers for Medicare & Medicaid Services (CMS) in implementing the "Standards for Privacy of Individually Identifiable Health Information" ("Privacy Rule") for the Original Medicare ("Original Medicare") Fee-For-Service (FFS) Health Plan. This guidance summarizes the operational activities that are being developed to ensure Original Medicare's compliance with the Privacy Rule by the April 14, 2003 compliance date required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA)."

www.hipaanotice.com

Notices of Privacy Practices on the Web

Links are not necessarily to the most current versions of the documents referenced and are not intended to constitute links to official versions of such documents. Contact the entity referenced at any linked site in order to obtain the official and most current document version.

>*Readability of HIPAA Privacy Notices*

Mark Hochhauser, Ph.D., Readability Consultant, 3.12.03, "...had a consulting relationship with the US Department of Health and Human Services and the Health Resources and Services Administration (HRSA) in 2002 on the readability of HIPAA privacy notices."

>*Centers for Medicare & Medicaid Services Notice*

>*MetLife® Dental HIPAA Notice*
>*MetLife® Long Term Care HIPAA Notice*
>*MetLife® Medical Insurance HIPAA Notice*
>*Aetna Notices*
>*University of Michigan Health System*
>*WorkCare™*
>*Bothwell Regional Health Center*
>*Siouxland Community Health Center*
>*Rhode Island Department of Human Services (Long Version)*
>*Rhode Island Department of Human Services Notice (Short Version)*
>*American Republic Insurance Company*
>*United Concordia Dental Insurer*

Lawyers & HIPAA Administrative Simplification Privacy Rule Business Associate Agreements

>*Preamble, Final Privacy Rule Amendments, Lawyers & Business Associate Agreements*
>*North Carolina Society of Healthcare Attorneys HIPAA and Business Associate Agreements for Lawyers*
>*NCSHA Business Associate Agreement Proposal*

Goldberg Dates HIPAA(sm)

(Webmaster's Chart of Some Important HIPAA Administrative Simplification Dates)

The Webmaster's US Government & Other LeadingLinks (SM) & Information

THOMAS

Library of Congress Databases -- Legislation, Congressional Record, and Committees

Centers for Medicare & Medicaid Services HIPAA Administrative Simplification

>*Delegation of authority within Centers for Medicare & Medicaid Services for HIPAA Administrative Simplification*

>*CMS Provider HIPAA Readiness Checklist - Getting Started- Moving toward Compliance with the Electronic Transactions & Code Sets Requirements*

>*CMS HIPAA Electronic Transactions & Code Sets Information Series - HIPAA 101 For Health Care Providers' Offices - 1/03*

>*CMS Medicare Handbook Including Medicare Program HIPAA Medicare & You: Notice of Privacy Practices 2003 (via CMS Web site)*

>*HHS Frequently Asked Questions About Electronic Transaction Standards Adopted Under HIPAA*

>*HHS Frequently Asked Questions*

>*Office of Management & Budget - Office of Information and Regulatory Affairs (OIRA) - Executive Order Submissions Under Review*

>*Federal Register Online*

>*OIG/American Health Lawyers As'n -- Corporate Responsibility & Corporate Compliance: A Resource for Health Care Boards of Directors (corrected version, 4/03)*

>*Office of the Inspector General*

>*Corporate Integrity Agreements*

>*Excluded Individuals*

6. *Point of Contact.* Tim Burke, Director, Travel Management Policy Division (MTT), Office of Governmentwide Policy, General Services Administration, Washington, DC 20405; telephone 703–872–8611; e-mail, *timothy.burke@gsa.gov.*

7. *Expiration Date.* This bulletin expires when the new eTravel services is fully implemented within your agency.

[FR Doc. 03–6662 Filed 3–19–03; 8:45 am]

BILLING CODE 6820–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

Notice of Addresses for Submission of HIPAA Health Information Privacy Complaints

AGENCY: Office for Civil Rights, HHS.

ACTION: Notification of addresses for submission of HIPAA Health Information Privacy Complaints for violations occurring on or after April 14, 2003.

SUMMARY: This notice sets out the addresses for filing a complaint with the Secretary of the Department of Health and Human Services, for non-compliance by a covered entity with the standards for privacy of individually identifiable health information under 45 CFR parts 160 and 164 (the Privacy Rule). The Privacy Rule implements certain provisions of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191. Complaints must be submitted in writing to the Office for Civil Rights at the appropriate address, as described below.

EFFECTIVE DATE: April 14, 2003.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for the list of addresses for filing complaints.

SUPPLEMENTARY INFORMATION: 45 CFR section 160.306 establishes general provisions for submission of complaints against a covered entity for non-compliance with the HIPAA Privacy Rule. A person who believes a covered entity is not complying with these requirements may file a complaint with the Secretary. A covered entity is a health plan, health care clearinghouse, and any health care provider who conducts certain health care transactions electronically. Complaints to the Secretary must: (1) Be filed in writing, either on paper or electronically; (2) name the entity that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable requirements of part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164; and (3) be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Office for Civil Rights for good cause shown. Complaints to the Secretary may be filed only with respect to alleged violations occurring on or after April 14, 2003.

The Secretary has delegated to the Office for Civil Rights (OCR) the authority to receive and investigate complaints as they may relate to the Privacy Rule. *See* 65 FR 82381 (Dec. 28, 2000). Individuals may file written complaints with OCR by mail, fax or e-mail at the addresses listed below. Individuals may, but are not required to, use OCR's Health Information Privacy Complaint Form. To obtain a copy of this form, or for more information about the Privacy Rule or how to file a complaint with OCR, contact any OCR office or go to *www.hhs.gov/ocr/hipaa/.* For more information on what entities are covered by HIPAA, go to *www.cms/hipaa/hipaa2/support/tools/decisionsupport/default.asp.*

As listed below, health information privacy complaints to the Secretary should be addressed to the OCR regional office that is responsible for matters relating to the Privacy Rule arising in the State or jurisdiction where the covered entity is located. Complaints may also be filed via email at the address noted below.

Where To File Complaints Concerning Health Information Privacy

For complaints involving covered entities located in Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, or Vermont:

Region I, Office for Civil Rights, U.S. Department of Health and Human Services, Government Center, J.F. Kennedy Federal Building—Room 1875, Boston, Massachusetts 02203. Voice phone (617) 565–1340. FAX (617) 565–3809. TDD (617) 565–1343.

For complaints involving covered entities located in New Jersey, New York, Puerto Rico, or Virgin Islands:

Region II, Office for Civil Rights, U.S. Department of Health and Human Services, Jacob Javits Federal Building, 26 Federal Plaza—Suite 3312, New York, New York, 10278. Voice Phone (212) 264–3313. FAX (212) 264–3039. TDD (212) 264–2355.

For complaints involving covered entities located in Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, or West Virginia:

Region III, Office for Civil Rights, U.S. Department of Health and Human Services, 150 S. Independence Mall West, Suite 372, Public Ledger Building, Philadelphia, PA 19106–9111. Main Line (215) 861–4441. Hotline (800) 368–1019. FAX (215) 861–4431. TDD (215) 861–4440.

For complaints involving covered entities located in Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, or Tennessee:

Region IV, Office for Civil Rights, U.S. Department of Health and Human Services, Atlanta Federal Center, Suite 3B70, 61 Forsyth Street, SW., Atlanta, GA 30303–8909. Voice Phone (404) 562–7886. FAX (404) 562–7881. TDD (404) 331–2867.

For complaints involving covered entities located in Illinois, Indiana, Michigan, Minnesota, Ohio, or Wisconsin:

Region V, Office for Civil Rights, U.S. Department of Health and Human Services, 233 N. Michigan Ave., Suite 240, Chicago, Ill. 60601. Voice Phone (312) 886–2359. FAX (312) 886–1807. TDD (312) 353–5693.

For complaints involving covered entities located in Arkansas, Louisiana, New Mexico, Oklahoma, or Texas:

Region VI, Office for Civil Rights, U.S. Department of Health and Human Services, 1301 Young Street, Suite 1169, Dallas, TX 75202. Voice Phone (214) 767–4056. FAX (214) 767–0432. TDD (214) 767–8940.

For complaints involving covered entities located in Iowa, Kansas, Missouri, or Nebraska:

Region VII, Office for Civil Rights, U.S. Department of Health and Human Services, 601 East 12th Street—Room 248, Kansas City, Missouri 64106. Voice Phone (816) 426–7278. FAX (816) 426–3686. TDD (816) 426–7065.

For complaints involving covered entities located in Colorado, Montana, North Dakota, South Dakota, Utah, or Wyoming:

Region VIII, Office for Civil Rights, U.S. Department of Health and Human Services, 1961 Stout Street—Room 1185 FOB, Denver, CO 80294–3538. Voice Phone (303) 844–2024. FAX (303) 844–2025. TDD (303) 844–3439.

For complaints involving covered entities located in American Samoa, Arizona, California, Guam, Hawaii, or Nevada:

Region IX, Office for Civil Rights, U.S. Department of Health and Human Services, 50 United Nations Plaza—

Room 322, San Francisco, CA 94102. Voice Phone (415) 437–8310. FAX (415) 437–8329. TDD (415) 437–8311.

For complaints involving covered entities located in Alaska, Idaho, Oregon, or Washington:

Region X, Office for Civil Rights, U.S. Department of Health and Human Services, 2201 Sixth Avenue—Suite 900, Seattle, Washington 98121–1831. Voice Phone (206) 615–2287. FAX (206) 615–2297. TDD (206) 615–2296.

For all complaints filed by e-mail send to: *OCRComplaint@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Lester Coffer, Office for Civil Rights, Department of Health and Human Services, Mail Stop Room 506F, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Telephone number: (202) 205–8725.

Dated: March 12, 2003.

Richard M. Campanelli,

Director, Office for Civil Rights.

[FR Doc. 03–6651 Filed 3–19–03; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, Announces the Following Meeting

Name: ICD–9–CM Coordination and Maintenance Committee Meeting.

Time and Date: 9 a.m.—4 p.m., April 3, 2003.

Place: Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland.

Status: Open to the public.

Purpose: The ICD–9–CM Coordination and Maintenance (C&M) Committee will hold its first meeting of the 2003 calendar year cycle on Thursday, April 3, 2003. The C&M meeting is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Ninth-Revision, and Clinical Modification.

Matters to be Discussed: Agenda items include: Hepatitis C, acute and unspecified; worn out joint prosthesis; deep vein thrombosis; aftercare following organ transplant; aftercare following abnormal pap smear; encounter for pregnancy test-negative result; allergic dermatitis due to animal dander; endometrial hyperplasia with and without atypia; mechanical complication of esophagostomy; and ICD–10 Procedure Classification System (PCS); Updates on: Bipolar Radiofrequency Ablation; and Blunt Micro-Dissection with Chronic Total Occlusion (CTO) Catheter Laparoscopic/Thorascopic approaches.

Contact Person for Additional Information: Amy Blum, Medical Classification Specialist, Classifications and Public Health Data Standards Staff, NCHS, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone 301–458–4106 (diagnosis), Amy Gruber, Health Insurance Specialist, Division of Acute Care, CMS, 7500 Security Blvd., Room C4–07–07, Baltimore, Maryland 21244, telephone 410–786–1542 (procedures).

Notice: In the interest of security, (CMS) has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Notice: This is a public meeting. However, because of fire code requirements, should the number of attendants meet the capacity of the room, the meeting will be closed.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 14, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–6681 Filed 3–19–03; 8:45 am]

BILLING CODE 4360–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health; Meeting

The National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Continue Discussions on the Approval of Respiratory Devices Used to Protect Workers in Hazardous Environments.

Times and Dates: 8 a.m.–11:30 a.m., April 10, 2003. 8 a.m.–11:30 a.m., April 24, 2003.

Place: Marriott Key Bridge, 1401 Lee Highway, Arlington, Virginia (April 10); Colorado School of Mines, 1500 Illinois Street, Golden, Colorado (April 24).

Status: These meetings are hosted by NIOSH and will be open to the public, limited only by the space available. The meeting room at each location will accommodate approximately 75 people. Interested parties should make hotel reservations directly with the Marriott Key Bridge (703–524–6400/800–327–9789) in Arlington, Virginia, or the Golden Hotel (303–279–0100/800–233–7214) in Golden, Colorado, referencing the NIOSH/NPPTL Public Meeting. Interested parties should confirm their attendance to either meeting by completing a registration form and forwarding it by e-mail (*confserv@netl.doe.gov*) or fax (304–285–4459) to the Event Management Office. A registration form may be obtained from the NIOSH Homepage (*http://www.cdc.gov/niosh*) by selecting Conferences and then the event.

Requests to make presentations at the public meeting should be mailed to the NIOSH Docket Officer, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513–533–8303, Fax 513–533–8285, E-mail *niocindocket@cdc.gov.* All requests to present should contain the name, address, telephone number, relevant business affiliations of the presenter, a brief summary of the presentation, and the approximate time requested for the presentation. Oral presentations should be limited to 15 minutes.

After reviewing the requests for presentation, NIOSH will notify each presenter of the approximate time that their presentation is scheduled to begin. If a participant is not present when their presentation is scheduled to begin, the remaining participants will be heard in order. At the conclusion of the meeting, an attempt will be made to allow presentations by any scheduled participants who missed their assigned times. Attendees who wish to speak but did not submit a request for the opportunity to make a presentation may be given the opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

Comments on the topics presented in this notice and at the meetings should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513–533–8303, Fax 513–533–8285. Comments may also be submitted by e-mail to

[TABLE OF CONTENTS] [SUMMARY]

PUBLIC LAW 104-191

AUG. 21, 1996

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

Public Law 104-191
104th Congress

An Act

To amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**--This Act may be cited as the "Health Insurance Portability and Accountability Act of 1996".

(b) **TABLE OF CONTENTS.**--The table of contents of this Act is as follows:

...

Subtitle F --Administrative Simplification

SEC. 261. PURPOSE.

It is the purpose of this subtitle to improve the Medicare program under title XVIII of the Social Security Act, the medicaid program under title XIX of such Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.

SEC. 262. ADMINISTRATIVE SIMPLIFICATION.

(a) IN GENERAL.--Title XI (42 U.S.C. 1301 et seq.) is amended by adding at the end the following:

"PART C--ADMINISTRATIVE SIMPLIFICATION

"DEFINITIONS

"**SEC. 1171**. For purposes of this part:

"(1) CODE SET.--The term 'code set' means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

"(2) HEALTH CARE CLEARINGHOUSE.--The term 'health care clearinghouse' means a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements.

"(3) HEALTH CARE PROVIDER.--The term 'health care provider' includes a provider of services (as defined in section 1861(u)), a provider of medical or other health services (as defined in section 1861 (s)), and any other person furnishing health care services or supplies.

"(4) HEALTH INFORMATION.--The term 'health information' means any information, whether oral or

recorded in any form or medium, that--

"(A) 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

"(B) 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.

"(5) HEALTH PLAN.--The term 'health plan' means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 2791 of the Public Health Service Act). Such term includes the following, and any combination thereof:

"(A) A group health plan (as defined in section 2791(a) of the Public Health Service Act), but only if the plan--

"(i) has 50 or more participants (as defined in section 3(7) of the Employee Retirement Income Security Act of 1974); or

"(ii) is administered by an entity other than the employer who established and maintains the plan.

"(B) A health insurance issuer (as defined in section 2791(b) of the Public Health Service Act).

"(C) A health maintenance organization (as defined in section 2791(b) of the Public Health Service Act).

"(D) Part A or part B of the Medicare program under title XVIII.

"(E) The medicaid program under title XIX.

"(F) A Medicare supplemental policy (as defined in section 1882(g)(1)).

"(G) A long-term care policy, including a nursing home fixed indemnity policy (unless the Secretary determines that such a policy does not provide sufficiently comprehensive coverage of a benefit so that the policy should be treated as a health plan).

"(H) An employee welfare benefit plan or any other arrangement which is established or maintained for the purpose of offering or providing health benefits to the employees of 2 or more employers.

"(I) The health care program for active military personnel under title 10, United States Code.

"(J) The veterans health care program under chapter 17 of title 38, United States Code.

"(K) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10, United States Code.

"(L) The Indian health service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

"(M) The Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code.

"(6) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.--The term 'individually identifiable health information' means any information, including demographic information collected from an individual, that--

"(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

"(B) 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, and--

"(i) identifies the individual; or

"(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

"(7) STANDARD.--The term 'standard', when used with reference to a data element of health information or a transaction referred to in section 1173(a)(1), means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1172 through 1174.

"(8) STANDARD SETTING ORGANIZATION.--The term 'standard setting organization' means a standard setting organization accredited by the American National Standards Institute, including the National Council for Prescription Drug Programs, that develops standards for information transactions, data elements, or any other standard that is necessary to, or will facilitate, the implementation of this part.

"GENERAL REQUIREMENTS FOR ADOPTION OF STANDARDS

"**SEC. 1172.** (a) APPLICABILITY.--Any standard adopted under this part shall apply, in whole or in part, to the following persons:

"(1) A health plan.

"(2) A health care clearinghouse.

"(3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1173(a)(1).

"(b) REDUCTION OF COSTS.--Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

"(c) ROLE OF STANDARD SETTING ORGANIZATIONS.--

"(1) IN GENERAL.--Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted, or modified by a standard setting organization.

"(2) SPECIAL RULES.--

"(A) DIFFERENT STANDARDS.--The Secretary may adopt a standard that is different from any

standard developed, adopted, or modified by a standard setting organization, if--

"(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

"(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code.

"(B) NO STANDARD BY STANDARD SETTING ORGANIZATION.--If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part--

"(i) paragraph (1) shall not apply; and

"(ii) subsection (f) shall apply.

(3) CONSULTATION REQUIREMENT.--

"(A) IN GENERAL.--A standard may not be adopted under this part unless--

"(i) in the case of a standard that has been developed, adopted, or modified by a standard setting organization, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification; and

"(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f), consulted with each of the organizations described in subparagraph (B) before adopting the standard.

"(B) ORGANIZATIONS DESCRIBED.--The organizations referred to in subparagraph (A) are the following:

"(i) The National Uniform Billing Committee.

"(ii) The National Uniform Claim Committee.

"(iii) The Workgroup for Electronic Data Interchange.

"(iv) The American Dental Association.

"(d) IMPLEMENTATION SPECIFICATIONS.--The Secretary shall establish

specifications for implementing each of the standards adopted under this

part.

"(e) PROTECTION OF TRADE SECRETS.--Except as otherwise required by law, a standard adopted under this part shall not require disclosure of trade secrets or confidential commercial information by a person required to comply with this part.

"(f) ASSISTANCE TO THE SECRETARY.--In complying with the requirements of this part, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics

established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)), and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.

(g) APPLICATION TO MODIFICATIONS OF STANDARDS.--This section shall apply to a modification to a standard (including an addition to a standard) adopted under section 1174(b) in the same manner as it applies to an initial standard adopted under section 1174(a).

"STANDARDS FOR INFORMATION TRANSACTIONS AND DATA ELEMENTS

"**SEC. 1173.** (a) STANDARDS TO ENABLE ELECTRONIC EXCHANGE.--

"(1) IN GENERAL.--The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for--

"(A) the financial and administrative transactions described in paragraph (2); and

"(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

"(2) TRANSACTIONS.--The transactions referred to in paragraph (1)(A) are transactions with respect to the following:

"(A) Health claims or equivalent encounter information.

"(B) Health claims attachments.

"(C) Enrollment and disenrollment in a health plan.

"(D) Eligibility for a health plan.

"(E) Health care payment and remittance advice.

"(F) Health plan premium payments.

"(G) First report of injury.

"(H) Health claim status.

"(I) Referral certification and authorization.

"(3) ACCOMMODATION OF SPECIFIC PROVIDERS.--The standards adopted by the Secretary under paragraph (1) shall accommodate the needs of different types of health care providers.

(b) UNIQUE HEALTH IDENTIFIERS.--

"(1) IN GENERAL.--The Secretary shall adopt standards providing for a standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system. In carrying out the preceding sentence for each health plan and health care provider, the

Secretary shall take into account multiple uses for identifiers and multiple locations and specialty classifications for health care providers.

"(2) USE OF IDENTIFIERS.--The standards adopted under paragraph (1) shall specify the purposes for which a unique health identifier may be used.

(c) CODE SETS.--

"(1) IN GENERAL.--The Secretary shall adopt standards that--

"(A) select code sets for appropriate data elements for the transactions referred to in subsection (a)(1) from among the code sets that have been developed by private and public entities; or

"(B) establish code sets for such data elements if no code sets for the data elements have been developed.

"(2) DISTRIBUTION.--The Secretary shall establish efficient and low-cost procedures for distribution (including electronic distribution) of code sets and modifications made to such code sets under section 1174(b).

(d) SECURITY STANDARDS FOR HEALTH INFORMATION.--

"(1) SECURITY STANDARDS.--The Secretary shall adopt security standards that--

"(A) take into account--

"(i) the technical capabilities of record systems used to maintain health information;

"(ii) the costs of security measures;

"(iii) the need for training persons who have access to health information;

"(iv) the value of audit trails in computerized record systems; and

"(v) the needs and capabilities of small health care providers and rural health care providers (as such providers are defined by the Secretary); and

"(B) ensure that a health care clearinghouse, if it is part of a larger organization, has policies and security procedures which isolate the activities of the health care clearinghouse with respect to processing information in a manner that prevents unauthorized access to such information by such larger organization.

"(2) SAFEGUARDS.--Each person described in section 1172(a) who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards--

"(A) to ensure the integrity and confidentiality of the information;

"(B) to protect against any reasonably anticipated--

"(i) threats or hazards to the security or integrity of the information; and

"(ii) unauthorized uses or disclosures of the information; and

"(C) otherwise to ensure compliance with this part by the officers and employees of such person.

(e) ELECTRONIC SIGNATURE.--

"(1) STANDARDS.--The Secretary, in coordination with the Secretary of Commerce, shall adopt standards specifying procedures for the electronic transmission and authentication of signatures with respect to the transactions referred to in subsection (a)(1).

"(2) EFFECT OF COMPLIANCE.--Compliance with the standards adopted under paragraph (1) shall be deemed to satisfy Federal and State statutory requirements for written signatures with respect to the transactions referred to in subsection (a)(1).

(f) TRANSFER OF INFORMATION AMONG HEALTH PLANS.--The Secretary shall adopt standards for transferring among health plans appropriate standard data elements needed for the coordination of benefits, the sequential processing of claims, and other data elements for individuals who have more than one health plan.

"TIMETABLES FOR ADOPTION OF STANDARDS

"**SEC. 1174.** (a) INITIAL STANDARDS.--The Secretary shall carry out section 1173 not later than 18 months after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, except that standards relating to claims attachments shall be adopted not later than 30 months after such date.

"(b) ADDITIONS AND MODIFICATIONS TO STANDARDS.--

"(1) IN GENERAL.--Except as provided in paragraph (2), the Secretary shall review the standards adopted under section 1173, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months. Any addition or modification to a standard shall be completed in a manner which minimizes the disruption and cost of compliance.

"(2) SPECIAL RULES.--

"(A) FIRST 12-MONTH PERIOD.--Except with respect to additions and modifications to code sets under subparagraph (B), the Secretary may not adopt any modification to a standard adopted under this part during the 12-month period beginning on the date the standard is initially adopted, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard.

"(B) ADDITIONS AND MODIFICATIONS TO CODE SETS.--

"(i) IN GENERAL.--The Secretary shall ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets.

"(ii) Additional rules.--If a code set is modified under this subsection, the modified code set shall include instructions on how data elements of health information that were encoded prior to the

modification may be converted or translated so as to preserve the informational value of the data elements that existed before the modification. Any modification to a code set under this subsection shall be implemented in a manner that minimizes the disruption and cost of complying with such modification.

"REQUIREMENTS

"**SEC. 1175.** (a) CONDUCT OF TRANSACTIONS BY PLANS.--

"(1) IN GENERAL.--If a person desires to conduct a transaction referred to in section 1173(a)(1) with a health plan as a standard transaction--

"(A) the health plan may not refuse to conduct such transaction as a standard transaction;

"(B) the insurance plan may not delay such transaction, or otherwise adversely affect, or attempt to adversely affect, the person or the transaction on the ground that the transaction is a standard transaction; and

"(C) the information transmitted and received in connection with the transaction shall be in the form of standard data elements of health information.

"(2) SATISFACTION OF REQUIREMENTS.--A health plan may satisfy the requirements under paragraph (1) by--

"(A) directly transmitting and receiving standard data elements of health information; or

"(B) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse, and receiving standard data elements through the health care clearinghouse.

"(3) TIMETABLE FOR COMPLIANCE.--Paragraph (1) shall not be construed to require a health plan to comply with any standard, implementation specification, or modification to a standard or specification adopted or established by the Secretary under sections 1172 through 1174 at any time prior to the date on which the plan is required to comply with the standard or specification under subsection (b).

"(b) COMPLIANCE WITH STANDARDS.--

"(1) INITIAL COMPLIANCE.--

"(A) IN GENERAL.--Not later than 24 months after the date on which an initial standard or implementation specification is adopted or established under sections 1172 and 1173, each person to whom the standard or implementation specification applies shall comply with the standard or specification.

"(B) SPECIAL RULE FOR SMALL HEALTH PLANS.--In the case of a small health plan, paragraph (1) shall be applied by substituting '36 months' for '24 months'. For purposes of this subsection, the Secretary shall determine the plans that qualify as small health plans.

"(2) COMPLIANCE WITH MODIFIED STANDARDS.--If the Secretary adopts a modification to a

standard or implementation specification under this part, each person to whom the standard or implementation specification applies shall comply with the modified standard or implementation specification at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification. The time determined appropriate under the preceding sentence may not be earlier than the last day of the 180-day period beginning on the date such modification is adopted. The Secretary may extend the time for compliance for small health plans, if the Secretary determines that such extension is appropriate.

"(3) CONSTRUCTION.--Nothing in this subsection shall be construed to prohibit any person from complying with a standard or specification by--

"(A) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse; or

"(B) receiving standard data elements through a health care clearinghouse.

"GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS

"**SEC. 1176.** (a) GENERAL PENALTY.--

"(1) IN GENERAL.--Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part a penalty of not more than $100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed $25,000.

"(2) PROCEDURES.--The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1128A.

"(b) LIMITATIONS.--

"(1) OFFENSES OTHERWISE PUNISHABLE.--A penalty may not be imposed under subsection (a) with respect to an act if the act constitutes an offense punishable under section 1177.

"(2) NONCOMPLIANCE NOT DISCOVERED.--A penalty may not be imposed under subsection (a) with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision.

"(3) FAILURES DUE TO REASONABLE CAUSE.--

"(A) IN GENERAL.--Except as provided in subparagraph (B), a penalty may not be imposed under subsection (a) if--

"(i) the failure to comply was due to reasonable cause and not to willful neglect; and

"(ii) the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to

comply occurred.

"(B) EXTENSION OF PERIOD.--

"(i) NO PENALTY.--The period referred to in subparagraph (A)(ii) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

"(ii) ASSISTANCE.--If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary.

"(4) REDUCTION.--In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

"WRONGFUL DISCLOSURE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

"**SEC. 1177.** (a) OFFENSE.--A person who knowingly and in violation of this part--

"(1) uses or causes to be used a unique health identifier;

"(2) obtains individually identifiable health information relating to an individual; or

"(3) discloses individually identifiable health information to another person,

shall be punished as provided in subsection (b).

"(b) PENALTIES.--A person described in subsection (a) shall--

"(1) be fined not more than $50,000, imprisoned not more than 1 year, or both;

"(2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; and

"(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than $250,000, imprisoned not more than 10 years, or both.

"EFFECT ON STATE LAW

"**SEC. 1178.** (a) GENERAL EFFECT.--

"(1) GENERAL RULE.--Except as provided in paragraph (2), a provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1172 through 1174, shall supersede any contrary provision of State law, including a provision of State law that requires medical or health plan records (including billing information) to be maintained or transmitted in written rather than electronic form.

"(2) EXCEPTIONS.--A provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1172 through 1174, shall not supersede a contrary provision of State law, if the provision of State law--

"(A) is a provision the Secretary determines--

"(i) is necessary--

"(I) to prevent fraud and abuse;

"(II) to ensure appropriate State regulation of insurance and health plans;

"(III) for State reporting on health care delivery or costs; or

"(IV) for other purposes; or

"(ii) addresses controlled substances; or

"(B) subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.

"(b) PUBLIC HEALTH.--Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

"(c) STATE REGULATORY REPORTING.--Nothing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

"PROCESSING PAYMENT TRANSACTIONS BY FINANCIAL INSTITUTIONS

"**SEC. 1179.** To the extent that an entity is engaged in activities of a financial institution (as defined in section 1101 of the Right to Financial Privacy Act of 1978), or is engaged in authorizing, processing, clearing, settling, billing,

transferring, reconciling, or collecting payments, for a financial institution, this part, and any standard adopted under this part, shall not apply to the entity with respect to such activities, including the following:

"(1) The use or disclosure of information by the entity for authorizing, processing, clearing, settling, billing, transferring, reconciling or collecting, a payment for, or related to, health plan premiums or health care, where such payment is made by any means, including a credit, debit, or other payment card, an account, check, or electronic funds transfer.

"(2) The request for, or the use or disclosure of, information by the entity with respect to a payment described in paragraph (1)--

"(A) for transferring receivables;

"(B) for auditing;

"(C) in connection with--

"(i) a customer dispute; or

"(ii) an inquiry from, or to, a customer;

"(D) in a communication to a customer of the entity regarding the customer's transactions, payment card, account, check, or electronic funds transfer;

"(E) for reporting to consumer reporting agencies; or

"(F) for complying with--

"(i) a civil or criminal subpoena; or

"(ii) a Federal or State law regulating the entity.".

(b) CONFORMING AMENDMENTS.--

(1) REQUIREMENT FOR MEDICARE PROVIDERS.--Section 1866(a)(1) (42 U.S.C. 1395cc(a)(1)) is amended--

(A) by striking ``and" at the end of subparagraph (P);

(B) by striking the period at the end of subparagraph (Q) and inserting "; and"; and

(C) by inserting immediately after subparagraph (Q) the following new subparagraph:

"(R) to contract only with a health care clearinghouse (as defined in section 1171) that meets each standard and implementation specification adopted or established under part C of title XI on or after the date on which the health care clearinghouse is required to comply with the standard or specification.".

(2) TITLE HEADING.--Title XI (42 U.S.C. 1301 et seq.) is amended by striking the title heading and inserting the following:

"TITLE XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION".

SEC. 263. CHANGES IN MEMBERSHIP AND DUTIES OF NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS.

Section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k))

is amended--

(1) in paragraph (1), by striking "16" and inserting "18";

(2) by amending paragraph (2) to read as follows:

"(2) The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.";

(3) by redesignating paragraphs (3) through (5) as paragraphs (4) through (6), respectively, and inserting after paragraph (2) the following:

"(3) Of the members of the Committee--

"(A) 1 shall be appointed, not later than 60 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, by the Speaker of the House of Representatives after consultation with the Minority Leader of the House of Representatives;

"(B) 1 shall be appointed, not later than 60 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, by the President pro tempore of the Senate after consultation with the Minority Leader of the Senate; and

"(C) 16 shall be appointed by the Secretary.";

(4) by amending paragraph (5) (as so redesignated) to read as follows:

"(5) The Committee--

"(A) shall assist and advise the Secretary--

"(i) to delineate statistical problems bearing on health and health services which are of national or international interest;

"(ii) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;

"(iii) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use (I) within the Department of Health and Human Services, (II) by all programs administered or funded by the Secretary, including the Federal-State-local cooperative health statistics system referred to in subsection (e), and (III) to the extent possible as determined by the head of the agency involved, by the Department of Veterans Affairs, the Department of Defense, and other Federal agencies concerned with health and health services;

"(iv) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health and Human Services, with respect to the Cooperative Health Statistics System established under subsection (e), and with respect to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j)(1);

"(v) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

"(vi) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest;

"(vii) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems; and

"(viii) in complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act;

"(B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;

"(C) shall report to the Secretary not later than 4 years after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange; and

"(D) shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act."; and

(5) by adding at the end the following:

"(7) Not later than 1 year after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

"(A) The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.

"(B) The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards.

"(C) Whether the Federal and State Governments are receiving information of sufficient quality to meet their responsibilities under such part.

"(D) Any problems that exist with respect to implementation of such part.

"(E) The extent to which timetables under such part are being met.".

SEC. 264. RECOMMENDATIONS WITH RESPECT TO PRIVACY OF CERTAIN HEALTH INFORMATION.

(a) IN GENERAL.--Not later than the date that is 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Labor and Human Resources and the Committee on Finance of the Senate and the Committee on Commerce and the

Committee on Ways and Means of the House of Representatives detailed recommendations on standards with respect to the privacy of individually identifiable health information.

(b) SUBJECTS FOR RECOMMENDATIONS.--The recommendations under subsection (a) shall address at least the following:

(1) The rights that an individual who is a subject of individually identifiable health information should have.

(2) The procedures that should be established for the exercise of such rights.

(3) The uses and disclosures of such information that should be authorized or required.

(c) REGULATIONS.--

(1) IN GENERAL.--If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173 (a) of the Social Security Act (as added by section 262) is not enacted by the date that is 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than the date that is 42 months after the date of the enactment of this Act. Such regulations shall address at least the subjects described in subsection (b).

(2) PREEMPTION.--A regulation promulgated under paragraph (1) shall not supercede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation.

(d) CONSULTATION.--In carrying out this section, the Secretary of Health and Human Services shall consult with--

(1) the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)); and

(2) the Attorney General.

...


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Adminstrative Simplification


NCVHS


Data Council


Department of Health & Human Services

Comments/suggestions and other questions about HIPAA should be directed to the Web Master.

Form Approved: OMB No. 0990-0269.
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

HEALTH INFORMATION PRIVACY COMPLAINT

If you have questions about this form, call OCR (toll-free) at:
1-800-368-1019 (any language) or 1-800-537-7697 (TDD)

YOUR FIRST NAME	YOUR LAST NAME

HOME PHONE	WORK PHONE
( )	( )

STREET ADDRESS	CITY

STATE	ZIP	E-MAIL ADDRESS *(If available)*

Are you filing this complaint for someone else? ☐ Yes ☐ No

If Yes, whose health information privacy rights do you believe were violated?

FIRST NAME	LAST NAME

Who (or what agency or organization, e.g., provider, health plan) do you believe violated your (or someone else's) health information privacy rights or committed another violation of the Privacy Rule?

PERSON / AGENCY / ORGANIZATION

STREET ADDRESS	CITY

STATE	ZIP	PHONE
		( )

When do you believe that the violation of health information privacy rights occurred?

LIST DATE(S)

Describe briefly what happened. How and why do you believe your (or someone else's) health information privacy rights were violated, or the privacy rule otherwise was violated? Please be as specific as possible. *(Attach additional pages as needed)*

Please sign and date this complaint.

SIGNATURE	DATE

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of the Privacy Rule issued pursuant to the Health Insurance Portability and Accountability Act of 1996. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible health information privacy violations, for internal systems operations, or for routine uses, which include disclosure of information outside the Department for purposes associated with health information privacy compliance and as permitted by law. It is illegal for a covered entity to intimidate, threaten, coerce, discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under the Privacy Rule. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to our web site at: **www.hhs.gov/ocr/privacyhowtofile.html** . To mail a complaint see reverse page for OCR Regional addresses.

(The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.)

Do you need special accommodations for us to communicate with you about this complaint (check all that apply)?

☐ Braille ☐ Large Print ☐ Cassette tape ☐ Computer diskette ☐ Electronic mail ☐ TDD

☐ Sign language interpreter *(specify language)*:

☐ Foreign language interpreter *(specify language)*: ☐ Other:

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME
HOME PHONE ( )	WORK PHONE ( )

STREET ADDRESS	CITY

STATE	ZIP	E-MAIL ADDRESS *(If available)*

Have you filed your complaint anywhere else? If so, please provide the following. (Attach additional pages as needed.)

PERSON / AGENCY / ORGANIZATION / COURT NAME(S)

DATE(S) FILED	CASE NUMBER(S) *(If known)*

To help us better serve the public, please provide the following information for the person you believe had their health information privacy rights violated (you or the person on whose behalf you are filing).

ETHNICITY *(select one)*

☐ Hispanic or Latino

☐ Not Hispanic or Latino

RACE *(select one or more)*

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American ☐ White ☐ Other *(specify)*:

PRIMARY LANGUAGE SPOKEN *(if other then English)*

HOW DID YOU LEARN ABOUT THE OFFICE FOR CIVIL RIGHTS?

To mail a complaint, please type or print, and return completed complaint to the OCR Regional Address based on the region where the alledged violation took place.

Region I - CT, ME, MA, NH, RI, VT
Office for Civil Rights
Department of Health & Human Services
JFK Federal Building - Room 1875
Boston, MA 02203
(617) 565-1340; (617) 565-1343 (TDD)
(617) 565-3809 FAX

Region II - NJ, NY, PR, VI
Office for Civil Rights
Department of Health & Human Services
26 Federal Plaza - Suite 3313
New York, NY 10278
(212) 264-3313; (212) 264-2355 (TDD)
(212) 264-3039 FAX

Region III - DE, DC, MD, PA, VA, WV
Office for Civil Rights
Department of Health & Human Services
150 S. Independence Mall West - Suite 372
Philadelphia, PA 19106-3499
(215) 861-4441; (215) 861-4440 (TDD)
(215) 861-4431 FAX

Region IV - AL, FL, GA, KY, MS, NC, SC, TN
Office for Civil Rights
Department of Health & Human Services
61 Forsyth Street, SW. - Suite 3B70
Atlanta, GA 30323
(404) 562-7886; (404) 331-2867 (TDD)
(404) 562-7881 FAX

Region V - IL, IN, MI, MN, OH, WI
Office for Civil Rights
Department of Health & Human Services
233 N. Michigan Ave. - Suite 240
Chicago, IL 60601
(312) 886-2359; (312) 353-5693 (TDD)
(312) 886-1807 FAX

Region VI - AR, LA, NM, OK, TX
Office for Civil Rights
Department of Health & Human Services
1301 Young Street - Suite 1169
Dallas, TX 75202
(214) 767-4056; (214) 767-8940 (TDD)
(214) 767-0432 FAX

Region VII - IA, KS, MO, NE
Office for Civil Rights
Department of Health & Human Services
601 East 12th Street - Room 248
Kansas City, MO 64106
(816) 426-7278; (816) 426-7065 (TDD)
(816) 426-3686 FAX

Region VIII - CO, MT, ND, SD, UT, WY
Office for Civil Rights
Department of Health & Human Services
1961 Stout Street - Room 1426
Denver, CO 80294
(303) 844-2024; (303) 844-3439 (TDD)
(303) 844-2025 FAX

Region IX - AZ, CA, HI, NV, AS, GU, The U.S. Affiliated Pacific Island Jurisdictions
Office for Civil Rights
Department of Health & Human Services
50 United Nations Plaza - Room 322
San Francisco, CA 94102
(415) 437-8310; (415) 437-8311 (TDD)
(415) 437-8329 FAX

Region X - AK, ID, OR, WA
Office for Civil Rights
Department of Health & Human Services
2201 Sixth Avenue - Mail Stop RX-11
Seattle, WA 98121
(206) 615-2290; (206) 615-2296 (TDD)
(206) 615-2297 FAX

Burden Statement

Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201.

FACT SHEET

U.S. Department of Health and Human Services • Office for Civil Rights

HOW TO FILE A HEALTH INFORMATION PRIVACY COMPLAINT WITH THE OFFICE FOR CIVIL RIGHTS

If you believe that a person, agency or organization covered under the HIPAA Privacy Rule ("a covered entity") violated your (or someone else's) health information privacy rights or committed another violation of the Privacy Rule, you may file a complaint with the Office for Civil Rights (OCR). OCR has authority to receive and investigate complaints against covered entities related to the Privacy Rule. A covered entity is a health plan, health care clearinghouse, and any health care provider who conducts certain health care transactions electronically. For more information about the Privacy Rule, please look at our responses to Frequently Asked Questions (FAQs) and our Privacy Guidance. (See the web link near the bottom of this form.)

Complaints to the Office for Civil Rights must: (1) Be filed in writing, either on paper or electronically; (2) name the entity that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable requirements of the Privacy Rule; and (3) be filed within 180 days of when you knew that the act or omission complained of occurred. OCR may extend the 180-day period if you can show "good cause." Any alleged violation must have occurred on or after April 14, 2003 (on or after April 14, 2004 for small health plans), for OCR to have authority to investigate.

Anyone can file written complaints with OCR by **mail, fax, or email**. If you need help filing a complaint or have a question about the complaint form, please call this OCR toll free number: 1-800-368-1019. OCR has ten regional offices, and each regional office covers certain states. You should send your complaint to the appropriate OCR Regional Office, **based on the region where the alleged violation took place.** Use the OCR Regions list at the end of this Fact Sheet, or you can look at the regional office map to help you

determine where to send your complaint. Complaints should be sent to the attention off the appropriate OCR Regional Manager.

You can submit your complaint in any written format. We recommend that you use the OCR Health Information Privacy Complaint Form which can be found on our web site or at an OCR Regional office. If you prefer, you may submit a written complaint in your own format. Be sure to include the following information in your *written* complaint:

Your name, full address, home and work telephone numbers, email address.

If you are filing a complaint on someone's behalf, also provide the name of the person on whose behalf you are filing.

Name, full address and phone of the person, agency or organization you believe violated your (or someone else's) health information privacy rights or committed another violation of the Privacy Rule.

Briefly describe what happened. How, why, and when do believe your (or someone else's) health information privacy rights were violated, or the Privacy Rule otherwise was violated?

Any other relevant information.

Please sign your name and date your letter.

The following information is optional:

Do you need special accommodations for us to communicate with you about this complaint?

If we cannot reach you directly, is there someone else we can contact to help us reach you?

Have you filed your complaint somewhere else?

The Privacy Rule, developed under authority of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), prohibits the alleged violating party from taking retaliatory action against anyone for filing a complaint with the Office for Civil Rights. You should notify OCR immediately in the event of any retaliatory action.

To submit a complaint with OCR, please use one of the following methods. If you mail or fax the complaint, be sure to follow the instructions above for determining the correct regional office.

Option 1: Open and print out the Health Information Privacy Complaint Form in PDF format (you will need Adobe Reader software) and fill it out. Return the completed complaint to the appropriate OCR Regional Office by mail or fax.

Option 2: Download the Health Information Privacy Complaint Form in Microsoft Word format to your own computer, fill out and save the form using Microsoft Word. Use the Tab and Shift/Tab on your keyboard to move from field to field in the form. Then, you can either: (a) print the completed form and mail or fax it to the appropriate OCR Regional Office; or (b) email the form to OCR at OCRComplaint@hhs.gov.

Option 3: If you choose not to use the OCR-provided Health Information Privacy Complaint Form (although we recommend that you do), please provide the information specified above and either: (a) send a letter or fax to the appropriate OCR Regional Office; or (b) send an email OCR at OCRComplaint@hhs.gov.

If you require an answer regarding a general health information privacy question, please view our Frequently Asked Questions (FAQs). If you still need assistance, you may call OCR (toll-free) at: 1-866-627-7748. You may also send an email to OCRPrivacy@hhs.gov with suggestions regarding future FAQs. Emails will not receive individual responses.

Website: http://www.hhs.gov/ocr/hipaa

OCR Regional Addresses	

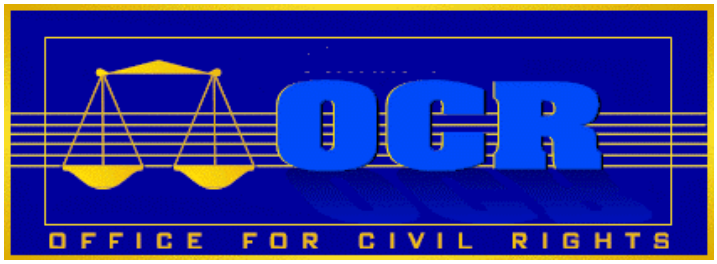
Region I - CT, ME, MA, NH, RI, VT Office for Civil Rights U.S. Department of Health & Human Services JFK Federal Building - Room 1875 Boston, MA 02203 (617) 565-1340; (617) 565-1343 (TDD) (617) 565-3809 FAX	**Region VI - AR, LA, NM, OK, TX** Office for Civil Rights U.S. Department of Health & Human Services 1301 Young Street - Suite 1169 Dallas, TX 75202 (214) 767-4056; (214) 767-8940 (TDD) (214) 767-0432 FAX
Region II - NJ, NY, PR, VI Office for Civil Rights U.S. Department of Health & Human Services 26 Federal Plaza - Suite 3313 New York, NY 10278 (212) 264-3313; (212) 264-2355 (TDD) (212) 264-3039 FAX	**Region VII - IA, KS, MO, NE** Office for Civil Rights U.S. Department of Health & Human Services 601 East 12th Street - Room 248 Kansas City, MO 64106 (816) 426-7278; (816) 426-7065 (TDD) (816) 426-3686 FAX
Region III - DE, DC, MD, PA, VA, WV Office for Civil Rights U.S. Department of Health & Human Services 150 S. Independence Mall West - Suite 372 Philadelphia, PA 19106-3499 (215) 861-4441; (215) 861-4440 (TDD) (215) 861-4431 FAX	**Region VIII - CO, MT, ND, SD, UT, WY** Office for Civil Rights U.S. Department of Health & Human Services 1961 Stout Street - Room 1426 Denver, CO 80294 (303) 844-2024; (303) 844-3439 (TDD) (303) 844-2025 FAX
Region IV - AL, FL, GA, KY, MS, NC, SC, TN Office for Civil Rights	**Region IX - AZ, CA, HI, NV, AS, GU, The U.S. Affiliated Pacific Island Jurisdictions** Office for Civil Rights

U.S. Department of Health & Human Services 61 Forsyth Street, SW. - Suite 3B70 Atlanta, GA 30323 (404) 562-7886; (404) 331-2867 (TDD) (404) 562-7881 FAX	U.S. Department of Health & Human Services 50 United Nations Plaza - Room 322 San Francisco, CA 94102 (415) 437-8310; (415) 437-8311 (TDD) (415) 437-8329 FAX
Region V - IL, IN, MI, MN, OH, WI Office for Civil Rights U.S. Department of Health & Human Services 233 N. Michigan Ave. - Suite 240 Chicago, IL 60601 (312) 886-2359; (312) 353-5693 (TDD) (312) 886-1807 FAX	**Region X - AK, ID, OR, WA** Office for Civil Rights U.S. Department of Health & Human Services 2201 Sixth Avenue - Mail Stop RX-11 Seattle, WA 98121 (206) 615-2290; (206) 615-2296 (TDD) (206) 615-2297 FAX

(H-13/June 2000)

O C R P R I V A C Y B R I E F

SUMMARY OF THE HIPAA PRIVACY RULE



HIPAA Compliance Assistance

SUMMARY OF
THE HIPAA PRIVACY RULE

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SUMMARY OF
THE HIPAA PRIVACY RULE

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").[1] 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 notes at the end of this document. To view the entire Rule, and for other additional helpful information about how it applies, see the OCR website: http://www.hhs.gov/ocr/hipaa. In the event of a conflict between this summary and the Rule, the Rule governs. Links to the OCR Guidance Document are provided throughout this paper. Provisions of the Rule referenced in this summary are cited in endnotes at the end of this document. To review the entire Rule itself, and for other additional helpful information about how it applies, see the OCR website: http://www.hhs.gov/ocr/hipaa.
Statutory & 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.[2] 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.[3] A text combining the final regulation and the modifications can be found at 45 CFR Part 160 and Part 164, Subparts A and E on the OCR website: http://www.hhs.gov/ocr/hipaa
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 the decision tool at: http://www.cms.hhs.gov/hipaa/hipaa2/support/tools/decisionsupport/default.asp **Health Plans.** Individual and group plans that provide or pay the cost of medical care are covered entities.[4] 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,[5] 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. **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.[6] 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.[7] 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.[8] 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.[9] 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.[10] 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 have an existing written contract or agreement with business associates prior to October 15, 2002, which is not renewed or modified prior to April 14, 2003, are permitted to continue to operate under that contract until they renew the contract or April 14, 2004, whichever is first.[11] Sample business associate contract language is available on the OCR website at: http://www.hhs.gov/ocr/hipaa/contractprov.html. Also see OCR "Business Associate" Guidance.
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)*."[12]

	"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 can be used to identify the individual.[13] 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.[14] 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.[15]
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 heath 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.[16] **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.[17] See OCR "Government Access" Guidance.
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.[18] 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.[19] 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 OCR "Treatment, Payment, Health Care Operations" Guidance.

> ***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.[20]
>
> ***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[21] 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.[22]

Most uses and disclosures of psychotherapy notes for treatment, payment, and health care operations purposes require an authorization as described below.[23]

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.[24] The content of a consent form, and the process for obtaining consent, are at the discretion of the covered entity electing to seek consent.

(3) Uses and Disclosures with Opportunity to Agree or Object. Informal permission may be obtained by asking the individual outright, or by circumstances that clearly give the individual the opportunity to agree, acquiesce, or object. Where the individual is incapacitated, in an emergency situation, or not available, covered entities generally may make such uses and disclosures, if in the exercise of their professional judgment, the use or disclosure is determined to be in the best interests of the individual.

> ***Facility Directories*** It is a common practice in many health care facilities, such as hospitals, to maintain a directory of patient contact information. A covered health care provider may rely on an individual's informal permission to list in its facility directory the individual's name, general condition, religious affiliation, and location in the provider's facility.[25] The provider may then disclose the individual's condition and location in the facility to anyone asking for the individual by name, and also may disclose religious affiliation to clergy. Members of the clergy are not required to ask for the individual by name when inquiring about patient religious affiliation.
>
> ***For Notification and Other Purposes*** A covered entity also may rely on an individual's informal permission to disclose to the individual's family, relatives, or friends, or to other persons whom the individual identifies, protected health information directly relevant to that person's involvement in the individual's care or payment for care.[26] This provision, for example, allows a pharmacist to dispense filled prescriptions to a person acting on behalf of the patient. Similarly, a covered entity may rely on an individual's informal permission to use or disclose protected health information for the purpose of notifying (including identifying or locating) family members, personal representatives, or others responsible for the individual's care of the individual's location, general condition, or death. In addition, protected health information may be disclosed for notification purposes to public or private entities authorized by law or charter to assist in disaster relief efforts.

(4) Incidental Use and Disclosure. The Privacy Rule does not require that every risk of an incidental use or disclosure of protected health information be eliminated. A use or disclosure of this information that occurs as a result of, or as "incident to," an otherwise permitted use or disclosure is permitted as long as the covered entity has adopted reasonable safeguards as required by the Privacy Rule, and the information being shared was limited to the "minimum necessary," as required by the Privacy Rule.[27] See OCR "Incidental Uses and Disclosures" Guidance.

(5) Public Interest and Benefit Activities. The Privacy Rule permits use and disclosure of protected health information, without an individual's authorization or permission, for 12 national priority purposes.[28] These disclosures are permitted, although not required, by the Rule in recognition of the important uses made of health information outside of the health care context. Specific conditions or limitations apply to each public interest purpose, striking the balance between the individual privacy interest and the public interest need for this information.

Required by Law. Covered entities may use and disclose protected health information without individual authorization as *required by law* (including by statute, regulation, or court orders).

Public Health Activities. Covered entities may disclose protected health information to: (1) public health authorities authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability and to public health or other government authorities authorized to receive reports of child abuse and neglect; (2) entities subject to FDA regulation regarding FDA regulated products or activities for purposes such as adverse event reporting, tracking of products, product recalls, and post-marketing surveillance; (3) individuals who may have contracted or been exposed to a communicable disease when notification is authorized by law; and (4) employers, regarding employees, when requested by employers, for information concerning a work-related illness or injury or workplace related medical surveillance, because such information is needed by the employer to comply with the Occupational Safety and Health Administration (OHSA), the Mine Safety and Health Administration (MHSA), or similar state law. See OCR "Public Health" Guidance.

Victims of Abuse, Neglect or Domestic Violence. In certain circumstances, covered entities may disclose protected health information to appropriate government authorities regarding victims of abuse, neglect, or domestic violence.

Health Oversight Activities. Covered entities may disclose protected health information to health oversight agencies (as defined in the Rule) for purposes of legally authorized health oversight activities, such as audits and investigations necessary for oversight of the health care system and government benefit programs.

Judicial and Administrative Proceedings. Covered entities may disclose protected health information in a judicial or administrative proceeding if the request for the information is through an order from a court or administrative tribunal. Such information may also be disclosed in response to a subpoena or other lawful process if certain assurances regarding notice to the individual or a protective order are provided.

Law Enforcement Purposes. Covered entities may disclose protected health information to law enforcement officials for law enforcement purposes under the following six circumstances, and subject to specified conditions: (1) as required by law (including court orders, court-ordered warrants, subpoenas) and administrative requests; (2) to identify or locate a suspect, fugitive, material witness, or missing person; (3) in response to a law enforcement official's request for information about a victim or suspected victim of a crime; (4) to alert law enforcement of a person's death, if the covered entity suspects that criminal activity caused the death; (5) when a covered entity believes that protected health information is evidence of a crime that occurred on its premises; and (6) by a covered health care provider in a medical emergency not occurring on its premises, when necessary to inform

law enforcement about the commission and nature of a crime, the location of the crime or crime victims, and the perpetrator of the crime.

Decedents. Covered entities may disclose protected health information to funeral directors as needed, and to coroners or medical examiners to identify a deceased person, determine the cause of death, and perform other functions authorized by law.

Cadaveric Organ, Eye, or Tissue Donation. Covered entities may use or disclose protected health information to facilitate the donation and transplantation of cadaveric organs, eyes, and tissue.

Research. "Research" is any systematic investigation designed to develop or contribute to generalizable knowledge.[29] The Privacy Rule permits a covered entity to use and disclose protected health information for research purposes, without an individual's authorization, provided the covered entity obtains either: (1) documentation that an alteration or waiver of individuals' authorization for the use or disclosure of protected health information about them for research purposes has been approved by an Institutional Review Board or Privacy Board; (2) representations from the researcher that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purpose preparatory to research, that the researcher will not remove any protected health information from the covered entity, and that protected health information for which access is sought is necessary for the research; or (3) representations from the researcher that the use or disclosure sought is solely for research on the protected health information of decedents, that the protected health information sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is sought.[30] A covered entity also may use or disclose, without an individuals' authorization, a limited data set of protected health information for research purposes (see discussion below).[31] See OCR "Research" Guidance.

Serious Threat to Health or Safety. Covered entities may disclose protected health information that they believe is necessary to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat (including the target of the threat). Covered entities may also disclose to law enforcement if the information is needed to identify or apprehend an escapee or violent criminal.

Essential Government Functions. An authorization is not required to use or disclose protected health information for certain essential government functions. Such functions include: assuring proper execution of a military mission, conducting intelligence and national security activities that are authorized by law, providing protective services to the President, making medical suitability determinations for U.S. State Department employees, protecting the health and safety of inmates or employees in a correctional institution, and determining eligibility for or conducting enrollment in certain government benefit programs.

	Workers' Compensation Covered entities may disclose protected health information as authorized by, and to comply with, workers' compensation laws and other similar programs providing benefits for work-related injuries or illnesses. See OCR "Workers' Compensation" Guidance. **(6) Limited Data Set**. A limited data set is protected health information from which certain specified direct identifiers of individuals and their relatives, household members, and employers have been removed.[32] A limited data set may be used and disclosed for research, health care operations, and public health purposes, provided the recipient enters into a data use agreement promising specified safeguards for the protected health information within the limited data set.
Authorized Uses and Disclosures	**Authorization.** A covered entity must obtain the individual's written authorization for any use or disclosure of protected health information that is not for treatment, payment or health care operations or otherwise permitted or required by the Privacy Rule.[33] A covered entity may not condition treatment, payment, enrollment, or benefits eligibility on an individual granting an authorization, except in limited circumstances.[34] An authorization must be written in specific terms. It may allow use and disclosure of protected health information by the covered entity seeking the authorization, or by a third party. Examples of disclosures that would require an individual's authorization include disclosures to a life insurer for coverage purposes, disclosures to an employer of the results of a pre-employment physical or lab test, or disclosures to a pharmaceutical firm for their own marketing purposes. All authorizations must be in plain language, and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data. The Privacy Rule contains transition provisions applicable to authorizations and other express legal permissions obtained prior to April 14, 2003. [35] **Psychotherapy Notes**[36]. A covered entity must obtain an individual's authorization to use or disclose psychotherapy notes with the following exceptions[37]: The covered entity who originated the notes may use them for treatment. A covered entity may use or disclose, without an individual's authorization, the psychotherapy notes, for its own training, and to defend itself in legal proceedings brought by the individual, for HHS to investigate or determine the covered entity's compliance with the Privacy Rules, to avert a serious and imminent threat to public health or safety, to a health oversight agency for lawful oversight of the originator of the psychotherapy notes, for the lawful activities of a coroner or medical examiner or as required by law. **Marketing**. Marketing is any communication about a product or service that encourages recipients to purchase or use the product or service.[38] The Privacy Rule carves out the following health-related activities from this definition of marketing: Communications to describe health-related products or services, or payment for them, provided by or included in a benefit plan of the covered entity

	making the communication; Communications about participating providers in a provider or health plan network, replacement of or enhancements to a health plan, and health-related products or services available only to a health plan's enrollees that add value to, but are not part of, the benefits plan; Communications for treatment of the individual; and Communications for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or care settings to the individual. Marketing also is an arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information, in exchange for direct or indirect remuneration, for the other entity to communicate about its own products or services encouraging the use or purchase of those products or services. A covered entity must obtain an authorization to use or disclose protected health information for marketing, except for face-to-face marketing communications between a covered entity and an individual, and for a covered entity's provision of promotional gifts of nominal value. No authorization is needed, however, to make a communication that falls within one of the exceptions to the marketing definition. An authorization for marketing that involves the covered entity's receipt of direct or indirect remuneration from a third party must reveal that fact. See OCR Marketing Guidance.
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.[39] 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 OCR "Minimum Necessary" Guidance. 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.[40] 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 OCR "Notice" Guidance. **Notice Distribution.** A covered health care provider with a *direct treatment relationship* with individuals must deliver a privacy practices notice to patients starting April 14, 2003 as follows: o 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); o 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 o 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.[41] 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.[42] 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.

Acknowledgement of Notice Receipt. A covered health care provider with a direct treatment relationship with individuals must make a good faith effort to obtain written acknowledgement from patients of receipt of the privacy practices notice.[43] The Privacy Rule does not prescribe any particular content for the acknowledgement. The provider must document the reason for any failure to obtain the patient's written acknowledgement. The provider is relieved of the need to request acknowledgement in an emergency treatment situation.

Access. Except in certain circumstances, individuals have the right to review and obtain a copy of their protected health information in a covered entity's *designated record set.*[44] The "designated record set" is that group of records maintained by or for a covered entity that is used, in whole or part, to make decisions about individuals, or that is a provider's medical and billing records about individuals or a health plan's enrollment, payment, claims adjudication, and case or medical management record systems.[45] The Rule excepts from the right of access the following protected health information: psychotherapy notes, information compiled for legal proceedings, laboratory results to which the Clinical Laboratory Improvement Act (CLIA) prohibits access, or information held by certain research laboratories. For information included within the right of access, covered entities may deny an individual access in certain specified situations, such as when a health care professional believes access could cause harm to the individual or another. In such situations, the individual must be given the right to have such denials reviewed by a licensed health care professional for a second opinion.[46] Covered entities may impose reasonable, cost-based fees for the cost of copying and postage.
See OCR "Miscellaneous" Guidance.

Amendment. The Rule gives individuals the right to have covered entities amend their protected health information in a designated record set when that information is inaccurate or incomplete.[47] If a covered entity accepts an amendment request, it must

make reasonable efforts to provide the amendment to persons that the individual has identified as needing it, and to persons that the covered entity knows might rely on the information to the individual's detriment.[48] If the request is denied, covered entities must provide the individual with a written denial and allow the individual to submit a statement of disagreement for inclusion in the record. The Rule specifies processes for requesting and responding to a request for amendment. A covered entity must amend protected health information in its designated record set upon receipt of notice to amend from another covered entity.

Disclosure Accounting. Individuals have a right to an accounting of the disclosures of their protected health information by a covered entity or the covered entity's business associates.[49] The maximum disclosure accounting period is the six years immediately preceding the accounting request, except a covered entity is not obligated to account for any disclosure made before its Privacy Rule compliance date.

The Privacy Rule does not require accounting for disclosures: (a) for treatment, payment, or health care operations; (b) to the individual or the individual's personal representative; (c) for notification of or to persons involved in an individual's health care or payment for health care, for disaster relief, or for facility directories; (d) pursuant to an authorization; (e) of a limited data set; (f) for national security or intelligence purposes; (g) to correctional institutions or law enforcement officials for certain purposes regarding inmates or individuals in lawful custody; or (h) incident to otherwise permitted or required uses or disclosures. Accounting for disclosures to health oversight agencies and law enforcement officials must be temporarily suspended on their written representation that an accounting would likely impede their activities.

Restriction Request. Individuals have the right to request that a covered entity restrict use or disclosure of protected health information for treatment, payment or health care operations, disclosure to persons involved in the individual's health care or payment for health care, or disclosure to notify family members or others about the individual's general condition, location, or death.[50] A covered entity is under no obligation to agree to requests for restrictions. A covered entity that does agree must comply with the agreed restrictions, except for purposes of treating the individual in a medical emergency.[51]

Confidential Communications Requirements. Health plans and covered health care providers must permit individuals to request an alternative means or location for receiving communications of protected health information by means other than those that the covered entity typically employs.[52] For example, an individual may request that the provider communicate with the individual through a designated address or phone number. Similarly, an individual may request that the provider send communications in a closed envelope rather than a post card.

Health plans must accommodate reasonable requests if the individual indicates that the disclosure of all or part of the protected health information could endanger the individual. The health plan may not question the individual's statement of endangerment. Any covered entity may condition compliance with a confidential communication request on the individual specifying an alternative address or method of contact and explaining how any payment will be handled.

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.[53]

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.[54]

Workforce Training and Management. 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.[55] A covered entity must have and apply appropriate sanctions against workforce members who violate its privacy policies and procedures or the Privacy Rule.[56]

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.[57]

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.[58] 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 OCR "Incidental Uses and Disclosures" Guidance.

Complaints. A covered entity must have procedures for individuals to complain about its compliance with its privacy policies and procedures and the Privacy Rule.[59] The covered entity must explain those procedures in its privacy practices notice.[60]

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.[61] A covered entity may not require an individual to waive any right under the Privacy Rule as a condition for obtaining treatment, payment, enrollment or benefits eligibility.[62]

	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.[63] **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.[64]
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."[65] (The activities that make a person or organization a covered entity are its "covered functions."[66]) 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.[67] 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."[68] Covered entities in an organized health care arrangement can share protected health information with each other for the arrangement's joint health care operations.[69] **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.[70] 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[71]: 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.[72] 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 OCR "Personal Representatives" Guidance.

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.[73] "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.[74] 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.** Consistent with the principles for achieving compliance provided in the Rule, HHS will seek the cooperation of covered entities and may provide technical assistance to help them comply voluntarily with the Rule.[75] The Rule provides processes for persons to file complaints with HHS, describes the responsibilities of covered entities to provide records and compliance reports and to cooperate with, and permit access to information for, investigations and compliance reviews. **Civil Money Penalties.** HHS may impose civil money penalties on a covered entity of $100 per failure to comply with a Privacy Rule requirement.[76] That penalty may not exceed $25,000 per year for multiple violations of the identical Privacy Rule requirement in a calendar year. HHS may not impose a civil money penalty under specific circumstances, such as when a violation is due to reasonable cause and did not involve willful neglect and the covered entity corrected the violation within 30 days of when it knew or should have known of the violation.

	Criminal Penalties. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA faces a fine of $50,000 and up to one-year imprisonment.[77] The criminal penalties increase to $100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses, and to $250,000 and up to ten years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm. Criminal sanctions will be enforced by the Department of Justice.
Compliance Dates	**Compliance Schedule.** All covered entities, except "small health plans," must be compliant with the Privacy Rule by April 14, 2003.[78] Small health plans, however, have 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.[79] 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.[80] See What constitutes a small health plan?
Copies of the Rule & Related Materials	The entire Privacy Rule, as well as guidance and additional materials, may be found on our website, http://www.hhs.gov/ocr/hipaa

End Notes

[1] Pub. L. 104-191.

[2] 65 FR 82462.

[3] 67 FR 53182.

[4] 45 C.F.R. §§ 160.102, 160.103.

[5] Even if an entity, such as a community health center, does not meet the definition of a health plan, it may, nonetheless, meet the definition of a health care provider, and, if it transmits health information in electronic form in connection with the transactions for which the Secretary of HHS has adopted standards under HIPAA, may still be a covered entity.

[6] 45 C.F.R. §§ 160.102, 160.103; *see* Social Security Act § 1172(a)(3), 42 U.S.C. § 1320d-1(a)(3). The transaction standards are established by the HIPAA Transactions Rule at 45 C.F.R. Part 162.

[7] 45 C.F.R. § 160.103.

[8] 45 C.F.R. § 164.500(b).

[9] 45 C.F.R. § 160.103.

[10] 45 C.F.R. §§ 164.502(e), 164.504(e).

[11] 45 C.F.R. § 164.532

[12] 45 C.F.R. § 160.103.

[13] 45 C.F.R. § 160.103

[14] 45 C.F.R. §§ 164.502(d)(2), 164.514(a) and (b).

[15] The following identifiers of the individual or of relatives, employers, or household members of the individual must be removed to achieve the "safe harbor" method of de-identification: (A) Names; (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census (1) the geographic units formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000; (C) All elements of dates (except year) for dates directly related to the individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older; (D) Telephone numbers; (E) Fax numbers; (F) Electronic mail addresses: (G) Social security numbers; (H) Medical record numbers; (I) Health plan beneficiary numbers; (J) Account numbers; (K) Certificate/license numbers; (L) Vehicle identifiers and serial numbers, including license plate numbers; (M) Device identifiers and serial numbers; (N) Web Universal Resource Locators (URLs); (O) Internet Protocol (IP) address numbers; (P) Biometric identifiers, including finger and voice prints; (Q) Full face photographic images and any comparable images; and ® any other unique identifying number, characteristic, or code, except as permitted for re-identification purposes provided certain conditions are met. In addition to the removal of the above-stated identifiers, the covered entity may not have actual knowledge that the remaining information could be used alone or in combination with any other information to identify an individual who is subject of the information. 45 C.F.R. § 164.514(b).

[16] 45 C.F.R. § 164.502(a).

[17] 45 C.F.R. § 164.502(a)(2).

[18] 45 C.F.R. § 164.502(a)(1).

[19] 45 C.F.R. § 164.506(c).

[20] 45 C.F.R. § 164.501.

[21] 45 C.F.R. § 164.501.

[22] 45 C.F.R. § 164.501.

[23] 45 C.F.R. § 164.508(a)(2)

[24] 45 C.F.R. § 164.506(b).

[25] 45 C.F.R. § 164.510(a).

[26] 45 C.F.R. § 164.510(b).

[27] 45 C.F.R. §§ 164.502(a)(1)(iii).

[28] *See* 45 C.F.R. § 164.512.

[29] The Privacy Rule defines research as, "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 164.501.

[30] 45 C.F.R. § 164.512(i).

[31] 45 CFR § 164.514(e).

[32] 45 C.F.R. § 164.514(e). A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information, other than town or city, State and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses: (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; (xvi) Full face photographic images and any comparable images. 45 C.F.R. § 164.514(e)(2).

[33] 45 C.F.R. § 164.508.

[34] A covered entity may condition the provision of health care solely to generate protected health information for disclosure to a third party on the individual giving authorization to disclose the information to the third party. For example, a covered entity physician may condition the provision of a physical examination to be paid for by a life insurance issuer on an individual's authorization to disclose the results of that examination to the life insurance issuer. A health plan may condition enrollment or benefits eligibility on the individual giving authorization, requested before the individual's enrollment, to obtain protected health information (other than psychotherapy notes) to determine the individual's eligibility or enrollment or for underwriting or risk rating. A covered health care provider may condition treatment related to research (e.g., clinical trials) on the individual giving authorization to use or disclose the individual's protected health information for the research. 45 C.F.R. 508(b)(4).

[35] 45 CFR § 164.532.

[36] "Psychotherapy notes" means 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 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 C.F.R. § 164.501.

[37] 45 C.F.R. § 164.508(a)(2).

[38] 45 C.F.R. §§ 164.501 and 164.508(a)(3).

[39] 45 C.F.R. §§ 164.502(b) and 164.514 (d).

[40] 45 C.F.R. §§ 164.520(a) and (b). A group health plan, or a health insurer or HMO with respect to the group health plan, that intends to disclose protected health information (including enrollment data or summary health information) to the plan sponsor, must state that fact in the notice. Special statements are also required in the notice if a covered entity intends to contact individuals about health-related benefits or services, treatment alternatives, or appointment reminders, or for the covered entity's own fundraising.

[41] 45 C.F.R. § 164.520(c).

[42] 45 C.F.R. § 164.520(d).

[43] 45 C.F.R. § 164.520(c).

[44] 45 C.F.R. § 164.524.

[45] 45 C.F.R. § 164.501.

[46] A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed by a licensed health care professional (who is designated by the covered entity and who did not participate in the original decision to deny), when a licensed health care professional has determined, in the exercise of professional judgment, that: (a) the access requested is reasonably likely to endanger the life or physical safety of the individual or another person; (b) the protected health information makes reference to another person (unless such other person is a health care provider) and the access requested is reasonably likely to cause substantial harm to such other person; or (c) the request for access is made by the individual's personal representative and the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

A covered entity may deny access to individuals, without providing the individual an opportunity for review, in the following protected situations: (a) the protected health information falls under an exception to the right of access; (b) an inmate request for protected health information under certain circumstances; (c) information that a provider creates or obtains in the course of research that includes treatment for which the individual has agreed not to have access as part of consenting to participate in the research (as long as access to the information is restored upon completion of the research); (d) for records subject to the Privacy Act, information to which access may be denied under the Privacy Act, 5 U.S.C. § 552a; and (e) information obtained under a promise of confidentiality from a source other than a health care provider, if granting access would likely reveal the source. 45 C.F.R. § 164.524.

[47] 45 C.F.R. § 164.526.

[48] Covered entities may deny an individual's request for amendment only under specified circumstances. A covered entity may deny the request if it: (a) may exclude the information from access by the individual; (b) did not create the information (unless the individual provides a reasonable basis to believe the originator is no longer available); (c) determines that the information is accurate and complete; or (d) does not hold the information in its designated record set. 164.526(a)(2).

[49] 45 C.F.R. § 164.528.

[50] 45 C.F.R. § 164.522(a).

[51] 45 C.F.R. § 164.522(a). In addition, a restriction agreed to by a covered entity is not effective under this subpart to prevent uses or disclosures permitted or required under §§ 164.502(a)(2)(ii), 164.510(a) or 164.512.

[52] 45 C.F.R. § 164.522(b).

[53] 45 C.F.R. § 164.530(i).

[54] 45 C.F.R. § 164.530(a).

[55] 45 C.F.R. § 164.530(b).

[56] 45 C.F.R. § 164.530(e).

[57] 45 C.F.R. § 164.530(f).

[58] 45 C.F.R. § 164.530(c).

[59] 45 C.F.R. § 164.530(d).

[60] 45 C.F.R. § 164.520(b)(1)(vi).

[61] 45 C.F.R. § 164.530(g).

[62] 45 C.F.R. § 164.530(h).

[63] 45 C.F.R. § 164.530(j).

[64] 45 C.F.R. § 164.530(k).

[65] 45 C.F.R. §§ 164.103, 164.105.

[66] 45 C.F.R. § 164.103.

[67] 45 C.F.R. §164.105. Common ownership exists if an entity possesses an ownership or equity interest of five percent or more in another entity; common control exists if an entity has the direct or indirect power significantly to influence or direct the actions or policies of another entity. 45 C.F.R. §§ 164.103.

[68] The Privacy Rule at 45 C.F.R. § 1640.103 identifies five types of organized health care arrangements:

- ?? A clinically-integrated setting where individuals typically receive health care from more than one provider.
- ?? An organized system of health care in which the participating covered entities hold themselves out to the public as part of a joint arrangement and jointly engage in utilization review, quality assessment and improvement activities, or risk-sharing payment activities.
- ?? A group health plan and the health insurer or HMO that insures the plan's benefits, with respect to protected health information created or received by the insurer or HMO that relates to individuals who are or have been participants or beneficiaries of the group health plan.
- ?? All group health plans maintained by the same plan sponsor.
- ?? All group health plans maintained by the same plan sponsor and all health insurers and HMOs that insure the plans' benefits, with respect to protected health information created or received by the insurers or HMOs that relates to individuals who are or have been participants or beneficiaries in the group health plans.

[69] 45 C.F.R. § 164.506(c)(5).

[70] 45 C.F.R. § 164.504(g).

[71] 45 C.F.R. § 164.504(f).

[72] 45 C.F.R. § 164.502(g).

[73] 45 C.F.R. §160.203.

[74] 45 C.F.R. § 160.202.

[75] 45 C.F.R.§ 160.304

[76] 42 U.S.C. § 1320d-5.

[77] 42 U.S.C. §1320d-6.

[78] 45 C.F.R. § 164.534.

[79] 45 C.F.R. § 160.103.

[80] Fully insured health plans should use the amount of total premiums that they paid for health insurance benefits during the plan's last full fiscal year. Self-insured plans, both funded and unfunded, should use the total amount paid for health care claims by the employer, plan sponsor or benefit fund, as applicable to their circumstances, on behalf of the plan during the plan's last full fiscal year. Those plans that provide health benefits through a mix of purchased insurance and self-insurance should combine proxy measures to determine their total annual receipts.

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Resume of Alan S. Goldberg, Esquire

Alan S. Goldberg is a member of the bars of the District of Columbia, Massachusetts and Florida. Mr. Goldberg concentrates in the practice of business and administrative law including the delivery of health care and information technology. Goulston & Storrs provides creative solutions in the areas of real estate, taxation, estate planning, bankruptcy, health care and medical devices, litigation, technology, and complex business transactions nationally, and internationally via a London, UK office.

Mr. Goldberg's introduction to health law occurred in the 1960s, during the dawning of the Medicare and Medicaid programs era as a judge advocate and prosecuting attorney in the United States Navy, and Mr. Goldberg was also involved in investigative actions relating to the USS Pueblo and the Sea-lab project. Mr. Goldberg joined Goulston & Storrs in 1967 upon graduation from Boston College Law School, where he was a member of the Law Review and received an academic scholarship, and as a Lecturer in Law presented a course in land finance. In 1978 Mr. Goldberg received an LL.M. (Taxation) from Boston University School of Law. Mr. Goldberg served as an Adjunct Professor at University of Maryland School of Law and Mr. Goldberg also taught at Boston's Suffolk University Law School. He is a Past President of National Health Lawyers Association ('91-'92) and served on its Board of Directors from 1981 to 1993; and served as an Internet advisor to the Health Lawyers Board. Mr. Goldberg received the National Health Lawyers Association David J. Greenburg Service Award in 1996.

Mr. Goldberg has published extensively on a broad range of health law, and many other legal issues and has frequently lectured for American Health Lawyers Association and also for many bar and for other associations; the Massachusetts Hospital Association, Dental Society, Medical Society, and Long Term Care Foundation, the American Telemedicine Association, the Workgroup For Electronic Data Interchange, the Healthcare Information and Management Systems Society, and for governmental and other organizations, and he participates in many national conferences as a moderator and a lecturer.

Mr. Goldberg was the moderator of the Health Law Forum computer on-line feature of CounselConnect; he is the Editor of a law and computer technology column entitled "The Computer Wizard" published by the American Bar Association's Business Law Section magazine "Business Law Today"; and he is the founding moderator of the American Health Lawyers Association Health Information and Technology Internet listserv. Mr. Goldberg has presented loss prevention seminars relating to technology issues to the membership of Attorneys' Liability Assurance Society. Among Mr. Goldberg's current interests are national and international challenges and opportunities involving the application of technology to the practice of law and medicine and to the delivery of healthcare, including issues involving the Internet, security and encryption, privacy and confidentiality, software licensing and devices, corporate compliance programs, and telemedicine. Mr. Goldberg has served as Vice Chair of the American Health Lawyers Association Health Information and Technology Practice Group, and Chair of the American Bar Association Health Law Section's e-Health & Privacy Interest Group; and he cochairs The National HIPAA Summit series of events and originated the HIPAA HERO® teaching methodology.

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