

HIPAA Summit West II
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HIPAA Implementation Strategies
for Small and Rural Providers

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HIPAA Humor?

“The Department believes that the requirements of the final rule will not be difficult to fulfill, and therefore, it has maintained the two year effective date.” 65 Fed Reg 82758 (December 28, 2000).

Is this persuasive authority?

Key Observations

- 82.6% of all health care establishments in the U.S. are “small entities”
- Small providers often have limited financial and educational resources
- Privacy Rule too voluminous for small providers to digest
- No general small entity exception under HIPAA
- Delay of Privacy Rule is unlikely (but assumed by many small providers)

Outline of Presentation:

- Addressing Implementation Timelines
- Enforcement Restrictions, Scalability, and Reasonableness
- Making HIPAA Rules Understandable and Brief
- Review of cooperative arrangements and resulting tools:
 - NCHICA and the State of Maryland Health Care Commission
 - HPAA Earlyview™ Privacy software tool

Addressing Implementation Timelines **with Providers**

- Recognize that small providers generally unaware of HIPAA
- Emphasize that HIPAA imposes current obligations on covered entities

HIPAA Privacy Reg. Compliance: **APRIL 14, 2003**

vs.

HIPAA Safeguard Statute Compliance: **August 21, 1996**

Addressing Implementation Timelines with Providers

HIPAA Safeguard Statute: 42 U.S.C. Sec. 1320d-2(d):

“Each person described in section 1320d-1(a) of this title 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.”

Enforcement Restrictions,
Scalability and Reasonableness
under HIPAA

Enforcement Discretion:

- No CMP where person demonstrates to satisfaction at the Secretary that person “did not know, and by exercising reasonable diligence would not have known” HIPAA violated [42 U.S.C. 1320d-5(b)(2)]
- NO CMP if failure due to reasonable cause and not to willful neglect; and the failure is corrected within 30 days [42 U.S.C. 1320d-5(b)(3)(A)]
- Thirty (30) day correction period may be extended by Secretary
[42 U.S.C. 1320d-5(b)(3)(B)(i)]

Enforcement Discretion (Continued):

- Secretary authorized to provide technical assistance during correction period:
“in any manner determined appropriate by the Secretary” [42 U.S.C. 1320d-5(b)(3)(B)(ii)]
- If CMP is excessive vis-à-vis compliance failure:
then Secretary may waive if failure due to reasonable cause and not willful neglect
[42 U.S.C. 1320d-5(b)(4)]

Enforcement Discretion (Continued):

“As to enforcement, a covered entity will not necessarily suffer a penalty solely because an act or omission violates the rule. ...[T]he Department will exercise discretion to consider not only the harm done, but the willingness of the covered entity to achieve voluntary compliance.”

65 Fed. Reg. 82603 (December 28, 2000).

“Scalability” of Regulations:

- Privacy regulations are scalable to reflect variations among covered entities
 - HHS expects small entities will develop “less expensive and less complex privacy measures”
- HHS’s scalable approach may benefit smaller providers
 - Limitations on small providers taken into account
- Regulations consider current business practices
 - Small providers “will not be required to change their business practices dramatically”

“Reasonableness” under Regulations

- There is no blanket “reasonable efforts” qualifier to privacy regulations
- “Reasonable efforts” approach is provision specific

Examples:

- Minimum Necessary Rule
- Mitigation of violations by business associates
- Consents after emergency treatment

Additional flexibility factor:

HHS belief that “the requirements of the final rule will not be difficult to fulfill”

Implementation Strategy: Make HIPAA Rules Understandable and Brief

STEP ONE: Be brief

STEP TWO: Educate

STEP THREE: Break Up the Privacy Rule to its essential tasks and identify scalability

STEP FOUR: Perform gap analysis

STEP FIVE: Identify available forms and implement in accordance with gap analysis report

Additional Implementation Strategy:

- Consider where groups of small entities can work through implementation together
- HHS encourages cooperative efforts
- State or local associations/societies as a resource

STEP ONE: Be Brief

- Convey that the HIPAA Regulations are about “Standards”
- Health Care Provider should understand underlying purpose of HIPAA privacy rule

STEP TWO: Educate

- Who to educate (versus who to train)
- Accomplish the “HIPAA Epiphany”
- Recognize available education resources
 - HHS Press Releases and Fact Sheets
 - Web sites:
 - www.hhs.gov/ocr/hipaa
 - www.hipaasummit.com
 - www.wedi.org (also White Paper)

STEP THREE: Break Up the Privacy Rule to its Essential Tasks and Identify Scalability

12 Essential Tasks/Scalability

1. Appoint a Privacy Officer and assign duties.
 - Implementation will vary by size of CE.
2. Adopt a notice of privacy practices.
 - Notice is complex. Use a form.
3. Adopt a HIPAA Consent form for Treatment, Payment and Health Care Operations.
 - Recognize consents are distinct from authorizations.

12 Essential Tasks/Scalability (Continued):

4. Adopt a HIPAA Authorization form.
 - Consider using a form developed by professional society/trade association.

5. Obtain patient Consents and Authorizations under adopted forms.
 - Consider procedure that makes sense given what CE currently doing.

6. Identify all “Business Associates,” adopt a form contract and enter into Business Associate Agreements with all “Business Associates.”
 - Final regs more workable than proposed rule.
 - Standard industry practice?

12 Essential Tasks/Scalability (Continued):

7. Adopt policies & procedures to handle patient requests regarding their protected health information.
 - Consider how currently handling requests.
8. Adopt policy regarding “Minimum Necessary” disclosures.
 - Similar to current practices?
9. Train all employees on HIPAA privacy standards, policies & procedures.
 - Nature and method of training left to CE.
10. Amend employee manual regarding the HIPAA privacy rules.
 - Small providers permitted more limited policies/procedures.

12 Essential Tasks/Scalability (Continued):

11. Implement HIPAA security safeguards.

- Proposed security regulations are just that: proposals
- But remember current statutory obligation

12. Adopt HIPAA privacy compliance record-keeping policies, including means to meet disclosure accounting requirement.

- Documentation requires are extensive
- Create checklists

STEP FOUR: Gap Analysis

- Identify the gaps:
 - Current policies, procedures, forms and contracts
 - Where CE maintains, uses, discloses, or accesses PHI
 - Where current policies/procedures/forms/contracts need to be modified or new ones added

STEP FOUR: Gap Analysis (cont'd)

- Start with assessment checklist; then do formal analysis
- Create implementation work plan
- Software Tools are available

STEP FIVE: Identify Forms and Implement in accordance with gap analysis report

- Forms available through many sources
- Obtain professional consensus on good (i.e., HIPAA compliant) forms
- Recognize that forms reflect the drafters
- Consider Trade or Professional Associations for source
- Remember: If your client adopts it, then it must comply with it.

Review of Cooperative Arrangements: NCHICA and the State of Maryland Health Care Commission

What is NCHICA?

North Carolina Healthcare Information and Communications Alliance

Approximately 200 members of NCHICA

- Health Plans
- Clearinghouses
- State and Federal Agencies
- Local Governments
- Vendors
- Professional Associations and Societies
- Research Organizations
- Law Firms

NCHICA's HIPAA Implementation Task Force

Work groups:

- Transactions, Coding and Identifiers
- Privacy
- Network Interoperability
- Data Security
- Awareness Education and Training

Over 300 participants have been involved in these efforts.

NCHICA “Deliverables”

- Education components.
- Forms:
Consents, Authorizations, Notices.
- Checklists for creation of HIPAA compliant forms.
- Model Agreements (incl. Provider-Attorney Bus. Assoc. Agreement developed with North Carolina Society of Health Care Attorneys).
- A HIPAA privacy regulation analysis flow chart.
- Identification of North Carolina State Laws and analysis of the “more stringent state laws” under the regulations.

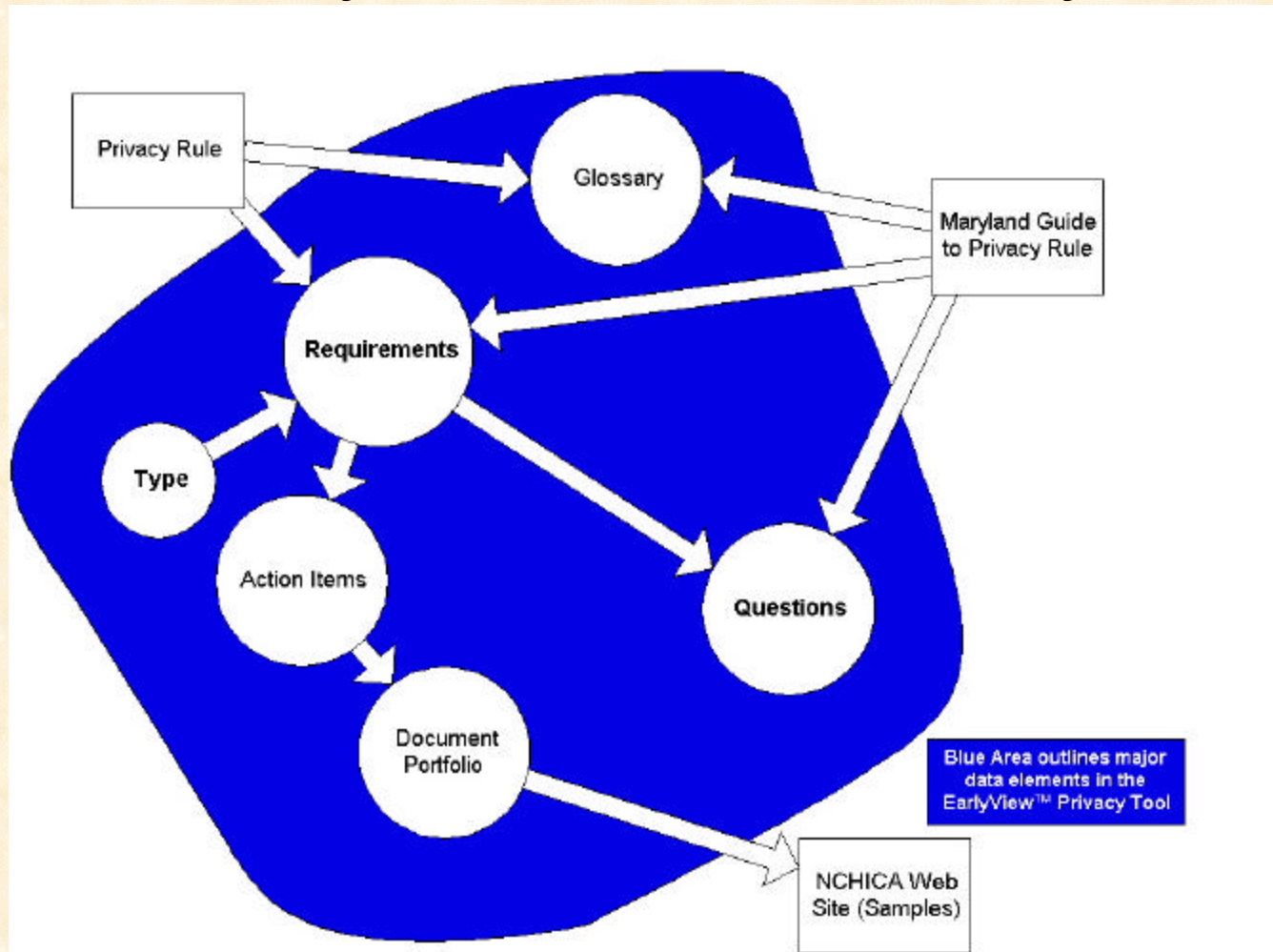
HIPAA Earlyview™ Privacy Software Tool

- Incorporates Maryland Guide to Privacy Rule with NCHICA “Deliverables”
- 33 Requirements from the Privacy Rule
- 43 Questions keyed to requirements
- Incorporates industry “best practices”

HIPAA Earlyview™ Privacy Software Tool **(Continued):**

- Includes recommended “action items” to fulfill each Requirement
- Links to online sample documents, document portfolio management facility
- Includes cross references to regulations, definitions, and related requirements within HIPAA
- User Guide

The EarlyView™ Privacy Tool



Greeting/Splash Screen

(reprinted with permission of NCHICA)



The image shows a screenshot of a software greeting screen. At the top left, there is a dark blue header bar with the word "Greeting" in white. The main content area has a light gray background. In the center, the text "NCHICA" is written in a bold, italicized black font. Below it, "HIPAA EarlyView™" is written in a large, bold, blue font, followed by "Privacy" in a slightly smaller, bold, blue font. Underneath, "HIPAA Privacy Regulation Self-Evaluation Tool" is written in a bold black font. At the bottom, the website "http://www.nchica.org" is shown in blue with a red underline, followed by the phone number "919-558-9258" and the copyright notice "Copyright 2000, 2001 NCHICA All Rights Reserved" in a smaller black font.

Greeting

NCHICA

HIPAA EarlyView™

Privacy

HIPAA Privacy Regulation Self-Evaluation Tool

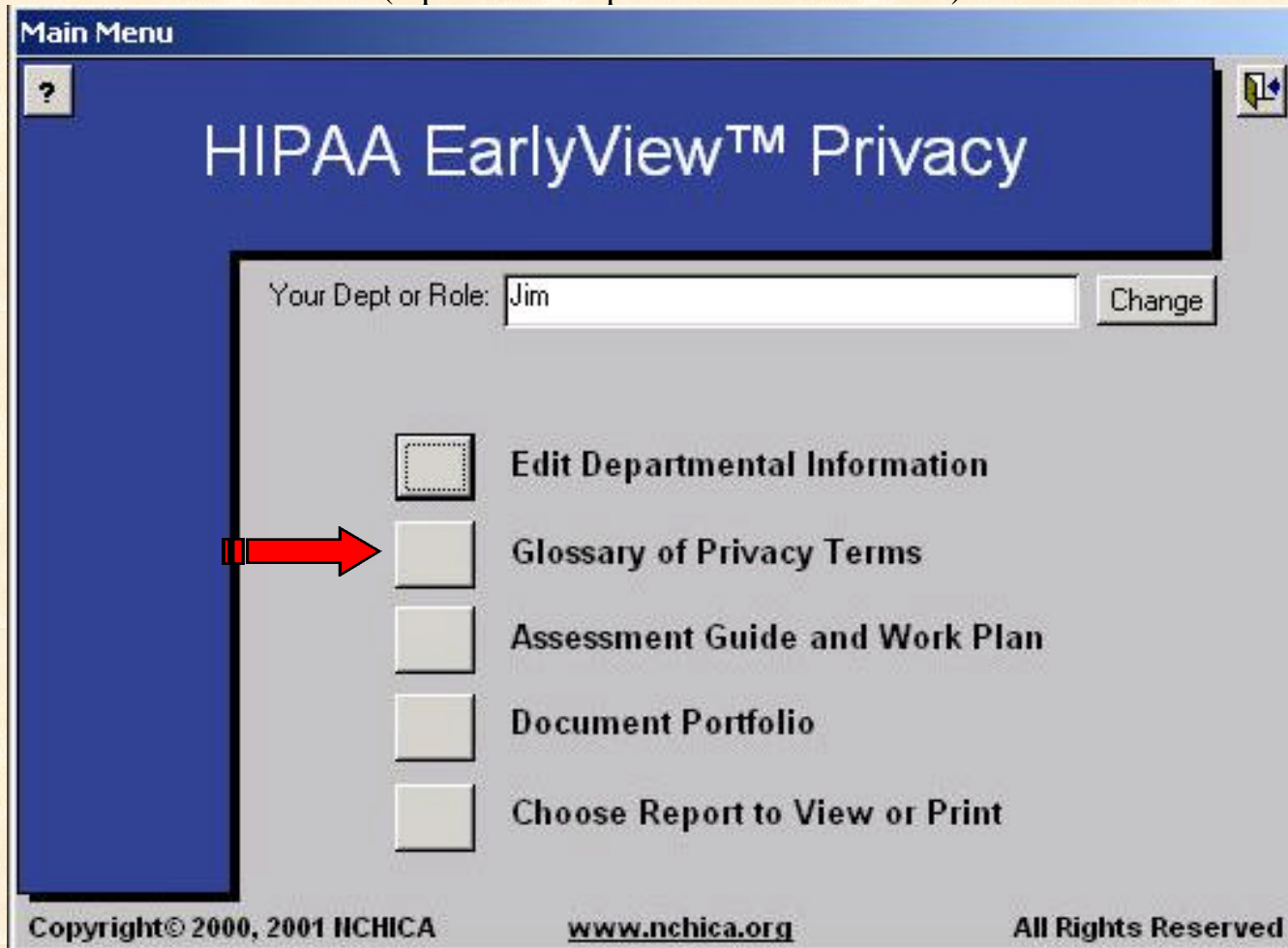
<http://www.nchica.org>

919-558-9258

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Main Menu (Others)

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Glossary

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The screenshot shows a web browser window titled "Glossary". The main heading is "Glossary of Privacy Terms". Below the heading is a search bar with a "Search:" label and a text input field. To the right of the search bar are three radio buttons: "Find all" (selected), "Find any", and "Exact". Below the search bar is a table with two columns: "Term" and "Definition". The table contains the following entries:

Term	Definition
Act (160.103)	[he Social Security Act
ANSI (160.103)	the American National Standards Institute
Authorization (MD Guide)	An authorization is a written document signed by a patient giving permission to a provider to disclose protected health information for purposes other than treatment, payment and health care operations. An
Business Associate (MD Guide)	A person or entity who performs a function for or assists a covered entity or health care arrangement with a function or activity involving the use or disclosure of individually identifiable health information.

At the bottom of the window, there is a footer with the text "Copyright© 2000, 2001 NCHICA www.nchica.org All Rights Reserved". Below the footer is a navigation bar with the text "Record: 1 of 79" and several navigation icons.

Performing the Assessment

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Questions in logical sequence

Explanations and clarifications at each step

Reports

Supporting sample documents, forms, and policies

“Action Items”

The screenshot shows a web-based questionnaire titled "Privacy Rule Self Assessment". The interface includes a "Show: All" dropdown menu, a "Progress" button, and a "Re(s)" button. The main content area displays the title "Uses and Disclosures of PHI (PHI)" and a requirement: "Privacy rules require consent for disclosure of PHI for treatment, payment and health care operations, and authorization for all other purposes for which written permission is required. These are different from consents for the treatment of a patient." Below this, there are two buttons: "Clarify Requirement" and "Suggested Approach". A question is posed: "Have you made a distinction between consent and authorization documents and added the appropriate language for use and disclosure of PHI?". The user's answer is currently "Not Answered", and there is a "Related Action(s)" button. The footer contains copyright information for NCHICA (2000, 2001), the website www.nchica.org, and a record indicator showing "Record: 1 of 86 (Filtered)".

References Screen

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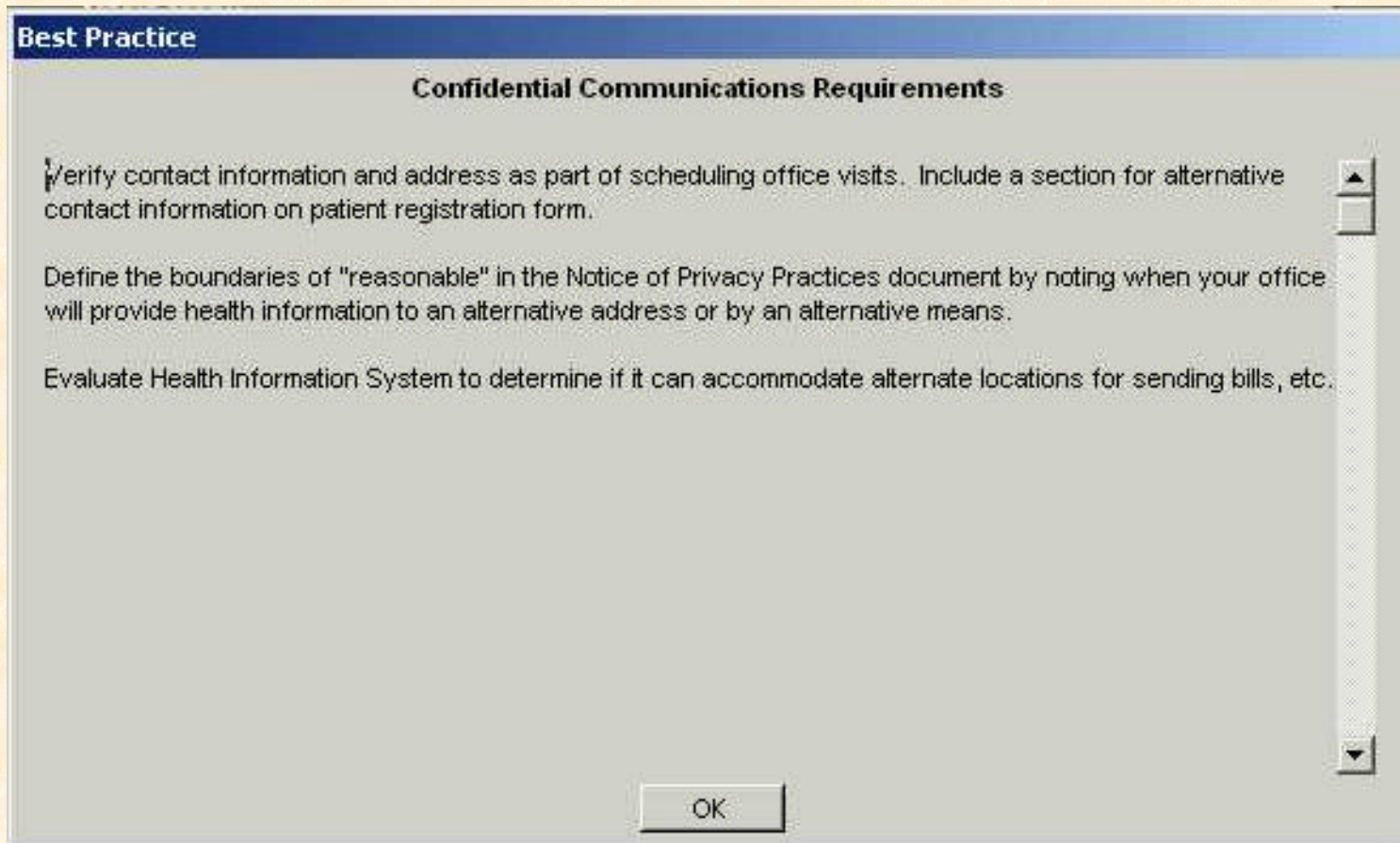
Clarification of Requirement

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Suggested Approach Screen

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Action Items for Requirement

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The screenshot shows a web application window titled "Recommended Actions". The main heading is "Action Items for 'Confidential Communications Requirements'". Below this, there is a list of three action items, each with an "Explain" and "Documents" button to its right. A red arrow points to the "Explain" button for the first item.

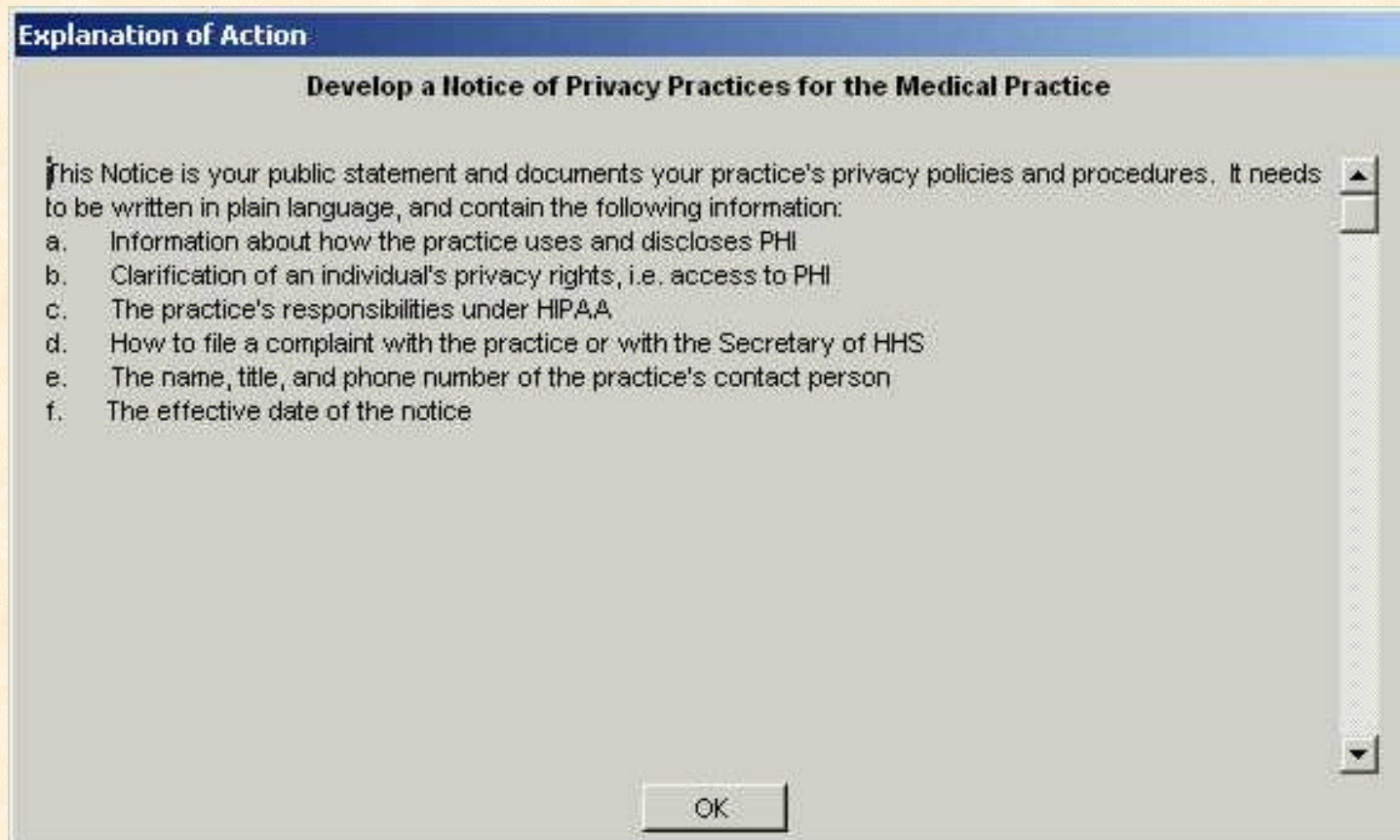
Action Item	Explain	Documents
Develop a Notice of Privacy Practices for the medical practice	Explain	Documents
Develop policies and procedures to handle patient PHI requests	Explain	Documents
Develop and implement a training program for all employees	Explain	Documents

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Record: 1 of 3 (Filtered)

Explain Action Item

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Documents for Action Item

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The screenshot displays two overlapping windows from a web application. The top window, titled 'Recommended Actions', shows a list of action items. The bottom window, titled 'Action Item Documents', shows a table of documents related to a specific action item.

Recommended Actions

- Action Items for "Confidential Communications Requirements"
- Develop a Notice of Privacy Practices for the medical practice [Explain] [Documents]
- Develop policies and procedures to handle patient PHI requests [Explain] [Documents]

Action Item Documents

Documents Related to "Develop policies and procedures to handle patient PHI requests"

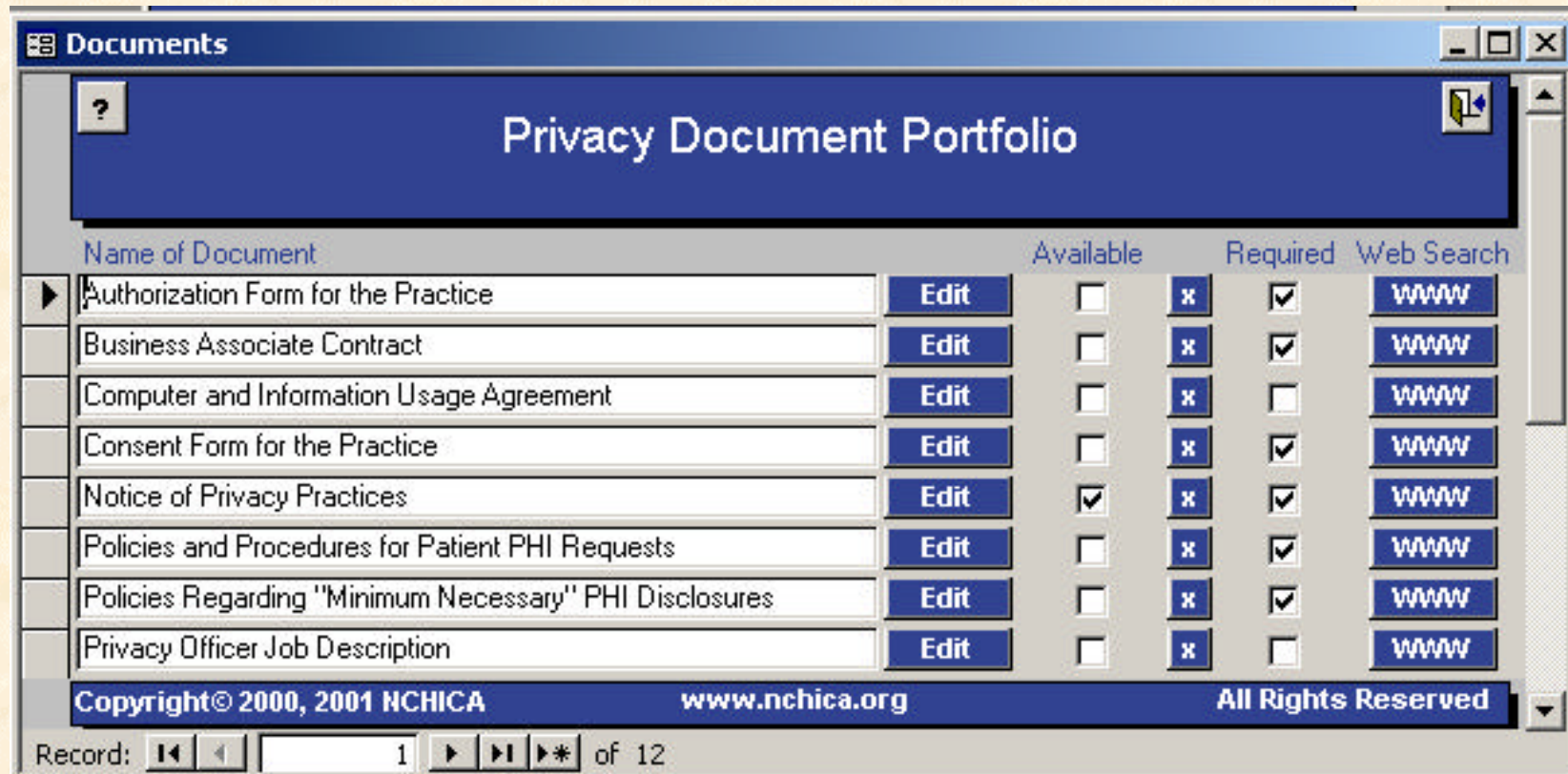
Name of Document	Available	Required	Web Search
Notice of Privacy Practices [Edit]	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	www
Policies and Procedures for Patient PHI Requests [Edit]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	www
Syllabus for Privacy Training [Edit]	<input type="checkbox"/>	<input type="checkbox"/>	www

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Record: 1 of 3 (Filtered)

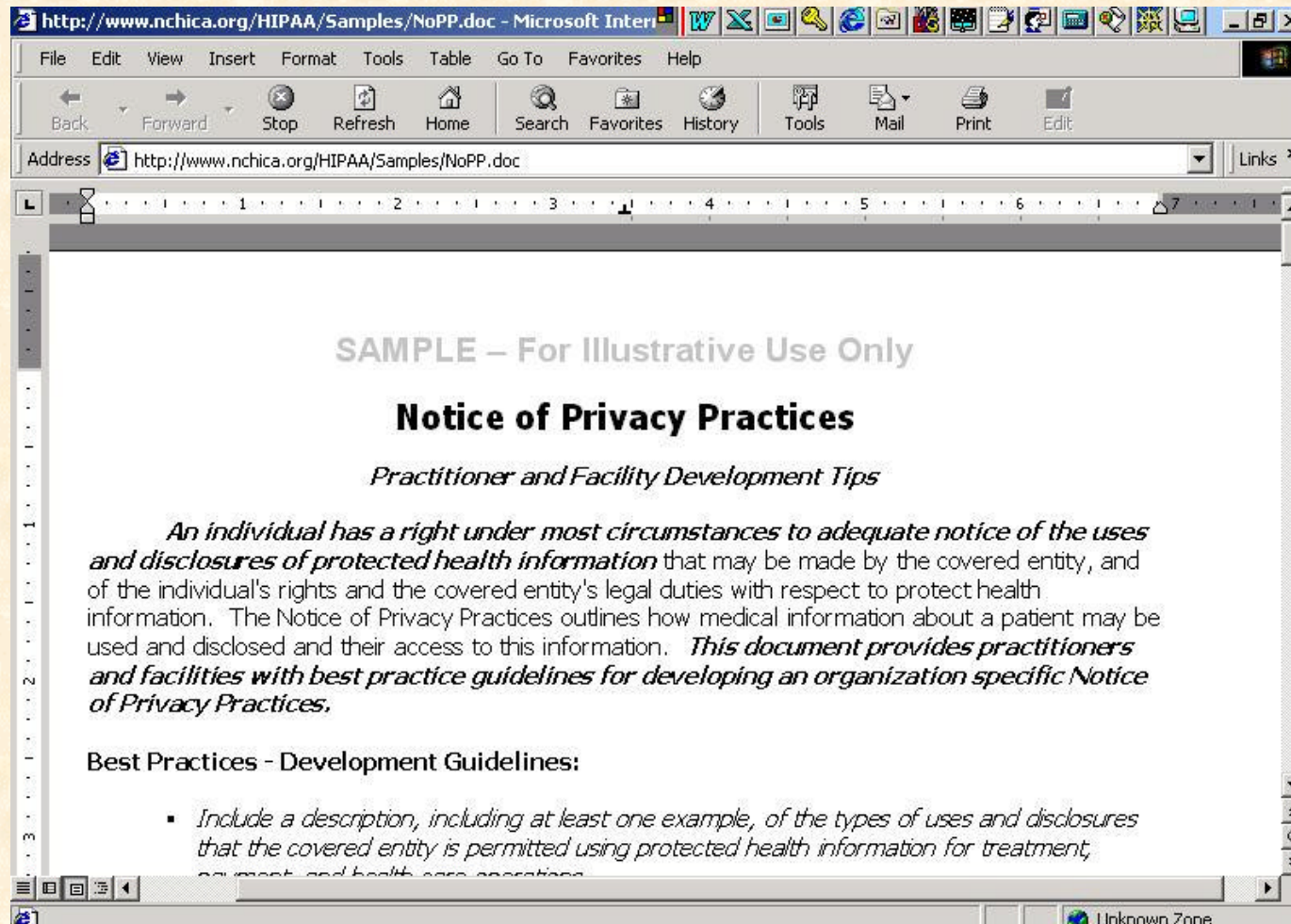
Create, Edit, Store and Print Documents from the Portfolio

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A Web Document (Linked)

(reprinted with permission of NCHICA)



Multiple Reports

(reprinted with permission of NCHICA)

Recommended Actions for HIPAA Privacy Rule Compliance

Designate a Privacy Official
 You have not completed this item.

Your organization must designate an individual to be responsible for the development and implementation of the policies and procedures that will be included here. This person or an alternative designee must also act as the contact person to receive inquiries and complaints about privacy, and to provide further information about the practice's privacy practices.

Example activities for the privacy official: oversee the development of the practice's Notice of Privacy Practices; develop the employee policies manual on HIPAA privacy standards.

In a small office, the privacy official may also serve as the security officer.

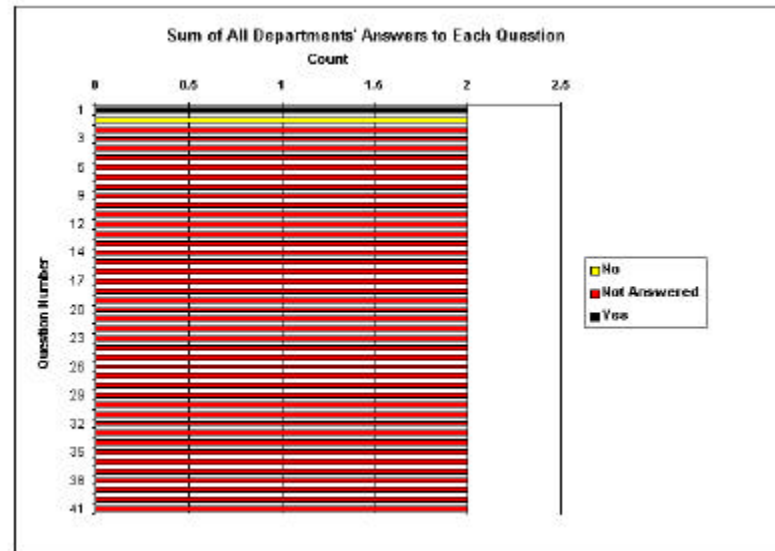
HHS Guideline: The privacy official at a small physician practice may be the office manager, who will have other non-privacy related duties; the privacy official at a large health plan may be a full-time position, and may have the regular support and advice of a privacy staff or board.

Develop a Notice of Privacy Practices for the Medical Practice
 You have not completed this item.

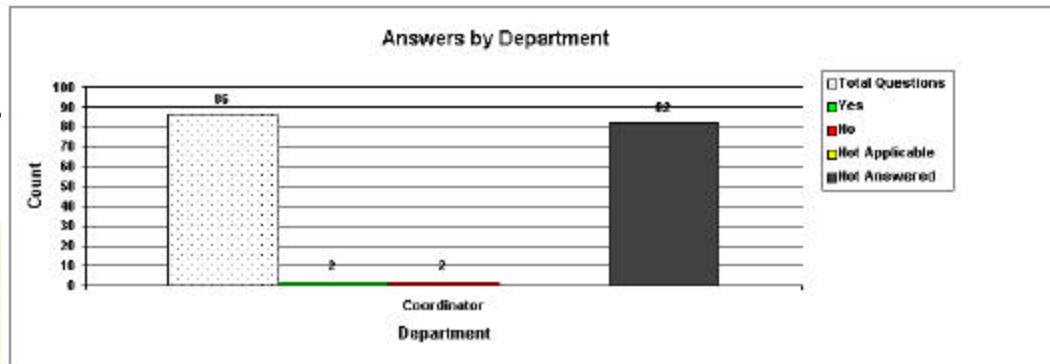
This Notice is your public statement and documents your practice's privacy policies and procedures. It needs to be written in plain language, and contain the following information:

- Information about how the practice uses and discloses PHI
- Clarification of an individual's privacy rights, i.e. access to PHI
- The practice's responsibilities under HIPAA
- How to file a complaint with the practice or with the Secretary of HHS
- The name, title, and phone number of the practice's contact person
- The effective date of the notice

HHS Guideline: The Privacy Rule does not require that the individual read the notice or that the covered entity explain each item in the notice before the individual provides consent. We expect that some patients will simply sign the consent while others will read the notice carefully and discuss some of the practices with the covered entity.



Thursday, August 30, 2001



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