INCORPORATING HIPAA PRIVACY RULE INTO MEDICAL RECORDS SURVEYS

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The National Center for Health Statistics runs a family of health care provider surveys, known as the National Health Care Survey (NHCS), to collect data from providers on patient encounters. The encounters sampled represent a broad range of service areas, from doctor visits and hospital discharges to nursing home stays. Sampled health care providers are asked to provide information for a sample of patient encounters to yield national estimates of utilization. Data on the sampled patient encounters are abstracted from the medical records. While the surveys are authorized under the Public Health Service Act, which assures confidentiality in law, the newly effective Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) sets further standards for providers (e.g., covered entities) when disclosing protected health information for research or public health purposes.[1] The various surveys in the NHCS each collect slightly different kinds of information and variables that are considered identifiable.

This paper describes the ways survey procedures were modified to assist providers in participating in the surveys under the new regulations. Modifications varied across surveys but, in general, included obtaining or modifying Institutional Review Board (IRB) approval, creating data use agreements, designing accounting documents to assist the providers' record keeping requirements to document disclosures, creating new training materials for field staff and new Web page materials for providers. The paper also describes the process by which modifications were discussed and approved. Finally, the paper describes any changes observed in response level or survey cost before and after the implementation date, April 14, 2003.

National Health Care Survey and the collection of protected health information

There are three major provider components to the NHCS: ambulatory care, hospital and surgical care, and long-term care. The various surveys within these components differ in regard to the type of protected health information (PHI) collected as specified by HIPAA's Privacy Rule (Table 1). Because the information collected differs, the level of review by IRBs differed prior to the Privacy Rule implementation. For example, historically the ambulatory care surveys rely solely on data already collected in medical records and no identifying patient information is collected, so they were exempt from IRB review for the protection of human subjects. However, because the long-term care surveys collect identifying data (e.g., Social Security number) to link to other databases, a full IRB review was required. The hospital and surgical care surveys collected a medical record number that could possibly, within the hospital, identify a patient, though outside of the hospital, it was not an identifying piece of information. These surveys generally received an expedited IRB review. Because the Privacy Rule indicated that a full IRB review would be required if the surveys were to be used for research purposes, as we approached the Privacy Rule compliance date, we sought a full IRB review of all the provider-based surveys. Additionally, while NCHS requests the health care provider to complete or assist in record abstraction, in some cases the provider requests the data collection agent to abstract the data. When this occurs the agent may see the patient's name and/or address, even though they are not collected. Under the Privacy Rule, this would be considered a disclosure of PHI. This situation is interpreted differently among various federal agencies such that some agencies interpreted such a disclosure to be "incidental" to a permitted disclosure for which no accounting is necessary.

Table 1: Protected health information collected or planned for collection in the National Health Care Survey prior to the Privacy Rule

Data element	***Ambulatory care***	***Hospital & surgical care***	***Long-term care***
Birth date *	X	X	X
Encounter date *	X	X	X
ZIP code *	X	X	
Medical record number		X	
Social Security number §			X
Medicare ID §			X
Patient name §			X

* Elements collected that are part of a limited data set.

§ Elements planned for collection in the 2004 National Nursing Home Survey.

Modifications made to survey procedures

With the publishing of the final rule in August, 2002, NCHS staff evaluated what kinds of modifications would be needed to ensure that medical providers would continue to provide survey data and then developed and implemented such modifications. These included introductory letters, data use agreements, accounting documents, data modifications, and development of special training. In the case of the ambulatory surveys, survey protocols were developed to obtain a full IRB review with a waiver of patient authorization. The nature of changes to survey collection procedures follows.

Introductory Letter: The introductory letter was modified to include a paragraph indicating that there were several ways that the Privacy Rule allowed survey participation, including disclosure for public health purposes as well as for research, approval of the survey protocol by an IRB, and the collection of minimum necessary PHI to accomplish the survey objectives.

Question and Answer: Special Q & A's were developed to help answer any concerns a sampled provider might have about survey participation and their compliance with the Privacy Rule.

Accounting Documentation: Each survey created a one-page document that could be used by providers to assist in their accounting for disclosure requirements, whether the document was for each sampled encounter or patient, or a summary accounting when more than 50 cases were abstracted.

Data Use Agreement: Because some surveys (e.g., the ambulatory care surveys) collected PHI that was designated by the Privacy Rule as part of limited data set (e.g., birth date, visit date and residential ZIP code), survey-specific data use agreements were developed (where applicable) providing the necessary assurances of confidentiality.

Training: Special training modules were developed for field representatives (FR) to explain to the providers how they are able to participate and still be compliant with the Privacy Rule. In the case of the ambulatory care surveys, the training included a 30-minute PowerPoint slide show with audio that was distributed on a CD/ROM for field staff to view, which led them through the new procedures and survey materials, including a new chapter in their field manual.

Provider Materials: Special participant Web sites were developed to display information about the surveys, including materials pertinent to the Privacy Rule (such as the IRB approval letters, Q & A's, data use agreements).[2] In the case of the ambulatory care participant Web pages, a seven-minute Flash presentation was developed to explain the survey and what the provider must do to comply with the Privacy Rule.

Modifications to PHI Collected: There were two instances in which modifications were made related to the information collected: the hospital and surgical care surveys deleted the collection of medical record number so that the information collected meets the definition of a limited data set, and the ambulatory care surveys allowed the respondents to enter patient age or month and year of birth rather than full birth date. The forms were not modified, but the field staff showed providers where to record age on the form if they objected to providing the full birth date. The other surveys already allowed the collection of patient age in place of birth date.

Other modifications: There were several other modifications made to planned data collection activities to accommodate the implementation of the Privacy Rule. The National Hospital Discharge Survey (NHDS), which normally collected data from the previous year through April, changed the 2002 panel deadline to April 11, 2003 so that the providers and field staff would not have to worry about collecting data past April 14. NCHS also delayed a study to collect medication data in the NHDS from the spring until the fall of 2003 to permit hospitals time to become accustomed to reporting under the new HIPAA requirements. Finally, several of the surveys created toll-free telephone numbers for the respondents to call if they have any concerns about how survey participation is affected by the Privacy Rule.

Review and approval process

After these modifications were developed, they were reviewed by Counsel at CDC in Atlanta who ensured that the materials accurately reflect the regulation. There are still areas of concern among government agencies regarding the interpretation of some of the requirements including the following: requiring individual accounting documentation when multiple records are disclosed for the same survey, and interpreting abstraction by our data collection agents as a disclosure rather than an "incidental" disclosure. Disclosures incidental to a permitted disclosure do not require documentation. For some of our surveys, incidentally seeing the patient name is the only disclosure that occurs; otherwise, the limited data set rule would apply. By considering FR abstraction to

be a "disclosure" of PHI rather than an "incidental disclosure", complicated rules for when the provider must account for disclosures are required (table 2). Also, because the some component surveys collect less than 50 records from the provider and others collect more than 50, the method of accounting is different across the components. For example, individual accounting is required for the National Ambulatory Medical Care Survey (NAMCS) and National Nursing Home Survey (NNHS) whereas one general accounting document can be left for the National Hospital Ambulatory Medical Care Survey (NHAMCS) and the NHDS.

Table 2: Accounting documentation instructions

Provision	***Abstractor***	***Accounting required***
Limited data set with a data use agreement	Provider	No
Public health	Provider or FR	Yes
Research with IRB approval	Provider or FR	Yes
De-identified data	Provider	No

Effects on survey participation

While it is still too early to provide definite statements regarding the HIPAA Privacy Rule's effect on survey participation, we can state that no major participation problems were identified between April and December, 2003. NCHS has received a handful of calls from doctors and hospitals expressing concern about the Privacy Rule and survey participation, but no effect has been noticed on general participation. The response rates for the ambulatory care surveys were essentially the same between January-March and April- July (NAMCS: 73% vs. 71% and NHAMCS: 95% vs. 91%). The field staff indicated that none of the hospitals' refusals in the second quarter were HIPAA-related. A NNHS pilot test in the summer of 2003 did not reveal any problems with participation, and the current research study on collecting medication data in the NHDS has also not shown any compromise on hospital response.

Data collected from the 2003 NAMCS indicate that since the Privacy Rule implementation date (April14-December 30, 2003) 80% of physicians accepted the data use agreement and only 10% asked to see the IRB approval letter. Accounting documents were not left in one-quarter of the cases when our data collection agent (Census field representatives- FRs) abstracted the medical record data because the physician used electronic medical records or preferred office staff to place the document in the medical record. It was thought that there may be less FR abstraction requested because of HIPAA, but the NAMCS data for 2003 indicate that the FR abstraction rate before implementation was the same as after (~31%). Anecdotal information also suggests that birth date and ZIP code may be missing more frequently from the abstracted data than it was in the past. Data from the 2003 emergency department visit records from the NHAMCS indicate that the item nonresponse rate increased by 52% for birth date (from 1.9 to 2.8 percent) and over 200% for ZIP codes (from 1.1 to 3.2 percent) before and after implementation. Further analysis of the 2003 data will be required before definitive conclusions about the effects on participation can be made.

In the spring of 2004 (one year after implementation of the Privacy Rule), we asked the data collection agent to tell us about the effects of HIPAA on NAMCS and NHAMCS participation after one year. Each supervisor in the 12 regional offices spoke with their FRs about the effects of the Rule. The summary comments we received from each regional office were similar. They indicated that additional hurdles were required for the NHAMCS because hospitals had privacy boards that must approve the study. In the case of the NAMCS, they reported that physicians were worried about breaking patient confidentiality or HIPAA laws. In both cases the data use agreements and IRB approval letters were considered important tools in obtaining participation. Occasionally, both hospitals and physicians stated that HIPAA's Privacy Rule affected their decision to decline participation in the surveys.

Effects on survey costs

The creation of the new materials utilized about six full-time equivalent employees during December 2002-March 2003. Additionally, the field costs for the ambulatory care surveys ran higher than expected for the field staff due to extra time spent in training and the extra time spent in data collection necessitated by the explanation of the new Privacy Rule-related information to providers. The HIPAA-related increase for the NAMCS and NHAMCS accounts for about 2% of the survey field costs. Budgeted costs for FY2004 also show an increase in cost of data collection due to HIPAA.

Summary

We believe that the preparation steps we took to clearly explain the interface between the Privacy Rule and participation in the NHCS, together with the new materials, helped to make a smooth transition from pre-to-post implementation.[3] Implementation of HIPAA's Privacy Rule has led to increased survey costs but has had less of an effect on survey response than originally conjectured. In some respects, the additional assurances of confidentiality made some providers more comfortable with providing patient data. However, the full impact on response rates will need to be measured over time as providers and survey organizations become more confident about the provisions in the Privacy Rule allowing continued survey participation.

Notes:

1. For the Privacy Rule regulations see www.hhs.gov/ocr/hipaa/finalreg.html .

2. Privacy Rule materials used in the NAMCS and NHAMCS (e.g., data use agreements, IRB approval letters, Q & A's) can be found on our participant pages at www.cdc.gov/NAMCS and www.cdc.gov/NHAMCS .

3. There is now available helpful information about the Privacy Rule for health survey researchers planning record-based studies. See http://privacyruleandresearch.nih.gov/research_repositories.asp
and http://www.nahdo.org/memberaccess/webcall.htm .