May 10, 2004

The Honorable Dennis Hastert
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

I am pleased to transmit our Sixth Annual Report to Congress on the Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act (HIPAA). In compliance with Section 263, Subtitle F of Public Law 104-191, the report was developed by the National Committee on Vital and Health Statistics (NCVHS), the public advisory committee to the U.S. Department of Health and Human Services on health data, privacy, and health information policy, and covers the period September 2002 through December 2003.

The Administrative Simplification provisions of HIPAA require the Secretary of Health and Human Services (HHS) to adopt a variety of standards to support electronic interchange for administrative and financial health care transactions, including standards for security and privacy to protect individually identifiable health information. In addition, the statute gives expanded responsibilities to the National Committee on Vital and Health Statistics for advising the Secretary on health information privacy and on the adoption of health data standards. The Committee is further directed to submit an annual report to Congress on the status of implementation of the Administrative Simplification effort.

As described in our report, significant progress occurred on several HIPAA Administrative Simplification standards during the past year. NCVHS applauds these accomplishments and reaffirms the importance of the HIPAA administrative simplification initiative for improving the efficiency and effectiveness of the health care system in the U.S. However, the full economic benefits of Administrative Simplification will only be realized when all of the standards are in place, and implementation activities and resource planning in the industry will be more effective when the entire suite of standards is finalized. Accordingly, we encourage the Secretary of HHS to expedite the publication of the remaining rules without delay, and urge Congress to provide sufficient resources and support to assure successful implementation of this important initiative.

We hope that you will find this sixth annual report informative and look forward to continued progress on these important issues for the nation's health system. If you or your staff would like a briefing presentation on any of our past or anticipated activities, please let me know.

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We are committed to improvements in health information systems that will enhance the quality of health care, lower costs, and facilitate access to care in the U.S.

Sincerely,

/s/

John R. Lumpkin, M.D., MPH, Chairman
National Committee on Vital and Health Statistics

Enclosure

Identical letters to:

Richard Cheney
President of the Senate
Washington, D.C. 20510

The Honorable Chuck Grassley
Chairman
Committee on Finance
219 Senate Dirksen Office Building
United States Senate
Washington, D.C. 20510

The Honorable Judd Gregg
Chairman
Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
United States Senate
Washington, D.C. 20510

The Honorable Bill Thomas
Chairman
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable John A. Boehner
Chairman
Committee on Education and the Workforce
U.S. House of Representatives
2181 Rayburn House Office Building
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NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

Administrative Simplification in Health Care: 2002 – 2003

Annual Report to Congress on the Implementation Of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996

Executive Summary

Executive Summary

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

Administrative Simplification in Health Care: 2002 – 2003

Annual Report to Congress on the Implementation
Of the Administrative Simplification Provisions of the
Health Insurance Portability and Accountability Act of 1996

This report describes the status of implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA.)

The Administrative Simplification provisions require the Secretary of Health and Human Services (HHS) to adopt standards for the electronic transmission of administrative and financial health care transactions, including data elements and code sets for those transactions; for unique health identifiers for health care providers, health plans, employers, and individuals for use in the health care system; and for security standards to protect individually identifiable health information. The law also requires standards to protect the privacy of health information.

Congress gave the National Committee on Vital and Health Statistics (NCVHS) the roles of advising the Secretary of Health and Human Services on the adoption of standards, monitoring their implementation, and reporting annually on progress. This report is the

sixth of those annual reports on implementation and covers the period September 2002 through December 2003.

Background About HIPAA Administrative Simplification

To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 included a series of "administrative simplification" provisions that required the Department of Health and Human Services (HHS) to adopt national standards for electronic health care transactions. By ensuring consistency throughout the industry, these national standards will make it easier for health plans, health care clearinghouses, doctors, hospitals and other health care providers to process claims and other transactions electronically. The law also requires the adoption of privacy and security standards in order to protect individually identifiable health information.

In HIPAA, Congress required health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions electronically (such as eligibility, referral authorizations, and claims) to comply with each set of standards. Other businesses may voluntarily comply with the standards, but the law does not require them to do so.

In general, the law requires covered entities to come into compliance with each set of standards within two years following adoption, except for small health plans, which have three years to come into compliance. For the electronic transaction and code sets rule only, Congress in 2001 enacted legislation (Administrative Simplification Compliance Act; Pub. L. No. 107-105) extending the deadline to Oct. 16, 2003 for all covered entities, including small health plans. The legislative extension did not affect the compliance dates for the health information privacy rule, which was April 14, 2003 for most covered entities (and April 14, 2004 for small health plans).

There are several regulations for HIPAA’s Administrative Simplification provisions.

Progress Since Last Report to Congress

While progress continued on industry readiness assessment and implementation planning for the suite of national standards for administrative transactions and code sets adopted as a final rule in 2000, Congress responded to industry requests to extend the compliance date for one year until October 16, 2003. The compliance date for small health plans was not changed. Based on testimony from the industry, the NCVHS believes that the one-year extension was a welcome and useful development. The Committee notes that it is incumbent on the industry, having had the extension, to direct focused effort and resources on implementing the standards.

As noted in our last report to Congress, the final modifications to the HIPAA Privacy Rule were issued in August 2002. Most entities covered by the regulation were required to come into compliance by April 14, 2003. The Committee's Subcommittee on Privacy and Confidentiality held hearings on the HIPAA Privacy Rule and early implementation efforts in Salt Lake City, Baltimore, and Boston during the fall of 2002. In addition, now that the April 14, 2003 compliance date for the HIPAA Privacy Rule has passed, the Subcommittee has begun to hold hearings on how the regulation has been implemented.

HHS and NCVHS worked extensively with the industry-led standards organizations to revise proposed rules for HIPAA transaction and code sets standards, which enabled HHS to issue final rules in February 2003. The final rule adopting standards for the security of electronic health information was also issued in February 2003. In April 2003 HHS issued an interim final rule establishing rules of procedure for the imposition of civil money penalties on entities that violate the Administrative Simplification regulations, including both the Privacy Rule and other standards. An interim final rule for electronic submission of claims to Medicare was issued in August 2003. Work continues on developing regulations for national identification numbering systems for providers and for health plans. Although HIPAA included a requirement for a unique personal health care identifier, HHS and Congress have put the development of such a standard on hold indefinitely.

In addition to a focus on administrative simplification in health care, HIPAA directed the NCVHS to study issues regarding electronic exchange of patient medical record information (PMRI). The Committee's 2000 report and subsequent recommendations in 2002 and 2003 served as the foundation for standards to be adopted through the Consolidated Health Informatics (CHI) Initiative, whose goal is to adopt uniform standards to promote interoperability of clinical information in the federal health care enterprise. In March 2003 the Departments of Health and Human Services, Defense, and Veterans Affairs announced the first set of uniform standards for the electronic exchange of clinical health information to be adopted across the federal government. CHI is the health care component of President Bush's eGov Initiatives.

The responsibility for implementation and enforcement of the HIPAA regulations is assigned to two organizations, the Office for Civil Rights (OCR) is responsible for the Privacy Rule, and the Centers for Medicare and Medicaid Services (CMS) is responsible for the rest of the administrative simplification standards. Both of these organizations have employed extensive multi-faceted outreach strategies to educate the public about HIPAA Administrative Simplification requirements. Elements of the strategy include informative web sites, frequently asked questions, conferences, toll free hotlines and target technical assistance materials.

The Committee has continued to serve as the Department's primary liaison with the private sector to obtain the views, perspectives, and concerns of interested and affected parties, as well as their input and advice, on health data standards and privacy. During 2002 and 2003, the focus of NCVHS public hearings and committee deliberations was on

implementation issues, industry readiness, obstacles in achieving successful implementation, and issues relating to implementation of the Privacy Rule.

The Subcommittee on Standards and Security held several hearings in 2002 and 2003 on the feasibility and desirability of replacing the current diagnosis and inpatient procedure classification system. It also commissioned an impact study by the Rand Corporation on the costs and benefits of making a migration to new code sets. In November 2003, the NCVHS sent recommendations to HHS, concluding that it is in the best interests of the country as a whole that ICD-10-CM and ICD-10-PCS be adopted as HIPAA standards for national implementation as replacements for current uses of ICD-9-CM, Vol. 1,2 and 3.

Several industry organizations, such as the Association for Electronic Health Care Transactions (AFEHCT) and the Workgroup for Electronic Data Interchange (WEDI) have continued to demonstrate national leadership by working to assist health plans, providers and clearinghouses implement the standards. The Public Health Data Standards Consortium has continued to be a key organization in the implementation of administrative simplification in the public health and health services research arenas.

Important Issues

NCVHS believes the one-year extension to the compliance date for the electronic transaction provisions of HIPAA provided the industry with sufficient time for implementation. NCVHS recommends that CMS and industry strategies for education and outreach be maintained to assist covered entities with implementation. NCVHS will continue to monitor the industry's implementation efforts.

NCVHS wishes to emphasize the need to issue the remaining HIPAA standards so that the Administrative Simplification provisions are effectively and efficiently implemented. It is essential to issue final rules for the national provider identification numbering system and for the national health plan identification numbering system. Currently, health care providers are assigned different ID numbers by each private health plan, hospital, nursing home, and public program such as Medicare and Medicaid. These multiple ID numbers result in slower payments, increased costs and a lack of coordination. Also crucial are standards that would create a unique identifier for health plans, making it more efficient for health care providers to conduct transactions with different health plans. The issuance of the proposed rule for claims attachments is essential so that the industry can begin planning and development for adoption of standards for attachments (e.g., electronic copies of parts of medical records, X-rays, etc.) to electronic claims.

Although the Committee has not yet completed its hearings on the Privacy Rule, it is the sense of the Committee that education, outreach, and technical assistance are crucial to

effecting the Rule's purpose in protecting patient privacy. The Committee believes HHS should continue its current strategy for issuing helpful frequently asked questions, and in addition, it urges HHS to increase its efforts to educate and provide to covered entities helpful written materials about the Rule.

Conclusions

The NCVHS reaffirms the importance of the HIPAA Administrative Simplification initiative and urges the Secretary to expedite the publication of the remaining rules. The full economic benefits of Administrative Simplification will only be realized when all of the standards are in place, and implementation activities and resource planning in the industry will be more effective when the regulatory framework for the entire suite of standards is final. Lastly, the NCVHS reaffirms the importance of HHS increasing its efforts to educate covered entities about the HIPAA Privacy Rule.

I. Introduction

This report describes the status of implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA.)

The Administrative Simplification provisions (title II, subtitle F of Pub. L. No. 104-191, adding a new title XI, part C, to the Social Security Act (42 U.S.C. 1320d et seq.)) require the Secretary of Health and Human Services (HHS) to adopt standards for the electronic transmission of administrative and financial health care transactions, including data elements and code sets for those transactions; for unique health identifiers for health care providers, health plans, employers, and individuals for use in the health care system; and for security standards to protect individually identifiable health information. The law also requires standards to protect the privacy of health information.

Congress gave the National Committee on Vital and Health Statistics (NCVHS) the roles of advising the Secretary of Health and Human Services on the adoption of standards, monitoring their implementation, and reporting annually on progress. This report is the sixth of those annual reports on implementation and covers the period September 2002 through December 2003. Previous NCVHS reports to congress about the progress of the implementation of administrative simplification may be found at the committee's web site, http://www.ncvhs.hhs.gov/.

The Committee has monitored the process of standards adoption and the issuance of proposed standards, as carried out by the Government and its advisory bodies. In addition, now that most of the standards have become finalized and attention turns to their implementation, the NCVHS is identifying and advising on implementation issues.

II. Background About HIPAA Administrative Simplification

To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 included a series of "administrative simplification" provisions that required the Department of Health and Human Services (HHS) to adopt national standards for electronic health care transactions. By ensuring consistency throughout the industry, these national standards will make it easier for health plans, health care clearinghouses, doctors, hospitals and other health care providers to process claims and other transactions electronically. The law also requires the adoption of privacy and security standards in order to protect individually identifiable health information. HIPAA administrative simplification regulations include:

- Electronic health care transaction and code sets (final rule issued);
- Health information privacy (final rule issued);

- Unique identifier for employers (final rule issued);
- Security requirements (final rule issued);
- Unique identifier for providers (proposed rule issued; final rule in development);
- Unique identifier for health plans (proposed rule in development); and
- Enforcement procedures (interim rule issued; proposed rule in development).

Organizations covered by HIPAA Administrative Simplification

In HIPAA, Congress required health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions electronically (such as eligibility, referral authorizations, and claims) to comply with each set of standards. Other businesses may voluntarily comply with the standards, but the law does not require them to do so.

Compliance Schedule

In general, the law requires covered entities to come into compliance with each set of standards within two years following adoption, except for small health plans, which have three years to come into compliance. For the electronic transaction and code sets rule only, Congress in 2001 enacted legislation (Administrative Simplification Compliance Act; Pub. L. No. 107-105) extending the deadline to October 16, 2003 for all covered entities, including small health plans. The legislative extension did not affect the compliance dates for the health information privacy rule, which was April 14, 2003 for most covered entities (and April 14, 2004 for small health plans).

HIPAA Transaction Standards

Under HIPAA, HHS must adopt recognized industry standards when appropriate (and as advised by NCVHS). HHS recognized the need for the ongoing maintenance of the HIPAA transaction standards, and especially the need for the industry to collect, review and recommend changes to the standards. The final regulation for transactions and code sets established a set of industry organizations called Designated Standards Maintenance Organizations (DSMOs) to receive and process requests for modifications to standards or for adopting new standards, and an accompanying notice named the following organizations as DSMOs:

- Accredited Standards Committee X12
- Dental Content Committee of the American Dental Association
- Health Level Seven
- National Council for Prescription Drug Programs
- National Uniform Billing Committee
- National Uniform Claim Committee

HIPAA Privacy Standards

In December 2000, HHS issued a final rule to protect the confidentiality of individually identifiable health information. The rule limits the use and disclosure of certain individually identifiable health information; gives patients the right to access their medical records; restricts most disclosure of health information to the minimum needed for the intended purpose; and establishes safeguards and restrictions regarding the use and disclosure of records for certain public responsibilities, such as public health, research and law enforcement. Improper uses or disclosures under the rule may be subject to criminal or civil sanctions prescribed in HIPAA.

After reopening the final rule for public comment, HHS Secretary Tommy G. Thompson allowed it to take effect as scheduled. In March 2002, HHS proposed specific changes to the privacy rule to ensure that it protects privacy without interfering with access to care or quality of care. After considering public comments, HHS issued a final set of modifications in August 2002. Most covered entities were required to comply with the privacy rule by April 14, 2003; small health plans have until April 14, 2004 to come into compliance, as required under the law.

Security Standards

In February 2003, HHS adopted final regulations for security standards to protect electronic health information systems from improper access or alteration. Under the security standards, covered entities must protect the confidentiality, integrity, and availability of electronic protected health information. The rule requires covered entities to implement administrative, physical and technical safeguards to protect electronic protected health information in their care. The standards use many of the same terms and definitions as the privacy rule to make it easier for covered entities to comply. The rule did not address the use of electronic signatures. Most covered entities must comply with the security standards by April 21, 2005, while small health plans will have an additional year to come into compliance.

Employer Identifier

In May 2002, HHS issued a final rule to standardize the identifying numbers assigned to employers in the health care industry by using the existing Employer Identification Number (EIN), which is assigned and maintained by the Internal Revenue Service. Businesses that pay wages to employees already have an EIN. Currently, health plans and providers may use different ID numbers for a single employer in their transactions, increasing the time and cost for routine activities such as health plan enrollments and premium payments. Most covered entities must comply with the EIN standard by July 30, 2004. (Small health plans have an additional year to comply.)

National Provider Identifier

In May 1998, HHS proposed standards to require hospitals, doctors, nursing homes, and other health care providers to obtain a unique identifier when filing electronic claims with public and private insurance programs. Providers would apply for an identifier once and keep it if they relocated or changed specialties. A final rule was well under development in 2003.

National Health Plan Identifier

HHS is working to propose standards that would create a unique identifier for health plans, making it easier for health care providers to conduct transactions with different health plans.

Unique Personal Identifier

Although HIPAA included a requirement for a unique personal health care identifier, HHS and Congress have put the development of such a standard on hold indefinitely. In 1998, HHS delayed any work on this standard until after comprehensive privacy protections were in place. Since 1999, Congress has adopted appropriations language to prevent appropriated funds from being used to promulgate such a standard. HHS has no plans to develop such an identifier.

Enforcement

HHS is developing a rule regarding enforcement of the HIPAA requirements. Part of this rule was issued as an interim final rule on April 17, 2003.

Other HIPAA Administrative Simplification Regulations

HHS is working on a proposed rule regarding a standard for attachments (e.g., copies of parts of medical records, X-rays, etc.) to electronic claims. HHS is waiting for industry consensus on a transaction for the first report of workplace injury before proceeding with any rule to adopt as a HIPAA standard

Federal Government Web Sites for HIPAA Administrative Simplification

In addition to the NCVHS web site, http://www.ncvhs.hhs.gov/, two other web sites containing HIPAA administrative simplification regulations, frequently asked questions, and other helpful materials are: the HHS Office for Civil Rights, http://www.hhs.gov/ocr/; and, the HHS Centers for Medicare and Medicaid Services, http://www.cms.hhs.gov/hipaa/hipaa2.

III. Progress Since Last Report to Congress

While progress continued on industry readiness assessment and implementation planning for the suite of national standards for administrative transactions and code sets adopted as a final rule in 2000, Congress responded to industry requests to extend the compliance date for one year until October 16, 2003. The compliance date for small health plans was not changed. The statute providing for the extension, the Administrative Simplification Compliance Act (Pub. L. No. 107-105), was signed into law on December 27, 2001. The law provided a 12-month extension for transaction and code set compliance. The extension was available to a covered entity that submitted a compliance extension plan to HHS before October 16, 2002, summarizing how it would come into compliance by October 2003. About 550,000 covered entities submitted plans. The deadlines for compliance with the HIPAA privacy rule were unaffected.

Although the industry made much progress toward compliance with the transactions and code set standards and productively used the extension provided, there was some concern that a substantial number of covered entities might not be sufficiently far along to achieve compliance by the October 2003 deadline. In fact, NCVHS held ongoing hearings to assess industry readiness and identified these concerns as the deadlines approached. In light of these concerns, HHS in July 2003 released a guidance document outlining its approach to handling compliance issues after the deadline, as well as gave the industry guidance on flexibility it had to implement contingency plans to enable a successful implementation. The Centers for Medicare and Medicaid Services (CMS), which is the HHS agency responsible for enforcing HIPAA electronic transaction and code set standards, will focus on obtaining voluntary compliance and use a complaint-driven approach.

CMS announced on September 23, 2003 that it would implement a contingency plan to accept noncompliant electronic transactions after the October 16, 2003 deadline. This ensured continued processing of claims from thousands of providers who would not have been able to meet the deadline and otherwise would have had their Medicare claims rejected. In addition, implementing this contingency plan moves toward the dual goals of achieving HIPAA compliance while not disrupting providers' cash flow and operations, so that beneficiaries can continue to get the health care services they need. Most other participants in the industry have also implemented similar contingency plans to ease the implementation.

Based on testimony from the industry, the NCVHS believes that the one-year extension was a welcome and useful development. The Committee notes that it is incumbent on the industry, having had the extension, to direct focused effort and resources on implementing the standards.

As noted in our last report to Congress, the final modifications to the HIPAA Privacy Rule were issued in August 2002. Most entities covered by the regulation were required to come into compliance by April 14, 2003. The Committee's Subcommittee on Privacy

and Confidentiality held hearings on the HIPAA Privacy Rule and early implementation efforts in Salt Lake City, Baltimore, and Boston during the fall of 2002. In addition, now that the April 14, 2003 compliance date for the HIPAA Privacy Rule has passed, the Subcommittee has begun to hold hearings on how the regulation has been implemented.

Final Rules Completed

In February 2003, HHS issued the final rule adopting industry-requested modifications to the HIPAA transaction and code set standards. Preceded by a proposed rule in May 2002, the final rule adopted modifications to several of the transaction standards as requested by the industry. HHS and NCVHS worked extensively with the Designated Standards Maintenance Organizations (DSMOs) to revise the proposed standards. The final rule adopts technical implementation specifications for electronic retail pharmacy claims. The rule repeals the adoption of the National Drug Codes as the standard medical code set for reporting drugs and biologics in all standard electronic transactions except for retail pharmacy transactions. The rule adopts the National Council for Prescription Drug Programs Batch Standards Implementation Guide (Version 1, Release 1.) Further, the rule adopts certain modifications to the HIPAA electronic transactions standards recommended by the DSMOs. Lastly, the rule also adopted modified standards that were not included in the proposed rules – premium payments and coordination of benefits.

The final rule adopting standards for the security of electronic health information was also issued in February 2003. It specifies a series of administrative, technical, and physical security measures that covered entities must take to ensure the confidentiality of electronic protected health information. The standard lists protective measures that must be taken in particular named areas, with some, described as "required," that must be applied in all cases, and others, described as "addressable," that must be considered in light of the local circumstances and applied if appropriate. The NCVHS is currently monitoring the early stages of implementation of this rule.

Rules Awaiting Completion or Under Development

In April 2003 HHS issued an interim final rule establishing rules of procedure for the imposition of civil money penalties on entities that violate the Administrative Simplification regulations, including both the Privacy Rule and other standards. HHS announced that it intended this interim final rule to be the first installment of a rule, termed the Enforcement Rule, which, when issued in complete form, will set forth procedural and substantive requirements for imposition of civil money penalties. Meanwhile, the interim final rule informs regulated entities of HHS's approach to enforcement and sets out certain procedures that will be followed with regard to enforcement.

An interim final rule for electronic submission of claims to Medicare was issued in August 2003. This rule implements the requirement in the Administrative Simplification Compliance Act (ASCA) that all claims sent to the Medicare Program be submitted electronically starting October 16, 2003, with some limited exceptions.

Work continues on developing regulations for national identification numbering systems for providers and for health plans. In May 1998, HHS proposed standards to require hospitals, doctors, nursing homes, and other health care providers to obtain a unique identifier when filing electronic claims with public and private insurance programs. Providers would apply for an identifier once and keep it if they relocated or changed specialties. HHS is working to propose standards that would create a unique identifier for health plans, making it easier for health care providers to conduct transactions with different health plans.

The standard for a doctor's first report of workplace injury was not included in the proposed or final rule for HIPAA transaction standards because at that time there was neither a millennium-compliant version of an implementation guide nor a complete data dictionary for the ASC X12N 148 - Report of Injury, Illness, or Incident transaction. The industry continues to make progress on this standard and NCVHS will assess the status of this standard in the coming year.

HIPAA gave an additional 12 months beyond the general standards adoption deadline for the adoption of electronic standards for attachments (e.g., copies of medical records, X-rays, etc.) to electronic claims. The proposed rule for this standard is under development and is being revised in response to a request from an industry standards organization, Health Level Seven, which is updating its original work on the standard.

As noted earlier in this report the final Rule adopting standards for the security of electronic health information was issued in February 2003. The final rule did not include an electronic signature standard. While the proposed rule included criteria for an electronic signature standard, no consensus industry standard for electronic signature standards could be identified at the time the proposed rule was published. At the request of the Commerce Department's National Institute of Standards and Technology, HHS deferred publication of the electronic signature standard to permit a more thorough assessment of evolving technology and current industry consensus on this issue. A final rule on an electronic signature standard will depend on industry progress on this issue and the outcome of these activities. NCVHS intends to revisit this issue as part of it responsibility to recommend e-prescribing standards under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (section 1860D-4 (e) (4) of the Social Security Act (42 U.S.C. 1395w-104 (e) (4).)

Standards for Patient Medical Record Information

In addition to a focus on administrative simplification in health care, HIPAA directed the NCVHS to study issues regarding electronic exchange of patient medical record information (PMRI). The Committee's report on this matter, *Report on Uniform Data Standards for Patient Medical Record Information*, was submitted to the Secretary in July 2000. The report did not actually include recommendations for specific PMRI standards, but it did include recommendations relating to the selection, development, and early adoption of such standards, and the relationship of PMRI standards to other issues.

Progress reports indicate that a number of HHS agencies continue or have begun work on virtually all of the recommendations.

Subsequent recommendations by NCVHS in 2002 and 2003 specified many of the standards, which served as the foundation for standards to be adopted within the Federal enterprise through the Consolidated Health Informatics (CHI) Initiative. The goal of CHI is to adopt uniform standards to promote interoperability of clinical information in the federal health care enterprise. The work of the NCVHS informed the first set of CHI adopted standards announced in March 2003 by Secretary Tommy Thompson. These included Health Level Seven (HL7) messaging standards for patient care transactions, National Council of Prescription Drug Programs SCRIPT standard for retail pharmacy transactions, IEEE 1073 series of messaging standards for device communications, Digital Imaging and Communications in Medicine (DICOM) standard for imaging, and Laboratory Logical Observation Identifier name Codes (LOINC) to standardize the electronic exchange of clinical laboratory results.

HHS Implementation of Clinical Standards

The HHS implementation strategy for clinical standards is designed to ensure coordination among HHS agencies and participation by other Federal departments, as well as interaction with the industry and the research and public health communities.

In March 2003 the Departments of Health and Human Services, Defense, and Veterans Affairs announced the first set of uniform standards for the electronic exchange of clinical health information to be adopted across the federal government. These three federal departments deliver health care services and are coordinating with numerous other federal agencies to standardize federal clinical health information as part of the Consolidated Health Informatics initiative (CHI). CHI is the health care component of President Bush's eGov Initiatives, created under the President's Management Agenda, to make it easier for citizens and businesses to interact with the government. The NCVHS has served as the public advisory body for this important activity.

HHS Outreach Activities

Within HHS, the Secretary has assigned responsibility for implementation and enforcement of the HIPAA regulations to two organizations: the Office for Civil Rights (OCR) is responsible for the Privacy Rule, and the Centers for Medicare and Medicaid Services (CMS) is responsible for the rest of the administrative simplification standards. In addition, the NCVHS has a prominent role in monitoring the implementation of HIPAA’s administrative simplification standards.

Office for Civil Rights

The Office for Civil Rights is employing a multi-faceted outreach strategy to educate the public about the HIPAA Privacy Rule. Their strategy includes the following:

Website. OCR created and maintained a website, www.hhs.gov/ocr/hipaa/. From January through October 2003, OCR's Privacy Rule homepage was visited over 1 million times. Resources available from the site include a comprehensive Summary of the HIPAA Privacy Rule, a Covered Entity Decision Tool, Sample Business Associate Provisions, extensive guidance on particular aspects of the Rule, links to NIH Guides to Research ("Protecting Personal Health Information in Research; Understanding the HIPAA Privacy Rule"; "Authorizations for Research and Institutional Review Boards"); links to CDC Guidance ("HIPAA Privacy Rule and Public Health"); and fact sheets for consumers, ("How to File a Health Information Privacy Complaint", "Protecting the Privacy of Patient's Health Information"). The website is organized to be as helpful as possible. For example, there is a link to materials believed to be of particular interest to small providers and small businesses.

FAQ's. Also, the OCR Privacy Rule website has responses to over 200 frequently asked questions. From mid-March 2003, when the FAQs were first posted in an easy-to-retrieve format, through December 2003, visitors to the FAQ site viewed 1,635,184 (or: over 1.6 million) answers to frequently asked questions. The questions and answers enable OCR to provide clarification in helpful areas and to clear up misconceptions when they arise.

Conferences. OCR conducted four national, all day HIPAA Privacy Rule conferences in February and March 2003. These were sponsored in conjunction with universities and key industry groups, at which OCR and other Department experts in the Rule offered in-depth seminars and answered questions on all aspects of the Privacy Rule.

Toll Free Hotline. The Department offers a free call-in line, 1-866-627-7728, sponsored by CMS and OCR, for HIPAA questions. Operators on this line are able to respond directly to many frequently asked questions. If the operators cannot answer the caller's question, the caller is directed to a phone line where he or she can leave a specific message, and OCR regional and headquarters staff return the call for inquiries related to the Privacy Rule. From April 2003 through the end of December 2003, operators and OCR headquarters and regional staff handled nearly 20,000 phone inquiries concerning the Privacy Rule.

Speaking Engagements. OCR has made its senior experts available on a regional and national basis for presentations at over 100 conferences and seminars during 2003 that were attended by a range of audiences including smaller providers and businesses.

Free Telephone Conferences. OCR also made its experts available to providers and those with limited resources through numerous toll-free telephone conferences. For instance, on March 27, 2003, the Office for Civil Rights sponsored a free call-in line on HIPAA Privacy. Over 4,500 telephone lines, with

an estimated 8,350 individuals, a record for the Department, joined in the call. Moreover, OCR participated in numerous CMS national HIPAA Roundtable Conference Calls targeted to providers and payers.

Translated Materials. OCR translated particular outreach materials, including the Summary of the HIPAA Privacy Rule, the HHS-700 HIPAA Complaint Form, and the "How to File a HIPAA Complaint" fact sheet into Spanish. OCR also has translated and will be posting on its website its Privacy fact sheet in Chinese, Korean, Polish, Russian, Tagalog, Vietnamese, and Spanish.

Targeted Technical Assistance Materials. OCR is developing additional targeted technical assistance materials, focusing on explaining the Privacy Rule to consumers as well as specific industry groups, required to comply with the Rule.

Both the NCVHS and HHS realize that providing information and education on Administrative Simplification to the health care community is an enormous task. While HIPAA is a federal law, it reflects a government-industry partnership framework, so that responsibility for publicity and education must be shared between the public and private sectors. While HHS must take full responsibility for the Medicare, Medicaid, and Indian Health Service health plans, it has relied and will continue to rely on partnerships with a wide range of private sector organizations to ensure that the message and reality of Administrative Simplification reaches everyone involved, and that training and technical assistance opportunities exist.

Centers for Medicare and Medicaid Services

The Centers for Medicare and Medicaid Services (CMS) is also employing an extensive, multi-faceted outreach strategy on HIPAA Administrative Simplification that includes the following:

Website. CMS created and maintained a website, www.cms.hhs.gov/hipaa/hipaa2, that routinely receives 350,000 hits per month. Resources available from the site include responses to over 80 frequently asked questions as well as informational papers, checklists and links to HIPAA regulations.

Roundtables. CMS conducted 15 free national HIPAA Roundtable Conference Calls reaching more than 40,000 people in 2003 as well as many regional office Roundtable Calls that were targeted to providers and payers.

Toll Free Hotline. CMS established the HIPAA Hotline (1-866-282-0659) to provide general information and respond to questions on Administrative Simplification. The hotline was established in September 2002 and receives questions 24 hours a day. Calls come in via a toll-free voice line, toll-free fax and a TTY line. More than 40,000 calls were received from April 2003 through December 2003.

Webcast. CMS created a free webcast available to the public 24 hours a day. The webcast is divided into different topics including an overview of transactions and code sets, security, and more technical presentations on the 837I and 837P claims transactions and a segment on post-October 16 guidance. Most presentations are accompanied by slide presentations that viewers can download. More than 20,000 persons have viewed the webcast.

Faxback. CMS created a fax back service to provide HIPAA materials to those without Internet and e-mail access. More than 3,000 persons used it in 2003.

E-mail Technical Assistance. CMS established the "AskHIPAA" e-mail box to provide an alternative way for providers, payers and others to ask questions on HIPAA implementation since it was first implemented in the summer of 2002. On average, CMS has been responding to approximately 500 e-mails per month.

Listserv. CMS established an outreach listserv to notify subscribers of the latest HIPAA Administrative Simplification outreach materials and events. Nearly 7,000 individuals subscribe as of October 31, 2003.

National Ad Campaign. CMS implemented a national HIPAA public service ad campaign that focused on the importance of testing before the October 16, 2003 deadline, and the potential impact non-compliance will have on provider cash flow. The full-page black and white ad appeared in 13 major health care journals and publications in September 2003. The circulation for these publications is more than a million.

Outreach Materials. CMS developed and disseminated a myriad of outreach materials, many of which are available in Spanish in addition to English and the majority of which are free to the public. These materials include covered entity decision tools, a series of ten informational papers on HIPAA transactions and code sets, checklists, and slides.

Partnering. CMS established partnering relationships with national organizations such as AHA, AMA, and various medical specialty societies. CMS also has participated in more than a dozen compliance assistance seminars on HIPAA and other health laws sponsored by the U.S. Department of Labor for employers, health plans and benefits administrators.

Regional Outreach. CMS conducted numerous outreach events/conferences in each region and at least one in each State.

Video. CMS created a video, *HIPAA 101: The Basics of HIPAA Administrative Simplification*, approximately 45 minutes long, which gives an overview of HIPAA. In addition to providing more than 5,000 free videos and 425 free CD-ROMs, CMS broadcast the video on three separate dates; in addition, GE Medical

Networks (GEM) also broadcast the video to 2041 hospitals across the country, while Comcast in Maryland (cable channel 25) began broadcasting on July 1, 2003.

Workshops. CMS conducted 17 HIPAA Readiness Workshops targeting small providers in various cities across the country between Syracuse, NY to Honolulu, HI.

Conferences. CMS conducted a HIPAA vendor conference in December 2002 and an employer conference in July 2003. In addition, HIPAA information was disseminated at all CMS Open Door Forums, aimed at physicians, other health providers, health plans, clearinghouses and vendors.

National Committee on Vital and Health Statistics

The Committee has continued to serve as the Department's primary liaison with the private sector to obtain the views, perspectives, and concerns of interested and affected parties, as well as their input and advice, on health data standards and privacy. During 2002 and 2003, the focus of NCVHS public hearings and committee deliberations was on implementation issues, industry readiness, obstacles in achieving successful implementation, and issues relating to implementation of the Privacy Rule. The Committee also dedicated a major effort to identifying and assessing candidates that might be recommended to HHS for adoption as Patient Medical Record Information (PMRI) Standards. NCVHS provided to Secretary Thompson recommendations on PMRI message format standards in February 2002 and recommendations on PMRI terminology standards in November 2003.

The Committee's Subcommittee on Privacy and Confidentiality held hearings on the HIPAA Privacy Rule and early implementation efforts in Salt Lake City, Baltimore, and Boston during the fall of 2002. Based on information developed during those hearings, the Committee advised the Secretary of its views on certain aspects of implementation planning in letters in September and November 2002. In its letters the Committee advised the Secretary of several concerns that it heard at the hearings, including the desire of covered entities and others for HHS to provide practical guidance, sample forms, and other implementation aids; failure to report public health information out of a misunderstanding of the regulation's requirements; and uncertainty about the respective roles of the Federal regulation and State law.

Now that the health care and payment community is implementing the regulation, the Subcommittee on Privacy and Confidentiality has begun to hold hearings to determine how the regulation has affected the level of privacy for individuals, to identify best practices employed by covered entities to comply with the regulation and protect privacy, and to identify and resolve barriers to compliance. Although the Committee has not yet completed its recommendations based on these hearings, it notes that outreach and

technical assistance by the Department are important elements in assisting entities to comply.

The Subcommittee on Standards and Security held several hearings in 2002 and 2003 on the feasibility and desirability of replacing the current diagnosis and inpatient procedure classification system, ICD-9-CM, volumes 1, 2, and 3, with a newer and expanded version, ICD-10-CM and ICD-10-PCS. It also commissioned an impact study by the Rand Corporation on the costs and benefits of making this migration to the new code sets. In November 2003, the NCVHS sent recommendations to HHS, concluding that it is in the best interests of the country as a whole that ICD-10-CM and ICD-10-PCS be adopted as HIPAA standards for national implementation as replacements for current uses of ICD-9-CM, Vol. 1,2 and 3. This would not affect the usage of other code sets under HIPAA, such as CPT-4 and HCPCS Level II (Healthcare Common Procedure Coding System).

In 2003, the NCVHS received input on the development and adoption of clinical standards under the Consolidated Health Informatics (CHI) initiative. NCVHS is working closely with CHI to study, select and recommend domain-specific patient medical record terminology standards.

HIPAA Implementation Activities by Industry

The Public Health Data Standards Consortium has continued to be a key organization in the implementation of administrative simplification in the public health and health services research arenas. Importantly, during 2002 and 2003 the Consortium developed and received final approval from ANSI ASC X12 for the *Health Care Service: Data Reporting Guide*, which makes use of the claim/encounter standard for public health and related reporting. This is the first attempt to standardize public health administrative data for all care in an institutional setting. The guide incorporates and standardizes state reporting requirements for encounter data and is expected to promote migration by States and others to a HIPAA-compatible standard. All entities, which conduct quality measurement, community assessment, disease surveillance, and other comparative studies, will now have a national standard for institutional health care service information.

Several industry organizations have continued to demonstrate national leadership by working to assist health plans, providers and clearinghouses implement the standards. Both the Association for Electronic Health Care Transactions (AFEHCT) and the Workgroup for Electronic Data Interchange (WEDI) have papers on their web sites. WEDI in particular is sponsoring the Strategic National Implementation Process (SNIP). SNIP has regularly brought participants from all facets of the industry (plans, providers, vendors) together to provide implementation education, assistance, time frames and solutions to problems with the aim of facilitating and coordinating HIPAA implementation nationwide. Several regional health data consortia are also assisting with HIPAA awareness and implementation efforts, including the Massachusetts Health Data

Consortium, the North Carolina Health Care Information and Communications Alliance, and the Utah Health Information Network.

IV. Important Issues

Industry Readiness for HIPAA

Based upon written statements, letters and testimony in 2003 from several industry representatives and advisory bodies, the NCVHS believed that the industry was not ready to implement the electronic transaction provisions of HIPAA for several reasons. A substantial segment of the industry was unable to comply with the October 16, 2003 implementation deadline. It seemed that private health plans could not accept noncompliant electronic claims without jeopardizing their own compliance status and risking enforcement action. Lastly, providers were thought to possibly face significant cash flow problems as HIPAA implementation proceeded, which could adversely affect their financial viability and thus affect the availability and quality of patient care.

NCVHS believes the one-year extension to the compliance date for the electronic transaction provisions of HIPAA provided the industry with sufficient time for implementation. NCVHS recommends that CMS and industry strategies for education and outreach be maintained to assist covered entities with implementation. NCVHS will continue to monitor the industry's implementation efforts.

Issuance of Remaining HIPAA Standards Essential for Effective and Efficient Implementation

It is essential to issue final rules for the national provider identification numbering system and for the national health plan identification numbering system. In 1998 standards were proposed to require hospitals, doctors, nursing homes, and other health care providers to obtain a unique identifier when filing electronic claims with public and private insurance programs. Currently, health care providers are assigned different ID numbers by each private health plan, hospital, nursing home, and public program such as Medicare and Medicaid. These multiple ID numbers result in slower payments, increased costs and a lack of coordination. Also crucial are standards that would create a unique identifier for health plans, making it more efficient for health care providers to conduct transactions with different health plans.

The issuance of the proposed rule for claims attachments is essential so that the industry can begin planning and development for adoption of standards for attachments (e.g., electronic copies of parts of medical records, X-rays, etc.) to electronic claims. The NCVHS held public hearings on standards for claims attachments in 1998 and provided recommendations to HHS. Accordingly, the NCVHS urges the Secretary to issue the standard without further delay.

Outreach and Education About the HIPAA Privacy Rule

Although the Committee has not yet completed its hearings on the Privacy Rule, it is the sense of the Committee that education, outreach, and technical assistance are crucial to effecting the Rule's purpose in protecting patient privacy. The Committee believes HHS should continue its current strategy for issuing helpful FAQs, and in addition, it urges HHS to increase its efforts to educate and provide to covered entities helpful written materials about the Rule.

VI. Conclusions

The NCVHS reaffirms the importance of the HIPAA Administrative Simplification initiative and urges the Secretary to expedite the publication of the remaining rules. The enactment of the one-year extension for compliance only increases the urgency of the situation. The full economic benefits of Administrative Simplification will only be realized when all of the standards are in place, and implementation activities and resource planning in the industry will be more effective when the regulatory framework for the entire suite of standards is final. Lastly, the NCVHS reaffirms the importance of HHS increasing its efforts to educate covered entities about the HIPAA Privacy Rule.

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