Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ELECTRONIC DATA INTERCHANGE AND PAPERLESS PROCESSING:

ISSUES AND CHALLENGES

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Inspector General

MARCH 1994
OEI-12-93-00080

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EXECUTIVE SUMMARY

PURPOSE

The purpose of this document is to (1) identify emerging issues in the expansion of the Health Care Financing Administration's (HCFA) use of electronic data interchange (EDI) and related technology to achieve paperless processing, and (2) discuss the Office of Inspector General's (OIG) current plans to provide oversight of HCFA's strategy to implement a paperless environment. We have developed it through a review of literature and consultation within the OIG, and with HCFA and others.

BACKGROUND

Electronic Data Interchange is the electronic transfer of information, such as electronic media claims, in a standard format between trading partners. As it relates to health care, this new technology will allow entities within the health care system, connected by an integrated system of electronic communication networks, to exchange medical, billing, and other information and process transactions in a manner which is fast and cost effective. Most of these improvements are likely to result from the significant reduction or elimination of paper transactions.

ISSUES

The HCFA's far-reaching implementation of EDI and paperless processing contains many parts which all relate to the larger strategy and goals of this initiative. Among the significant issues affecting this strategy are the following:

- *Systems*--such as the Medicare Transaction System (MTS), Medicaid Management Information Systems (MMIS), and point-of-service claims management systems under Medicaid--to process electronically submitted claims and manage data more efficiently.
- *Standardization*, to facilitate the electronic flow of claims, patient, and reimbursement data between providers, payers, and quality-of-care reviewers.
- *Incentives and barriers*, to encourage providers to submit claims and patient data electronically.
- *Companion technologies*, such as smart cards for computerized patient identification and medical records, and national data communications networks for transmission of health care data to complete the electronic cycle.

We discuss the need for a cohesive strategic systems plan covering EDI and paperless processing, to encourage HCFA's information resources management program to address Medicare contractor systems and Federal Medicaid initiatives.

The implementation of these new systems, in particular, carries with it myriad questions regarding trustworthiness and reliability of data as it moves from one partner in electronic commerce to another and from one process to another. Specific issues raised with regard to electronic submission and processing of claims include:

- *Confidentiality and privacy of patient records*, to ensure that the confidentiality of personally-identifiable health insurance data be strictly maintained and the privacy of patients be maintained.
- *Internal controls*, to address the adequacy of management controls over operations and specific requirements for controls to safeguard assets against waste, fraud, and abuse.
- *Audits and certification*, to place more focus on systems at the provider level and to ensure that all EDI and paperless processing systems are trustworthy and reliable.
- *Contractor conflict of interest*, to pursue the Medicare contractor conflict of interest issue as it relates to proprietary EDI and paperless processing market-driven ventures.
- *Valid contracts*, to determine the degree of compliance of current and planned Medicare contract requirements with the National Institute of Standards and Technology standards.
- *Legal use of information submitted*, to ensure the integrity of information through the use of provider agreements, a valid chain of custody, attestation and originator authentication, and the need for audit trails.

CONCLUSION

This document, prepared in response to HCFA's briefing for OIG personnel on EDI and paperless processing issues and its request for more information on the OIG's concerns and plans, has identified numerous issues and goals related to HCFA's use of EDI and paperless processing technology. Issues related to the overall strategy of this initiative concern the development of various systems which will allow HCFA to process electronically submitted claims more efficiently. Other broad issues are standardization, incentives, companion technologies, Medicare contractor systems, and Federal Medicaid initiatives.

This document also raises issues regarding the trustworthiness and reliability of data as it moves from one partner in electronic commerce to another and from one process to another. These issues include confidentiality and privacy, management controls over operations, internal controls, audits and systems certifications, Medicare contractor conflict of interest, validity of contracts, and the integrity of information. Besides having a significant impact on HHS and HCFA's ability to manage the Medicare and Medicaid programs, these issues are critical to the detection of fraud and abuse. We plan to analyze many of these issues for the purpose of preparing our workplan over the next few years.

AGENCY COMMENTS

The Health Care Financing Administration (HCFA) commented on a draft version of this report. The HCFA suggested changes in the report to better reflect its activities and those of the Department with respect to EDI and paperless processing, made suggestions about the focus of OIG's work in this area, and gave us technical comments. We have revised our report to address many of HCFA's comments and also provide additional comments on HCFA's response in Appendix B. The full text of HCFA's comments can be found in Appendix A.

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INTRODUCTION

PURPOSE

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BACKGROUND

Electronic Data Interchange is the electronic transfer of information, such as electronic media claims, in a standard format between trading partners. As it relates to health care, this new technology will allow entities within the health care system, connected by an integrated system of electronic communication networks, to exchange medical, billing and other information and process transactions in a manner which is fast and cost effective. Most of these improvements are likely to result from the significant reduction or elimination of paper transactions.

Electronic Billing

The HCFA has encouraged electronic submission of claims under Medicare for some time, and has recently stepped up its efforts to lead increased electronic billing under the Medicaid program. New incentives for the use of electronic billing are now in place. Providers submitting claims electronically are paid faster than providers submitting paper claims. The HCFA also has taken steps to move towards adoption of nationwide standardized electronic billing formats for both Part A and Part B.

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[1]This document describes OIG projects which are either in progress or planned for completion by the end of FY 1995. These projects are subject to change depending on our availability of resources, continuing review of priorities, and assessment of new research in the field.

Electronic Adjudication and Payment

All payers, including the Medicare and Medicaid programs, are moving towards paperless billing and adjudication and payment of claims. HCFA plans to have the Medicare Transaction System (MTS) in place by 1998. This system, which will combine Part A and Part B of the Medicare program for the purposes of claims submission, adjudication and payment, will replace the 14 software processing programs used by the 48 fiscal intermediaries and 34 carriers that currently process Medicare claims.

Furthermore, most of the health care reform bills now being considered include provisions for simplification in the administration of health care benefits through the use of standardized electronic billing and payment procedures. Several of the reform bills also call for use of an electronically readable card to be used to verify eligibility for benefits.

Beyond the Claims Environment

Other initiatives will also use technology to improve the health care information system. The Computer-Based Patient Record Institute (CPRI) is the organization that has been given the responsibility to initiate and coordinate all activities which will establish the routine use of computer-based patient records in all health care settings by the year 2001. Its mission is to support the effective and efficient use of computer-based patient information and to foster the computer-based patient record (CPR) as the primary vehicle for collecting patient data.

These initiatives are important ones for the entire health care system, and for the Medicare and Medicaid programs in particular. They hold out the promise of more efficient administration of program benefits, faster claims processing, reduced administrative costs and hassle for both providers and program administrators, and more effective coordination of benefits and care for patients. Yet, they also hold risks. As with any implementation of major new initiatives, thoughtful and careful planning is essential. Coordination among groups within and outside the Department of Health and Human Services must take place to avoid stumbling blocks. Goals, objectives and timetables must be set. All tasks must work together to form a coherent strategy. New vulnerabilities and problems which might be introduced by new systems and strategies must be anticipated and overcome.

ISSUES

Major issues relating to HCFA's EDI and paperless processing initiatives can be grouped into two major categories: (1) policy direction; and (2) policy implementation, including trustworthiness and reliability of systems.

POLICY DIRECTION

The HCFA's far-reaching EDI and paperless processing initiative, in both the Medicare and Medicaid programs, contains many parts. Each of these parts is worthy of examination in its own right and as it relates to the larger strategy and goals of this initiative. Among the significant elements of this strategy are the following:

- *Systems*--such as the Medicare Transaction System (MTS), Medicaid Management Information Systems (MMIS), and point-of-service claims management systems under Medicaid--to more efficiently process electronically submitted claims and manage data.
- *Standardization*, to facilitate the electronic flow of claims, patient, and reimbursement data between providers, payers, and quality-of-care reviewers.
- *Incentives*, to encourage providers to submit claims and patient data electronically.
- *Companion technologies*, such as smart cards for computerized patient identification and medical records, and national data communications networks for transmission of health care data to complete the electronic cycle.

We also discuss the need for a cohesive strategic systems plan covering EDI and paperless processing, to encourage HCFA's information resources management program to address Medicare contractor systems and Federal Medicaid initiatives.

SYSTEMS

Medicare Transaction System (MTS)

The HCFA's 48 fiscal intermediaries and 34 carriers currently use 14 shared software systems to process bills and pay claims. Under MTS, HCFA plans to replace the current Part A and Part B systems with one unified system. This new system will consolidate the claims-processing function into anywhere from 1 to 10 contractors. Current contractors would continue to handle beneficiary inquires and payment safeguard functions, and would input paper claims to electronic format before sending them to the processing centers. The MTS is projected to be in place by 1998 and is expected to make it easier for HCFA to make the system changes required to put new Medicare regulations and payment policies into effect. The MTS is also expected to make it easier for providers to inquire about the status of their outstanding claims.

The HCFA feels that MTS is necessary to help control the rise in Medicare processing costs since it projects a 50 percent increase in claims volume by 1997.

Recently, HCFA awarded a $19 million, six-year contract for MTS design and development support services to GTE Government Systems Corporation. The General Accounting Office (GAO) was asked by Congress to review the MTS procurement. The GAO final report, transmitted to HHS on March 1, 1994, recommended that the Secretary ensure continuous involvement in MTS by HCFA top management, participation by Department information resources management officials and other experts, and reporting on progress and project status each January to congressional appropriations and oversight committees.

The OIG has previously recommended[2] that HCFA undertake a strategic planning initiative to streamline, consolidate, and integrate Medicare claims processing. The HCFA has indicated that MTS addresses this recommendation. Thus, OIG plans to review[3] the MTS systems design process, with particular emphasis on how HCFA plans to improve payment safeguards, provider accountability, internal systems controls, and financial management through implementation of the system. The results of this review should clarify issues raised by GAO and should be of use to HCFA as specifications are developed for the new MTS, particularly with respect to the sufficiency of HCFA's safeguards designed to ensure proper payment.

Medicaid Management Information Systems (MMIS)

Each of the jurisdictions (State or territory) operating a Medicaid program is entitled to enhanced Federal financial participation for the development and operation of a Medicaid claims processing system--referred to by HCFA as a Medicaid Management Information System--in accordance with minimum Federal standards. All but one of the Medicaid jurisdictions have either implemented such a system or are in the process of doing so.

A number of these systems have either been installed initially or have been replaced within the last 5 years. Many of these newer MMIS incorporate in their design features (such as State-wide data communications networks) to facilitate electronic billing, adjudication, and payment of Medicaid claims. And, a number of these systems are integrated with State Family Assistance Management Information Systems (FAMIS) and State-wide data communications networks to facilitate EDI and paperless processing in both the Medicaid and Aid for Families with Dependent Children programs.

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[2]"Review of Medicare Bill and Claim Processing: Opportunities for Long Term Improvement," A-14-91-02532, August 1992.

[3]As part of "Electronic Claims Processing - Medicare," planned for completion at the end of FY 1995.

The OIG plans to review recent State efforts to implement MMIS and integrated FAMIS/MMIS to determine the adequacy of the planning process, the thoroughness of the risk analysis, and the degree of success in meeting system goals.

Medicaid Point of Service (POS) Claims Management Systems

The OIG will review the States' use of MMIS data in conducting utilization review and analysis as part of our planned work in assessing innovative approaches to Medicaid utilization review.

Point of Service claims management systems use computers and telecommunications networks to perform one or more of four related but distinct claims management functions. These are eligibility verification, claims submission, claims adjudication, and utilization review. POS systems allow all of these functions to be performed in a matter of seconds, before or while the services are being dispensed. Most existing POS systems are in the private sector and are used primarily for the management of prescription drug claims.

The Secretary of Health and Human Services (HHS), in response to requirements included on OBRA 1990 and in conjunction with the MMIS program, has encouraged State Medicaid programs to implement POS systems for managing prescription drug claims. The Federal Government provides up to 90 percent Federal financial participation for the development of these systems and has authorized the Secretary to waive certain paperwork requirements.

The OIG has performed a study of Medicaid POS systems.[4] In this study, the OIG found that POS systems, in the two States that have used them, have saved money and have enhanced program administration. It also found that few States plan to acquire POS systems. This is due primarily to the barriers that have limited States' implementation of POS systems and the inadequate and confusing information that many States have received about POS systems. We plan to examine these issues further in our upcoming MMIS review and to conduct a further study of States' implementation of the drug utilization review (DUR) requirements of OBRA 1990.

Since the OIG study on Medicaid POS systems, 8 State Medicaid agencies (SMA) have reported implementation systems for pharmacies (including 6 systems with utilization review capability). Ten additional SMAs indicated that they were developing POS modules for implementation by the end of calendar year 1993, and 21 of the remaining 33 SMAs noted that they were considering the development and implementation of POS modules for completion by late 1994.

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[4] "Point-Of-Service Claims Management Systems For Medicaid," OEI-01-91-00820, May 1992.

STANDARDIZATION

When encouraging the development and use of any new emerging technology, the establishment of standards becomes a critical issue which can "make or break" the technology. Take the example, from a few years ago, of quad-stereo. The fate of this superior sound technology was in the hands of a few manufacturers who could not agree on a standardized equipment format. Because of the lack of standardization, the technology never made the market penetration it was expected to achieve. While EDI, unlike quad-stereo, is here to stay, the fate of its universal acceptance does lie in the hands of those groups which are in the position to mandate equipment and software standards.

Currently, there is no national group which is responsible for the establishment of a uniform data set and uniform data element definitions with respect to health care transactions. Informational standard setting organizations, such as the National Uniform Billing Committee and the Uniform Claim Form Task Force, have not been given a clear role in defining data element definitions and reporting requirements. Also, compliance with the recommendations made by these groups is generally voluntary. There is an additional problem caused by the lack of coordination between the groups that develop the electronic formats (e.g. the American National Standards Institute or ANSI) and the standard setting groups. The standard setting groups are not always allowed to review the new EDI transaction data sets developed by ANSI and others.

The Federal Government has the opportunity to take the lead in encouraging (if necessary mandating) and guiding the development of EDI standards. But, if EDI is to be standardized throughout the entire health care community, the Federal Government must be prepared to modify substantially, if necessary, the current systems utilized by Medicare, State Medicaid programs, the Department of Veteran Affairs, Civilian Health and Medical Program of the Uniform Services (CHAMPUS), and the Indian Health Service.

In the previous administration, Secretary Sullivan of HHS established the Workgroup for Electronic Data Interchange (WEDI) to work with the insurance industry on standardizing electronic billing, remittance advice and banking formats, and moving towards an all-electronic environment for processing of health insurance claims in the public and private sectors. The impetus for this effort was a generally-accepted premise that costs of administering Medicare, Medicaid, and private health insurance plans and the paperwork burden imposed on providers by the insurance industry are inordinately high without significantly constraining health care costs.

Under this effort, some progress in standardization was made. The HCFA began active participation in the ANSI committee establishing standardized electronic formats for the health insurance industry. The HCFA then issued regulations calling for the use of ANSI standard transactions for electronic remittance notices and

payments by both the Medicare and Medicaid programs. The HCFA is planning to implement a standard uniform institutional billing form for Medicare and Medicaid over the next year. Legislation, which would have empowered national standards organizations to establish mandatory standards for electronic submission and payment of claims, facilitated establishment of a national telecommunications network for health care administrative data, and promoted the clearinghouse concept to improve the coordination of benefits between various public and private payers, was not passed in the last session of Congress. However, the Clinton Administration has recognized the importance of standards and integrated health information systems and communications networks as a way to promote administrative simplification in health care. It has included establishment of such standards and networks under the auspices of a National Health Board as part of its health care reform proposal.

We plan to track and analyze progress by the Department and HCFA in fostering standardization as part of our ongoing assessment of HCFA's ability to move to paperless processing in the age of EDI and electronic commerce.

INCENTIVES AND BARRIERS

The Providers' Perspective

An obvious obstacle to getting providers to "buy into" an EDI and paperless processing system is simply the resistance to change to a new method of doing business. Then there are more substantiated reasons for not wanting to use EDI and paperless processing. One example is that some provider types, especially DME suppliers, have refrained from using EDI and paperless processing because there are no electronic methods for submitting attachments. Another reason for not using EDI is the lack of standard data sets. This forces many providers to adopt an electronic format which is compatible with the payer to whom the provider submits the majority of their bills. Finally, there are the additional costs incurred by a provider who wishes to convert to EDI and paperless processing.

Issues which may need to be addressed include:

- What education programs can be put in place to help overcome provider resistance to change?

- Should HCFA create EDI and paperless processing benefit models based on provider size, geographic location, and patient mix, in order show providers how the benefits of EDI and paperless processing relate to them?

- What incentives are needed to bring providers into the EDI and paperless processing environment? What about tax incentives, low or no-cost software, or the elimination of the Medicare floor used to pay claims?

- What needs to be done to ensure that providers adopt a uniform EDI and paperless processing environment?

The HCFA Bureau of Program Operations (BPO) is currently studying those attachments to bills, such as Certificate of Medical Necessity (CMN) forms, that can be standardized, automated or eliminated. The BPO is also enlisting the support of national provider organizations and has developed a publicity campaign to promote the adoption of EDI technology. The BPO has two point-of-service pilot projects underway and has evaluated a number of innovative proposals for EDI and paperless processing projects.

Providers who decide to implement new EDI and paperless processing technology will be faced with incurring four types of costs. These costs are for hardware, software purchasing or leasing, installation and training, and telecommunication charges. Since most of these costs are relatively fixed (they exist whether the provider submits one claim, one hundred claims, or one million claims) and the gross savings accrue on a per claim or electronic transaction basis (the more claims or electronic transactions the more savings), overcoming these fixed costs is the principal factor that prevents low-volume providers from acquiring EDI and paperless processing technology. This problem is compounded by the fact that a significant number of small providers, especially rural providers, lack computerized offices. For these providers, investing in the required costs listed above would probably not be cost effective.

Issues with regard to small providers include the following:

- Will small providers, especially rural providers with small Medicare patient loads, be required to invest in EDI and paperless processing technology?

- What are the costs associated with conversion, installation, and maintenance of these systems and can small providers justify these costs? Can small providers pool operational costs?

- What alternatives exist for small providers?

The HCFA BPO is currently taking inventory of all of the low cost software that Medicare contractors are required to make available to providers. The HCFA Regional Offices will then determine contractor compliance. The BPO is also in the process of evaluating a number of pilot projects which are using emerging technologies in the payment area. Some of these, one example being fax imaging technology, may be feasible for small providers to use as a cost effective substitute for a complete EDI and paperless processing system.

The OIG plans to assess how different providers can be brought into the EDI and paperless processing environment, what barriers exist for providers, and whether HCFA's efforts address those barriers and provide proper incentives for providers.

The HCFA's Perspective

For the short term, some of the key issues of concern to the OIG are as follows:

- What changes have been made in Medicare claims processing as a result of the implementation of Medicare national claims formats and electronic funds transfer (EFT)?

- Have these changes been implemented successfully, i.e., is there a probability of payment errors or fraud?

The HCFA has identified increased electronic media claims (EMC) and EFT as the primary means for effecting short term reductions in Medicare claims-processing unit costs.[5] And, by the end of Fiscal Year 1993, HCFA will have invested over $21 million in EMC/EFT improvements at the Medicare contractors.

The HCFA as established the following goals for EMC:

- Increase the rate of EMC to 100 percent for hospitals and 75 percent for all other providers within 3 years.

- Increase the rate of EFT for Medicare payment to hospitals to 100 percent within 3 years.

- Increase the overall cost effectiveness of EMC.

These are challenging goals, and we are concerned that, with limited resources and many other operational issues that had to be dealt with at the same time, HCFA's planning and execution to reach these goals may not have been adequate. To address these concerns, we have initiated a review[6] during which we will determine if HCFA:

- Adequately assessed benefits and costs. (The HCFA believes that it will realize significant cost savings from full EFT implementation.)

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[5]Based on experience of the health insurance industry as a whole, HCFA believes that it is $0.50 per claim cheaper to process an electronically submitted claim than a hard-copy claim. This difference results primarily from data entry of hard-copy claims into electronic claims processing systems.

The HCFA believes that even more savings may accrue from EFT and electronic notice of remittance, rather than payment by check and paper remittance advice. These savings result primarily from reduced mail room and postage costs.

[6]"Electronic Claims Processing - Medicare," which is currently in the survey phase.

- Adequately assessed potential risks and vulnerabilities inherent in EMC, EFT, and paperless processing. (For example, HCFA does not believe that benefit payments made under EFT will be vulnerable to errors and/or fraud because the involved EFT parties of the contractors, Medicare banks, and the Automated Clearing House operators are bound by strict operating guidelines and Federal regulations concerning the initiation, transmission, and receipt of EFTs.)

- Provided adequate instructions, lead time, and resources to the Medicare contractors. (The HCFA has been providing technical specifications, procedural guidance, and appropriate funding since 1990.)

- Sufficiently track progress during implementation in a timely and effective manner to identify problems and resolve them. (The HCFA believes that it has been diligent in tracking the progress of contractors, providers, and SMAs in implementing EFT.)

We will also determine the degree of success that the Medicare contractors are having in implementing the changes called for, and reaching the EMC/EFT targets set by, HCFA.

COMPANION TECHNOLOGIES

Smart Cards

Smart cards are wallet-sized, machine-readable cards that contain an integrated chip (its own computer) which can store an individual's medical history and other forms of data. In its simplest form these cards allow access to a health care plan database. The health care industry continues to rely on identification cards to recognize plan members. Because of their extensive use, cards in one form or another are here to stay. As these identification cards become more sophisticated and become smart cards, the OIG should be concerned about two main issues. These issues are the cost of the cards and standardization.

The cost of machine-readable cards (equipment and installation) and the necessary infrastructure (training) to support the cards are certainly major drawbacks to a smart card system. A smart card system according to WEDI could cost hundreds of millions of dollars. Should smart cards be used when the less expensive magnetic strip or swipe card (credit card or ATM model) may contain all the information required?

Smart cards must contain a standard set of information. The issue is the amount of information required. In order to allow for an efficient electronic access to information, and the transfer of information between payers and providers, at a minimum this information must be able to identify the payor and the plan member. The decision must also be made as to the amount of patient clinical information that should be put on the smart card. Should patients be required to carry data bases

around in their pockets when central computer and communication networks are a capable alternative?

Currently, there are several ongoing experiments on the application of card technology for the health care industry. The States of New York and Massachusetts use the magnetic strip card with an on-line communications network to monitor eligibility and utilization for their Medicaid populations. Smart cards are being used to monitor Aid to Families with Dependent Children, food stamp, and Medicaid populations in various States.

Even though WEDI does not recommend the use of the smart cards because of its expense, we still recommend that HCFA look at smart cards (e.g. for use in verifying electronic signatures) and that HCFA study the results of the above experiments, and review the experience of States that have used various types of cards in the design of MTS and the implementation of the computerized patient record.

Computerized Patient Records

In order to be able to make informed health care decisions, policy decisions as well as clinical, the U.S. health care system needs better access to the information contain in patient records. This information, now contained in paper-based systems, is often fragmented, irretrievable, and illegible. The Institute of Medicine (IOM), after studying this issue for 18 months, has recommended that patient records be computer based. In addition, the IOM has endorsed the establishment of a private/public initiative which is to now called the CPRI. The CPRI, formed during the summer of 1991, will be responsible for the initiation and coordination of all work that will eventually establish the routine use of CPRs in all U.S. health care settings. The CPRI has formed five committees, and these committees will perform much of the work which is yet to be done.

HHS involvement in this area to date has consisted primarily of: the establishment of an HHS computerized Patient Records Council to promote and coordinate various Departmental activities; partial funding of the American National Standards Institute's Health Informatics Planning Panel; participation in the deliberations leading to the formation of the CPRI; participation in the American Hospital Association's Workgroup on Computerization of Patient Records and the WEDI; and the establishment of the HCFA Electronic Environment Steering Committee.

Because the establishment of the use of CPRs is still in its conceptual phase, various issues face the OIG:

- What are the benefits and the costs of the computerized patient record? The OIG should determine if a proper cost/benefit analysis has been performed to ensure, as best as possible, that CPRs will not only be useful and accessible, but also not so prohibitive that providers will not be able to afford their installation.

- What is required to guide the development of electronic clinical information or CPRs? What is needed to insure a uniform standard data set, definitions, and format? What needs to be included in patient records and which models of CPRs should be adapted? Will HCFA rely entirely on the CPRI to develop the standards? The OIG should be concerned that the Department have a place in the CPRI and that the Department give input at the early stages of the development of the CPR.

Leadership by HHS in the area of CPRs is particularly important because of the implications for:

- The Peer Review Organization (PRO) and SuperPRO activities relating to hospital utilization in Medicare.

- Utilization review activities of Medicare carriers.

- Utilization review activities of the States in their MMIS.

- Provider level interface with future health information systems at the State and Federal level.

In the future, the OIG will monitor the results from the work that is being performed by the five committees. In the mean time, we plan to address the issue of computerized patient records in the context of our ongoing review of MTS, upcoming review of MMIS, and a planned review of internal systems controls at the PROs.

THE NEED FOR A COHESIVE STRATEGIC SYSTEMS PLAN COVERING EDI

In a prior report[7], we indicated that Medicare contractor systems and Federal Medicaid data initiatives were not being addressed in HCFA's information resources management (IRM) program; HCFA had not sufficiently assigned duties to, or assured the independence of, its Principal IRM Official; and the Department had not sufficiently monitored HCFA's IRM activities. Furthermore, neither we nor GAO have been able to discern any comprehensive strategy on HCFA's part related to how Medicare and Medicaid will move into an all-electronic environment.

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[7]"Review of the Health Care Financing Administration's Implementation of the Project to Redesign Information Systems Management," A-14-91-02533. At that time, HCFA had elected to move forward with a strategic planning initiative to streamline, consolidate, and integrate Medicare and Medicaid claims processing, including EDI. This initiative had critical goals and objectives to standardize systems, provide appropriate incentives, and utilize companion technologies.

Meanwhile, however, private sector initiatives in the area of EDI standards and investment in private sector EDI networks and systems continues at an accelerating pace. These efforts are, in large measure, being driven by the Blue Cross/Blue Shield Association and its member plans, large commercial insurance companies, and commercial clearinghouses and data processors. Each of these parties is pursuing an EDI strategy based primarily on business concerns, and particularly market share. At the same time, numerous legislative proposals are being offered in conjunction with health care reform that would dramatically affect how EDI for health insurance information would be structured and operate in the future.

Without a viable Departmental strategy for channeling future EDI developments, we are concerned that:

- Medicare and Medicaid may not be able to make the most effective use of emerging EDI technology.

- The proliferation of EDI systems in the public and private sectors may accelerate.

- Reductions in administrative costs per claim may not be achieved to the degree now anticipated. And, issues similar to that of conflict of interest now faced in dealing with Medicare and Medicaid secondary payer issues will remain unresolved.

We plan to address some of these issues in our ongoing review of MTS and related HCFA EDI initiatives. And, we plan to re-examine the efficacy of HCFA's strategic systems planning process as one of a series of reviews of HCFA's IRM program.[8]

[8]"Review of General Systems Controls at HCFA - Phase I" planned for completion by the end of FY 1995.

POLICY IMPLEMENTATION

The implementation of new EDI and paperless processing systems, in particular, carries with it questions regarding trustworthiness and reliability of data as they moves from one partner in electronic commerce to another and from one process to another.

Specific questions raised with regard to electronic submission and processing of claims include:

- *Confidentiality and privacy of patient records.*
- *Internal controls.*
- *Audits and certification.*
- *Contractor conflict of interest.*
- *Valid contracts.*
- *Legal use of information submitted, stored and processed by new systems, including provider agreements, chain of custody, attestation and originator authentication, and the need for paper trails.*

CONFIDENTIALITY AND PRIVACY OF PATIENT RECORDS

Any EDI and paperless processing system will need to ensure that the confidentiality of personally identifiable health insurance data be strictly maintained and the privacy of patients be maintained. This area is made complex because traditionally the legal requirements covering privacy have been addressed on the State level with each State being unique. This is further complicated because providers and payers are subject to different sets of rules, with additional variation among types of providers.

The obligation that a provider must maintain the confidentiality of a patient's health insurance data is defined by statue, common law, and professional ethics. It is the same whether the transmission and storage of this data is paper or electronic. The very reason that providers changed from the more cumbersome paper records to the more efficient EDI and paperless processing systems is the same reason that makes these systems more vulnerable. While EDI and paperless processing allows for more sophisticated security protocols, once these protocols are breached, it allows for a very efficient method of conducting an unauthorized transmission and review of confidential health insurance data.

Because payers are required to release health insurance data to various sources, especially medical information, they must follow many conflicting legal requirements covering disclosure. This disclosure may be for claims adjudication and payment,

research, third party administration and utilization review, and audits. EDI and paperless processing must allow for these myriad of disclosures while protecting the privacy of the patients.

Two issues before HCFA in the areas of confidentiality and privacy are:

- What is required to ensure that all electronic health information remains at the required level of confidentiality?

- Have standards been established and have these standards been incorporated into legislation and systems development?

Although HCFA feels that the system security technology available at this time is more than adequate, we have little information to prove that this will be true into the future. The Privacy Act of 1974, 5 U.S.C. Section 552a, is the primary provision governing HCFA on the release of confidential health insurance data. On the provider side, the American Medical Association's Principles of Medical Ethics requires that physicians safeguard confidential patient information within the constraints of the law.

Confidentiality and the Privacy Act will be areas that HCFA must address in the concept development and design phases of MTS and other EDI and paperless processing systems. We will be looking at HCFA's treatment of the issues of privacy and confidentiality as part of our ongoing reviews of EMC/EFT implementation and MTS and in our future reviews of MMIS and PRO systems internal controls.

INTERNAL CONTROLS

Section 2 of the Federal Managers' Financial Integrity Act (FMFIA), among other things, addresses the adequacy of management controls over operations and specific requirements for controls to safeguard assets against waste, fraud, and abuse. The OMB Circular A-123, "Internal Control Systems," prescribes policies and standards for executive departments to implement Section 2 of the FMFIA by setting up, maintaining, testing, improving, and reporting on internal controls in their program and administrative activities. Also, each agency is required to report any material weaknesses in the agency's systems of internal controls and the planned actions for correcting such weaknesses.

We have had concerns with HCFA's application of FMFIA with respect to Medicare contractors because it has not performed reviews sufficient to assure itself that the Medicare contractors have adequate internal control systems. Our position has been and continues to be that we are concerned with the lack of review of contractor controls under the FMFIA and in the future this could impact on the positive assurance with respect to FMFIA that HCFA is expressing to the Secretary of HHS. Furthermore, various Medicare contractors have previously taken the position that their EMC departments are proprietary and should not be the subject of audits.

The HCFA acknowledges that the adequacy of HCFA's management controls over operations is an ongoing issue between HCFA and OIG and is the subject of extensive reviews by OIG. We believe that this issue exists due to HCFA and OIG having different philosophy and ways of performing internal control reviews. However, HCFA is aware of the importance of internal controls and evaluation activities in the area of EDI and welcomes the OIG's additional thoughts or recommendations that would strengthen its operations. Furthermore, HCFA is currently developing a plan to review the internal controls and systems of contractors for compliance with the FMFIA. Because these reviews have not taken place, it is unknown whether adequate controls do exist. Absent reviews of internal controls, no material internal control weaknesses have yet been reported. Consequently, the degree of trustworthiness and reliability of Medicare contractor systems in general, and especially their EMC/EFT systems, is a significant concern.

During the course of our ongoing review of HCFA's implementation to date of EMC and EFT in Medicare, we will evaluate the sufficiency of internal controls over Medicare EMC/EFT processing. Our objective is to determine the level of reliability of claims data and accountability of providers. We will obtain and analyze all Federal policy requirements relating to HCFA's application controls over Medicare electronic billing and payment. We will identify any deviations between HCFA's current set of controls and these Federal requirements. And, we will develop and analyze an applications controls matrix to identify high risk areas. Then, we will use the results of this analysis to determine if HCFA has noted any deficiencies and taken action to address them.

AUDITS AND CERTIFICATION

In the past, most audit interest has been focused on the main line processing systems at the Medicare contractors where most of the claims were received in paper form, keyed into electronic formats, edited, and processed through payment. With Medicare EMC being used for claims submission of an ever increasing percentage of claims and with increased use of EFT and electronic remittance notices (ERN) for payment, greater focus must be placed on systems at the provider level. Also, intermediaries and carriers typically use the same departments for Medicare EMC/EFT/ERN as they do for support of their "private side" operations. While these departments may not have been the focus of prior audit work because of the proprietary nature of their activities, they must be included in future work because their activities are integral to Medicare claims processing.

Contractor Audits

The Medicare contractors are responsible for assuring that claims submitted from providers are accurate and justified. This responsibility extends to insuring that provider-based systems used to submit claims electronically operate in a manner consistent with HCFA policies and instructions and in accordance with any additional requirements established by the servicing Medicare contractor.

In the claims processing market today, there are a variety of provider-based systems and external clearinghouses that may be used for EMC. Installation and operation of these systems at the provider level, however, is the responsibility of the individual provider. To fulfill their responsibilities, therefore, Medicare contractors need to ensure that provider-based systems not only operate as intended, but also are governed by sufficient internal controls to assure adequate system and data security, system backup, and availability of supporting documentation.

Because of the large number of low-volume Medicare providers (e.g., individual physician practices), the wide range of systems that providers may use and the variety of environments in which the providers operate these systems, the resources needed by the Medicare contractors to audit provider-based EDI and paperless processing systems on a 100 percent basis are likely to be prohibitive. Furthermore, our ongoing reviews of Medicare contractors suggest that funding for basic payment safeguard activities is so limited that the adequacy of selective audits of provider systems by their servicing Medicare contractors is problematic.

Our primary concern, therefore, is the appropriateness of the criteria used by the Medicare contractors to select specific provider systems for audit and how well such audits are coordinated with other contractor activities requiring on-site reviews at provider locations.

This issue is not being addressed specifically as an objective in our ongoing review of EMC/EFT implementation in Medicare. Rather, it will be addressed in the context of the compliance by the Medicare contractors with HCFA's requirements affecting EMC/EFT in the areas of:

- The solicitation and maintenance of provider attestations and certifications.
- The issuance of instructions to providers on record keeping in support of claims submitted.
- The establishment and maintenance of Medicare fraud and abuse programs.

Interim Certification

As noted above, the resource requirements to audit provider-based systems are likely to be so substantial that any audits of these systems by the Medicare contractors is problematic. The issue of systems certification, therefore, increases in importance.

Systems certification is recognized in HCFA's EMC strategy as a tool for providing some assurance that electronic billing systems used by providers meet basic industry and government standards. The HCFA has already established a two-tier list of sources for EMC packages: one list for sources meeting basic requirements; the other, a "select" list meeting more stringent requirements. There is no requirement, however, that providers use only those sources on the "selected" list.

Furthermore, many providers use external billing services and/or claims clearinghouses, either in conjunction with, or instead of, provider-based EDI and paperless processing systems. The HCFA does not appear to have addressed how such sources should be certified, either individually or in conjunction with any systems which the providers may use in conjunction with them.

As part of our ongoing review, we will obtain and analyze sufficient information to determine whether the maintainers and operators of EMC/EFT systems used in Medicare are in compliance with HCFA's requirements for systems certifications and testing.

Program Safeguards

As Peter Weiss, a governmental expert on EDI, noted in a recent paper,[9] trustworthiness and reliability of EDI systems are criteria critical to ensuring the suitability of electronic data as evidence in a court of law. Also, conformance with Federal requirements for systems security (including the Computer Security Act, Privacy Act, and OMB Circular A-130 systems security requirements) with respect to data and access security is essential if EDI systems are to be certified as "trustworthy and reliable."

This issue is being addressed as a specific objective of our ongoing review of EMC/EFT in Medicare. We will determine whether the EMC/EFT systems maintainers and operators are in compliance with HCFA's requirements in the areas of access and data security as well as the system. We will also review HCFA's requirements for, and contractor's compliance with procedures to identify those who

[9] "Security Requirements and Evidentiary Issues in the Interchange of Electronic Documents: Steps Toward Developing a Security Policy" presented at the Workshop on Security Procedures for the Interchange of Electronic Documents, National Institute of Standards and Technology, November 12-13, 1992.

input data, as well as those who use the data. We will likewise determine if HCFA's requirements are adequate and are being complied with for periodic certifications and maintenance of a chain of custody as the data move from user to user are adequate.

Compliance with Circular A-127

The OMB Circular A-127 addresses compliance with Section 4 of the FMFIA and includes requirements for reviews of systems which collect, process, and use financial data. Recently, this circular has assumed greater importance because it is one of the primary sources of criteria for determining whether an agency's financial systems can provide reliable data for use in preparation of financial statements, as called for under the Chief Financial Officer's Act.

In Medicare, among the data most critical to financial management are claims and claims payments; however, HCFA, to date, has not included Medicare contractor systems in the scope of their financial systems reviews program because these systems do not feed data directly into HCFA's general ledger accounts. Thus, the extent of compliance of EMC/EFT systems at the Medicare contractors and EDI and paperless processing systems at participating providers with the criteria for reliability of financial data established under A-127 is uncertain, at best.

This issue is being covered in part by our ongoing review of MTS and related EDI and paperless processing initiatives. This review will address whether the HCFA has an overall strategic plan for the development and implementation of the proposed MTS and the migration to increased use of EDI and paperless processing. And, if HCFA does have such a strategy, we will determine the degree to which this strategy is based on analyses called for under OMB Circular A-127 (financial management), as well as under OMB Circular A-123 (internal controls) and A-130 (IRM/systems security).

CONTRACTOR CONFLICT OF INTEREST

The HCFA and the OIG have become aware of allegations that certain contractors refuse to cooperate with some billing services which wish to submit Medicare claims electronically. The HCFA has forwarded instructions to the contractors requiring that third party software be made available to the providers. Compliance with these instructions still needs to be tested.

Even though this area was studied in an OIG Management Advisory Report dated July 1992, the following issues will need further review:

- Are Medicare contractors selling EDI and paperless processing systems (hardware and software) with an unfair competitive advantage and therefore in violation of antitrust law?

- Is there a conflict of interest with the contractor marketing EDI and paperless processing systems to providers and then being required to audit and look for problems in these systems?

The OIG has performed a limited review of four Medicare contractors (three intermediaries and one carrier).[10] This review found that the four contractors appeared to comply with the requirements of Transmittal 1507 regarding the timeliness with which contractors fill requests for lists of edits. It found that the three intermediaries refused to accept direct computer-to-computer EMC submissions for their private line of business unless the provider uses their subsidiary's software for the transaction. Finally, it found that the practice of requiring billing services and health care providers to use the contractors' for-profit subsidiaries may violate Federal antitrust laws.

Because the growth in the use of EDI and paperless processing, its emergence as a major issue in health care reform, and the involvement of Medicare contractors in proprietary market-driven ventures, the OIG needs to pursue the conflict-of-interest issue. We will address Medicare contractor compliance with HCFA's current EMC instructions as part of our ongoing review of EMC/EFT implementation in the Medicare program. We plan to address the longer term issue of contractor conflict of interest in our review of MTS and related EDI and paperless processing initiatives, and as part of our continuing work in the area of Medicare secondary payer.

VALID CONTRACTS

In order to be able to create valid contracts under EDI systems, payers (including HCFA) and providers must recognize that information that is created, transmitted, or stored in electronic form does satisfy the legal requirements regarding a written signature the same as information that is recorded on paper. But, they must also recognize that appropriate security techniques, practices and procedures must incorporated into EDI systems before electronic contracts can be considered valid.

The GAO has addressed this issue in their December 13, 1991 decision memorandum, "National Institute of Standards and Technology -- Use of Electronic Interchange Technology to Create Valid Obligations." The GAO prepared this memo in response to a request by the Computer Systems Laboratory, National Institute of Standards and Technology (NIST). The NIST asked GAO if Federal agencies can use EDI technologies, such as message authentication codes and digital signatures, to create valid contracts consistent with 31 U.S.C. Section 1501. Section 1501 establishes the criteria for recording obligations against the government. The GAO concluded that government agencies can create valid obligations by using EDI systems which meet NIST standards for security and privacy.

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[10] Management Advisory Report, "Electronic Media Claims and Contractors' For Profit Subsidiaries," OEI-12-91-01410, July 1992.

A remaining question in this area is whether EDI systems being used by the Medicare contractors and the providers meet the NIST standards for security and privacy. We will determine the degree of compliance of current and planned Medicare requirements with NIST standards as part of our ongoing reviews of EMC/EFT and of MTS and related EDI initiatives.

LEGAL USE OF INFORMATION SUBMITTED

Provider Agreements

The integrity of the Medicare and Medicaid programs depend upon monitoring the submission of claims and ensuring provider accountability. Consequently, this issue affects OIG investigations and prosecutions of suspected fraudulent or abusive providers. Clear and uniformly enforceable provider agreements are necessary in order to hold providers personally responsible for every claim submitted and to provide sufficient evidence for prosecution of fraud.

Two recent court cases provide evidence that provider agreements may well become an issue in future court proceedings. In United States v. Mostaan, the defense claimed that the computerized claims lacked proper certification that the provider submitted claims only for services actually rendered by provider or an employee under the provider's supervision. The Government survived a defense motion for acquittal. In United States v. Lofton, the Government could not introduce medical records because of another certification problem. The case was eventually dismissed by the Court on other grounds.

The volume of claims involved in EDI applications such as Medicare EMC means that there may not be any certification by a provider that he or she has rendered services submitted for reimbursement. If provider agreements do not have uniform form and content, program integrity will be jeopardized and cases will be difficult to prosecute.

According to a HCFA memorandum on EMC (written in July or August 1992), in order to submit claims via electronic media, a provider must first receive Automated Claims Input Authorization. This requires the provider to sign an agreement with the contractor. Any agreement signed between the provider and the contractor must establish clear guidelines for the handling of claims, as well as the assumption of responsibility for the completeness, accuracy and truthfulness of all claims submitted via electronic media.

The memo indicated that HCFA has not yet standardized provider agreements, but has established guidelines which have "standard key elements" for agreements (Blue Cross/Blue Shield Medicare Agreement was attached as a model, but is a 1984 form). No certification of accuracy or statement of liability is required.

The HCFA memo stated that most agreements require the provider to maintain all original source documents and medical records pertaining to any particular Medicare claim for at least 6 years following the month of payment.

The HCFA welcomes the OIG's review of the standard EMC agreement currently being developed by HCFA. The OIG plans to review provider agreements and determine if they are adequate for ensuring accountability. This includes the responsibilities of all parties in the EDI environment and the ownership of and responsibility for Medicare and Medicaid data at each point in the data flow.

Chain of Custody

Prosecutors must prove who had custody and control of claim documentation at each step of the billing process in order to successfully prosecute providers for fraudulent or abusive claims. A valid "chain of custody" will establish who was responsible for generating and storing electronic records. Record custodians must be able to account for each link in the chain of events involved in producing the records. Should the Government fail to meet this challenge, it likely will be unable to introduce critical evidence.

According to the HCFA memo, no audit requirements exist for reviewing documentation, validation, or electronic transmission flows; nor for reviewing screens, edits, or internal controls. No requirements exist for assessing system security; nor for reviewing cases for service appropriateness, or for analyzing charges and costs for services provided.

The memo indicated that (at least as of mid-1992) audits are not conducted for bills submitted electronically. The HCFA requires an annual "verification" for Medicare Part B EMC. However, with approved plans, contractors may extend the annual cycle for verification of provider records. The standards require that the contractor review a random sample of one percent of provider-submitted EMC. The verification is narrow in focus. The purpose of the review is to establish that documentation for EMC is on file and is equivalent to that provided on a hard copy claim (a patient record exists, patient and physician signatures are on file, and other support documentation is available).

Based on the above information, the audit requirements do not ensure that a valid chain of custody has been maintained at each step in the system.

As the HCFA paper recommended, some procedures should be developed to identify each individual systems operator to avoid diffusion of responsibility, thereby making it easier to hold a particular provider accountable. Furthermore, stringent audit requirements should be developed to mandate review of internal controls and systems security.

Adequate systems safeguards are necessary to ensure that data is not misused or lost, and that unauthorized persons cannot access it. Since the sensitive information involved in EDI and paperless processing is subject to considerable fraud and abuse, it must be properly protected to ensure provider accountability and thus be useful to investigations and prosecutions.

Attestation and Originator Authentication

Attestation and originator authentication must be established to show provider accountability and thus are important evidentiary items in investigations and prosecutions of suspected fraudulent or abusive providers. Technological advances may create new efficiencies in this. Among the issues of interest to the OIG are:

- Are there better methods to verify "attestation" (i.e., acknowledgment of a submission by a provider) or "originator authentication" (i.e., assurance that the source of the message is the named originator and not some other entity) when using personal identification numbers (PIN)?

- Has EDI technology advanced far enough to allow HCFA to consider fingerprinting (electronically read thumb prints) and retina scanning as forms of electronic signatures?

As part of its review of provider accountability, the OIG will assess whether Medicare and Medicaid systems allow for proper attestation and originator authentication.

Maintaining Audit Trails

Lack of hard copy Medicare claims may adversely affect OIG's ability to establish provider accountability (i.e., who submitted what claim and when, who received the claim, and whether the claims accuracy can be verified). Without the necessary documentation, the Government will be unable to prove fraud or abuse since a provider may contend that "I never reviewed the claim data." Unless providers are required to retain hard copy of claims,
meaningful review which ensures provider accountability may not be possible. On the other hand, retention of hard copies of claims may negate or reduce some of the benefits of moving to electronic submission of claims.

A regulation issued by the National Archives and Records Administration, "Requirements for the Management of Electronic Records," 36 CFR Part 1234, states that electronic records may be admitted in Federal court proceedings if trustworthiness is established. Some of these requirements should be incorporated by HCFA to help ensure that EMC data will be admissible in Federal Court.

Further, it is generally recognized that the need for accounts reconciliation, periodic audits, and recovery from emergency/disaster situations in an EDI and paperless processing environment, where no paper records may be generated, necessitates the

establishment of a suitable electronic audit trail. With respect to Medicare EMC/EFT/ERN, specific requirements for this audit trail should be based on considerations of legality (e.g., covering time frames consistent with the statue of limitations), audit cycles, structure of the overall Medicare claims process (i.e., consideration of the number of separate internal control areas), and technology (e.g., electronic media can experience degradation of data quality after no more than 2-3 years of storage without use).

In the course of our work in reviewing implementation of EMC/EFT in Medicare, we will determine whether the EMC/EFT maintainers and operators are in compliance with HCFA's requirements for audit trails and related processing controls, as well as with requirements covering instructions to providers on record keeping to support claims submitted.

CONCLUSIONS

BASIS FOR REPORT

This report is in response to the Health Care Financing Administration's (HCFA) briefing for the Office of Inspector General (OIG) personnel on electronic data interchange (EDI) and paperless processing issues and its request for more information on the OIG's concerns and plans.

ISSUES

This document has identified numerous issues and goals related to HCFA's use of EDI and paperless processing technology. Issues related to the overall strategy of the EDI and paperless processing initiative concern the development of systems such as the Medicare Transaction System, and the further development and use the Medicaid Management Information Systems, and the point-of-service claims management systems under Medicaid. These systems will allow HCFA to process electronically submitted claims and manage information more efficiently. In order to facilitate the electronic flow of claims, patient, and reimbursement data between providers, payers, and quality-of-care reviewers, HCFA must require standardization. To encourage providers to submit claims and patient data electronically, HCFA must eliminate not only barriers to provider participation, but also develop incentives. Various companion technologies, such as smart cards for computerized patient identification and medical records, and national data communications networks for transmission of health care data, will need further development. Additionally, HCFA's overall strategy must encourage HCFA's information resources management program to address Medicare contractor systems and Federal Medicaid initiatives.

This document also raises issues regarding the trustworthiness and reliability of data as it moves from one partner in electronic commerce to another and from one process to another. Issues raised with regard to electronic submission and processing of claims include the requirement that the confidentiality of personally-identifiable health insurance data be strictly maintained and the privacy of patients be protected. In order to address the adequacy of management controls over operations and specific requirements for controls to safeguard assets against waste, fraud, and abuse, internal controls must be reviewed. Audits and the systems certifications must be performed to ensure that all EDI and paperless processing systems are trustworthy and reliable, and that there is no Medicare contractor conflict of interest. For electronic contracts to be valid, they must be in compliance with the contract requirements of the NIST. Finally, HCFA must ensure the integrity of information, through the use of provider agreements, a valid chain of custody, attestation and originator authentication, and proper audit trails.

FUTURE ACTION

Because of the large number of issues and the our limited resources, we cannot possibly examine nor audit all of the issues related to EDI and paperless processing. As part of our oversight function, we plan to analyze all of the various issues listed above for the purpose of preparing our workplan over the next few years. We also recognize that HCFA has particular concerns about making its systems environment less susceptible to fraud and abuse and about the development of approaches for increasing small provider participation in the EDI and paperless processing environment. With respect to fraud and abuse, we are currently in the survey phase of reviewing electronic controls in the Medicare program and with respect to small providers, we are planning to study incentives for and barriers to small provider participation in EDI and paperless processing.

AGENCY COMMENTS

The Health Care Financing Administration (HCFA) commented on a draft version of this report. The HCFA suggested changes in the report to better reflect its activities and those of the Department with respect to EDI and paperless processing, made suggestions about the focus of OIG's work in this area, and gave us technical comments. We have revised our report to address many of HCFA's comments and also provide additional comments on HCFA's response in Appendix B. The full text of HCFA's comments can be found in Appendix A.

APPENDIX A

HEALTH CARE FINANCING ADMINISTRATION COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Date DEC 29 1993

From Bruce C. Vladeck
Administrator

Subject Office of Inspector General (OIG) Draft Report: "Electronic Data Interchange: Issues and Challenges" (OEI-12-93-00080)

To
June Gibbs Brown
Inspector General

We reviewed the subject draft report on electronic data interchange (EDI) issues.

OIG does a credible job in identifying the enormous number of issues, potential problems, and tasks confronting the Federal government, and the Health Care Financing Administration (HCFA) in particular, in moving to a more fully automated environment. We are well aware of the monumental task facing HCFA with the implementation of EDI. We appreciate and share OIG's concerns regarding EDI and believe OIG has an important role in its development and implementation. We look forward to working with OIG in this process. Our comments are attached for your review.

Thank you for the opportunity to review and comment on this draft report. Please advise us if you wish to discuss our response.

Attachment

IG	✓
SAIG	✓
PDIG	
DIG-AS	
DIG-EI	✓
DIG-OI	
AIG-MP	
OGC/IG	
EXSEC	✓
DATE SENT	1-6-94

Comments of the Health Care Financing Administration (HCFA)
on the Office of Inspector General (OIG) Draft Report:
"Electronic Data Interchange: Issues and Challenges"
(OEI-12-93-00080)

General Comments

OIG clearly demonstrates that it understands our goal of evolving Medicare and Medicaid into an all-electronic environment, our plans for achieving this goal, and the barriers that must be crossed before this goal can be realized. However, the report implies that the Department of Health and Human Services (HHS) has not taken a leadership role in the development of computerized patient records. On page 2 of the Introduction and page 10 of the Companion Technologies section, for example, the report does not fully acknowledge HHS' leadership in this area. We think that the report should be revised to reflect the following:

- Establishment of an HHS computerized Patient Records Council to coordinate various Departmental activities and promote HHS leadership in the development of computer-based patient records systems. The council has met twice and will presumably be the focus of HHS activities in this area in the future.

- Partial funding, through the Agency for Health Care Policy and Research, of the activities of the American National Standards Institute's Health Informatics Planning Panel (HISPP). The HISPP is coordinating various standard setting efforts in the area of health informatics. Such coordination is essential to the development of useful computerized patient records.

- Participation in the deliberations leading to the formation of the Computerized Patient Records Institute.

- Participation in the American Hospital Association's Work Group on Computerization of Patient Records. The work group was formed at the request of former Secretary Sullivan and recently released its draft report to Secretary Shalala.

- Establishment of a HCFA Electronic Environment Steering Committee and participation in the Work Group for Electronic Data Interchange (WEDI) and the American National Standards Institute (ANSI), to develop and implement standardization not only between Medicaid and Medicare, but between these programs and all other health care insurers.

We believe the definition of electronic data interchange (EDI) is not fully set forth in the report. As stated in the introduction, EDI is the electronic transfer of data, in a standard format, between trading partners. It should be made clear that EDI relates only to the data that are output from an applications system, e.g., a provider's billing system, and how those data are transported to another applications system, e.g., a contractor's claim payment system. EDI does not apply to how that applications system actually processes the data.

In addition, we believe OIG would be far more effective and helpful to HCFA by focusing its resources on those issues impacting most directly on the potential for fraud and abuse in the Medicare and Medicaid programs (i.e., certifications, accountability, controls, integrity, conflict of interests, contracts, legal use of information, audit trails, and audits). We would welcome OIG's recommendations relative to potential fraud and abuse issues.

Also, we believe OIG has an important role to play in reviewing the sufficiency of our safeguards designed to ensure proper payment. We welcome OIG's review of the standard Electronic Media Claim (EMC) agreement currently being developed. This standard agreement will detail the responsibilities of all parties in the EDI environment, and specify the ownership of and responsibility for Medicare and Medicaid data at each point in the data flow.

Finally, we suggest that OIG, in a separate report, develop the issue of small provider conversion to EMC/electronic funds transfer (EFT). Once EDI reaches a "critical mass," the continued use of manual paper data systems will become increasingly inefficient. In developing incentive or cost-subsidization programs for small providers, consideration should be given to the burden and cost they will create for HCFA if they do not interface with HCFA's electronic system.

The following comments are being offered under the designated headings reflected in the Issues section of the report:

POLICY DIRECTION

Medicare Transaction System (MTS): At the present time, MTS has not addressed the issue of smart card technology. The basic methods of access and entitlement verification are still being reviewed. Medicare and Medicaid program staff have attended the technical advisory group (TAG) meetings of WEDI. WEDI recommended moving away from expensive smart card technology to the use of the data base. This recommendation did not require that users opt for a plastic card for identification. This TAG suggested that we study the use of computerized patient records in our medical review activities.

Medicaid Point of Service (POS) Claims Management Systems: As noted in our comments on a previous OIG report, (Point-Of-Service Claims Management Systems for Medicaid, OEI-01-91-00820, May 1992), we are fully committed to improving the efficiency of the State Medicaid Agency (SMA) Medicaid Management Information Systems operations through standardization and the use of electronic technology. Since this OIG report was issued, eight SMAs have reported implementation of POS systems for pharmacies (including six systems with utilization review capability) with three of these systems being expanded and made available to providers other than pharmacies. Ten additional SMAs are currently developing POS modules for implementation by the end of calendar year 1993, and 21 of the remaining 33 SMAs are considering the development and implementation of POS modules for completion by late 1994.

THE NEED FOR A COHESIVE STRATEGIC SYSTEMS PLAN COVERING EDI

HCFA is moving forward with a strategic planning initiative to streamline, consolidate, and integrate Medicare and Medicaid claims processing, including EDI. Standardizing of systems, providing appropriate incentives, and utilizing companion technologies are critical goals and objectives of this initiative.

POLICY IMPLEMENTATION

Internal Controls on EDI: This is an ongoing issue between HCFA and OIG regarding the adequacy of HCFA's management controls over operations and the subject of extensive reviews by OIG. We perform reviews deemed sufficient to ensure that the Medicare contractors and SMAs have adequate internal controls. In the course of our oversight activities, we review many of the procedures and processes (i.e., internal controls) followed by the contractors. These oversight activities are performed by both central office and regional office staffs. We perform reviews that are formal and repetitive in nature, and which are used to evaluate performance. There are many other reviews and contacts that are less formal which arise to address specific issues. In both cases, HCFA is aware of the importance of internal controls and evaluation activities in the area of EDI.

Data Safeguards: Any electronic data exchange system must safeguard access to the system itself in order to protect the data within. This requires us to identify those who input data, as well as those who use the data, and it also requires periodic certifications and maintenance of a change of custody as the data move from user to user.

In both of the above areas, HCFA is aware of the importance of internal controls and evaluation activities in the area of EDI. We welcome OIG's additional thoughts or recommendations that would strengthen our operations.

Electronic Funds Transfer (EFT): On page 8, The HCFA Perspective, OIG expresses concern about the changes that have been made in Medicare claims processing as a result of the implementation of Medicare national claims formats and EFT. The EFT systems modifications were made by HCFA's standard system maintainers and consisted primarily of installing the capability to initiate EFT with the Medicare bank. This function required system programming and liaison activities with the Medicare bank to ensure the establishment of proper EFT transmission protocols.

Since contractors initiate EFTs and send these transmissions through the Medicare bank (the Automated Clearing House (ACH)), and ultimately to the provider's bank, every precaution has been taken to ensure the accuracy and integrity of each electronic payment transaction. The contractors, Medicare banks, and ACH operators are bound by strict operating guidelines and Federal regulations concerning the initiation, transmission, and receipt of EFTs. The benefits accounting and reporting functions that occur with EFT transactions mirror those that currently exist under the checks paid method of advancing funds under the Letter of Credit system. Therefore, we do not anticipate that benefit payments made under EFT will be vulnerable to errors and/or fraud.

Specific Comments

Page 9, second bullet point:

> HCFA's goal is to increase the rate of EFT for Medicare payments made to hospitals to 100 percent within 3 years.

HCFA is currently reviewing public comments received in response to BPO-104-PN which was published on January 15. This notice proposes to require hospitals to submit all inpatient and outpatient bills electronically and to receive payments and remittance advices electronically. In response to the many comments urging HCFA to extend the implementation timeframe for BPO-104-PN, we anticipate that hospitals will be given at least 6 months from the date of publication of the final notice in which to comply with its requirements. We anticipate that the final version of this notice will be published no sooner than early in fiscal year 1994.

Page 9, fourth bullet point:

> OIG will determine if HCFA adequately assessed benefits and costs.

The full benefits of EMC and EFT are to be achieved in an integrated and fully interactive claims submission and payment environment. Our estimates of the benefits and costs of EFT have always been conservative and are predicated on the fact that EFT among physicians and suppliers will be implemented at a much slower rate than with institutional providers. Because of the relatively low volume of payments made to institutional providers, we have yet to realize significant cost savings from EFT usage. We anticipate that as the technology spreads throughout the entire provider community, cost savings will increase dramatically.

In a recent OIG report, Electronic Funds Transfer for Medicaid Providers, OEI-01-91-00821, OIG recommended that HCFA assist States in developing billing agreements for providers who use electronic claims, remittance advisories, and funds transfers; and to develop guidelines for provider participation in EFT. OIG agreed to consider conducting an inspection or audit on the benefits and costs of EFT to help HCFA develop guidelines for States.

Page 9, fifth bullet point:

> OIG will determine if HCFA provided adequate instructions, lead time, and resources to the Medicare contractors.

In early 1990, HCFA began exploring EFT technology for the Medicare program. EFT soon became a critical component of HCFA's commitment to establishing a totally electronic billing and payment environment for all Medicare contractors and providers. HCFA provided technical specifications, procedural guidance, and appropriate funding throughout the implementation of EFT. This support continues as increasing numbers of Medicare providers elect to receive payments via EFT.

Page 9, sixth bullet point:

> OIG will determine if HCFA is tracking progress during implementation sufficiently to identify problems and resolve them effectively and in a timely manner.

HCFA has been quite diligent in tracking the progress of contractors, providers, and SMAs in implementing EFT. Staff has worked in conjunction with the contractor community throughout the implementation process. HCFA circulated draft contractor instructions for several months prior to their effective date to ensure that all concerns were taken into consideration in the final product. All problems identified by contractors were addressed in a timely and professional manner.

Technical Comments

- Page 3, last paragraph, fourth line from bottom - replace "transcribe" with "input."

- Page 6, first full paragraph, third line from bottom - remove the word "processing" from the sentence. ANSI formats are for transmission of data, not processing. The "they" used in the beginning of the last sentence needs to be identified.

- Page 6, third paragraph, third line from bottom - it is not clear what is meant ". . . that recordkeeping requirements in the insurance industry as a whole increase paperwork burden . . . ." Doctors need to keep records so that they know what procedures they have performed on patients, and to whom they have referred the patients, etc.

- Page 6, fourth paragraph, fourth sentence - HCFA is not planning to implement an ANSI standard uniform billing form. ANSI is a data transmission standard, not a billing form.

- Page 6, last paragraph, fifth sentence - OIG references specific legislation which would empower national standards organizations to establish mandatory standards for electronic transmission and payment of claims; please provide the bill number and the session of Congress.

- Page 17, Program Safeguards, first paragraph - OIG cites a paper written by Peter Weiss on EDI. Please provide a citation for this paper.

APPENDIX B

OIG RESPONSE TO AGENCY COMMENTS

The Health Care Financing Administration (HCFA) commented on a draft version of this report. The HCFA suggested changes in the report to better reflect its activities and those of the Department with respect to EDI and paperless processing, made suggestions about the focus of OIG's work in this area, and gave us technical comments. We have revised our report to address many of HCFA's comments and also provide additional comments on HCFA's response below.

GENERAL COMMENTS

HCFA Comments

The HCFA believes that the OIG would be more effective and helpful to focus its resources on those issues impacting most directly on the potential for fraud and abuse in the Medicare and Medicaid programs (i.e., certifications, accountability, controls, integrity, conflict of interests, contracts, legal use of information, audit trails, and audits).

OIG Response

The OIG recognizes that these areas are critically important and does plan to address them in our current and upcoming reviews. The OIG believes, however, that the other areas identified in this report also will have a direct bearing on Medicare and Medicaid operational efficiency, controls, and economy, as well as on financial management and reporting. Thus, OIG sees a need to address a broad range of EDI and paperless processing issues in its current and future work plans.

HCFA Comments

Because the continued use of manual paper data systems will become increasingly inefficient, the HCFA has suggested that the OIG, in a separate report, develop the issue of small provider conversion to electronic media claims and electronic funds transfer.

OIG Response

The OIG has developed a workplan item, "Adding Incentives and Removing Barriers to Provider Participation in EDI and Paperless Processing." The purpose of this study is to assess how different providers can be brought into the EDI and paperless processing environment, what barriers exist for providers, and whether HCFA's efforts address those barriers and provide proper incentives for providers.

INCENTIVES AND BARRIERS

HCFA Comments

In response to this report on the issue of HCFA's goal to increase the rate of EFT for Medicare payments made to hospital to 100 percent within 3 years, HCFA indicated that it was reviewing public comments received in a response to its proposed notice published January 15, 1993. This notice was intended to promote the use of standardized electronic billing and payment by hospitals. Since then, HCFA concluded that it had no legal authority to penalize hospitals that fail to comply with the notice. When HCFA withdrew this notice on January 24, 1994, HCFA stated that the hospital electronic media claims submission rates exceeded 90 percent.

OIG Response

The OIG is pleased to see that HCFA has achieved a rate of EFT for Medicare payments made to hospitals exceeding 90 percent, but OIG is concerned about the remaining hospitals that do not participate in the use of standardized electronic billing and payment mechanisms. As we have indicated in this report, we plan to look at provider participation in EFT as part of our review of Medicare claims processing.

APPENDIX C

ACRONYMS USED IN THIS REPORT

ANSI	American National Standards Institute
ATM	automatic teller machine
BPO	Bureau of Program Operations
CHAMPUS	Civilian Health and Medical Program of the Uniform Services
CMN	Certificate of Medical Necessity
CPR	computer-based patient record
CPRI	Computer-Based Patient Record Institute
DME	durable medical equipment
DUR	drug utilization review
EDI	electronic data interchange
EFT	electronic funds transfer
EMC	electronic media claims
ERN	electronic remittance notices
FAMIS	Family Assistance Management Information Systems
FMFIA	Federal Managers' Financial Integrity Act
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Health and Human Services
IOM	Institute of Medicine
IRM	information resources management

MMIS	Medicaid Management Information Systems
MTS	Medicare Transaction System
NIST	National Institute of Standards and Technology
OBRA	Omnibus Budget Reconciliation Act
OIG	Office of Inspector General
PIN	personal identification numbers
POS	point of service
PRO	Peer Review Organization
SMA	State Medicaid agencies
WEDI	Workgroup for Electronic Data Interchange