DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

SMDL #02-005

April 4, 2002

Dear State Medicaid Director:

The purpose of this letter is to provide you with assistance in your on-going activities to implement the Health Insurance Portability and Accountability Act's (HIPAA) Administrative Simplification (A/S) provisions. Guidance on submitting a compliance plan to obtain a one-year delay in the compliance date until October 17, 2002, for the HIPAA Transaction Rule was sent in a separate letter (SMD #02-003) dated March 7, 2002.

Enclosed with this letter are two sets of documents. One is titled "Electronic Data Interchange Transaction: HIPAA Readiness Checklist." The other is a model Advance Planning Document (APD) designed to help expedite your requests for enhanced Federal financial assistance relative to HIPAA-related changes to your Medicaid Management Information System.

HIPAA READINESS CHECKLIST

This checklist was designed by experts to assist states in cataloguing the actions they have taken, and those they plan to take, to become HIPAA compliant. It provides a set of useful benchmarks that can help gauge the degree of progress you have made to date, and the activities still remaining to be undertaken or completed. This is a self-assessment tool designed specifically by and for state Medicaid agencies. Should anyone on your staff need assistance regarding its use, they should contact their respective regional office Medicaid systems lead or Henry Chao, here in Baltimore, at (410) 786-7811, hchao@cms.hhs.gov.

MODEL ADVANCE PLANNING DOCUMENTS FOR HIPAA

Use of the enclosed model APD should significantly shorten the traditional APD process. Its use is completely voluntary but we believe it will help focus both of our efforts on the most important issues which need to be aired. It was designed with the help of state system staff who have had considerable experience in submitting APDs in the past, and we think this is a faster, better way to achieve mutually satisfactory results relative to systems changes needed under HIPAA.

In all, this package contains the following documents:

- Attachment A: An APD Guidance Document. This document provides details on the APD process, and appropriate sections of the regulations.
- Attachment B: Appropriate sections of Part 11 of the State Medicaid Manual (SMM) provide detailed information on allowable costs.
- Attachment C: Model HIPAA Planning APD
- Attachment D: Model HIPAA Implementation APD
- Attachment E: State Medicaid Director letter dated December 5, 1995 clarifies policy regarding sole-source procurements.

If your staff has any questions regarding the enclosed documentation, please have them contact your MMIS representative in your regional office, or Jason Goldwater of my staff, at (410) 786-0476.

Sincerely,

/s/

Dennis G. Smith
Director

Enclosures

cc:
CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

State Chief Information Officer

State HIPAA Coordinator

William Davis
Acting Director, Division of State Systems Policy
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Joy Wilson
Director, Health Committee
National Conference of State Legislatures

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Association of State and Territorial Health Officials

Matt Salo
Director of Health Legislation
National Governors Association

Trudi Matthews
Senior Health Policy Analyst
Council of Governments

Technical Support Services
for the Medicaid
HIPAA-Compliant
Concept Model
(MHCCM)

HIPAA EDI Transaction Risk Assessment Checklist

(For State Self-Assessment)

February 12, 2002

Prepared for:
Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations
7500 Security Boulevard
Baltimore, MD 21244 – 1850

HIPAA EDI TRANSACTION RISK ASSESSMENT CHECKLIST
(STATE SELF-ASSESSMENT)

The risk assessment checklist is provided as a self-assessment tool to allow States or agencies to gauge where they are in the overall picture of HIPAA implementation. This checklist is intended to be used by the HIPAA Coordinator, HIPAA Project Lead, or other key agency representative in the State, Medicaid agency, or other agency. Use of this checklist is voluntary; it is intended to assist the agency and is not required to be submitted to CMS.

The Yes column following each item can be checked if the person completing it can respond positively to the question (i.e., the item is completed or in progress). The Yes column can also be checked if adequate resources and planning have been allocated for future efforts. If these criteria are not met, the No column should be checked. Two critical parameters often appear in the question sets. The first addresses whether a thorough analysis was performed resulting in a clear understanding of the task in question. The second addresses whether a firm commitment of specific allocation of funds and/or resources exists to accomplish the task.

There are no official score sheets or right or wrong answers; the list of questions is provided as an aid to help establish a barometer of progress and highlight work still needing to be accomplished. The list is also intended to provide ideas on areas that States or agencies may not have considered in their project efforts toward HIPAA compliance. It is in the organization's best interest to answer the questions as honestly and accurately as possible. The HIPAA Project Lead or HIPAA Project Coordinator is usually in the best position to provide accurate answers to the questions and can act as the best judge of the status of each project area in the checklist.

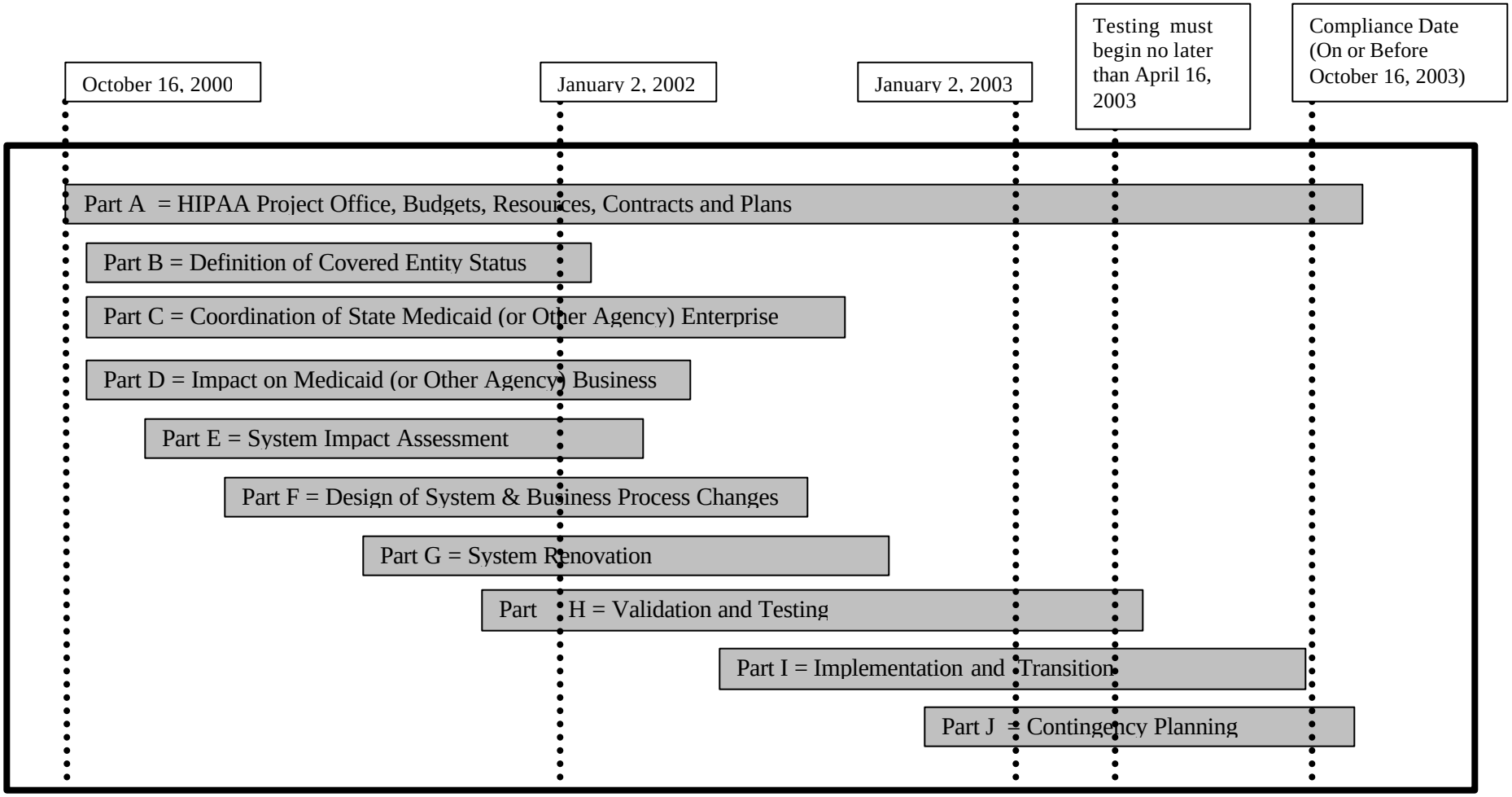
Each question for which a No answer was supplied should be examined, and the reason for which No was given should be understood. If, in fact the No answer is proper for the activities required to become HIPAA compliant, it need not be considered further and N/A can be put in the answer boxes. The checklist is intended to serve as a tool for identifying areas of risk. Every No answer remaining after the analysis is an indication of an area of risk. The more remaining Nos, the higher the risk for achieving HIPAA compliance. In general, the project is at low risk if the answers are mainly Yes or N/A. However, even in the case of many No responses to the questions, this checklist is not intended to give the impression that the organization is not going to successfully achieve HIPAA compliance. It should allow better focus of organization efforts in the time remaining until Oct. 16, 2003.

Please be aware that this checklist only applies to the Transaction Standard – Rule 1. Rule 2, Privacy, must also be implemented in this time period. Activities pertaining to Rule 2 are <u>not</u> included in this checklist.

The timeline graphic is based on the GAO guidelines for project implementation. It illustrates the overlapping of project phases and activities and the overall chronology of project activity. The timeline also provides comparison dates of January 2, 2002 and January 2, 2003 to provide a general indication of where each organization should be in the project timeline. This is a depiction of an "ideal project". Roughly, a HIPAA Project can correlate its own timeline to this one by aligning its actual start date with this timeline's start date (October 16, 2000) and then comparing its tasks and activities with the timeline for the 10 defined project areas (A-J).

Sources for useful HIPAA-related information are suggested in some of the checklist items below (CMS white papers can be found at either WWW.MHCCM.ORG or WWW.CMS.GOV). In addition, white papers on the WEDI-SNIP website (SNIP.WEDI.ORG) and the State NMEH representative can provide more information.

PLOTTING THE PROJECT TIMELINE



HIPAA EDI TRANSACTION RISK ASSESSMENT CHECKLIST – State Self-Assessment

Checklist Contents

	Page
Part A – HIPAA Project Office, Budgets, Resources, Contracts and Plans	**3**
Part B – Definition of Covered Entity Status	**5**
Part C – Coordination of State Medicaid (or Other Agency) Enterprise	**6**
Part D – Impact on Medicaid (or Other Agency) Business Processes	**7**
Part E – System Impact Assessment	**8**
Part F – Design of System and Business Process Changes	**10**
Part G – System Renovation	**10**
Part H – Validation and Testing	**11**
Part I – Implementation and Transition	**12**
Part J – Contingency Planning	**13**

Part A – HIPAA Project Office, Budgets, Resources, Contracts, and Plans

1. HIPAA Project Office (HPO) Established

*HPO can be statewide, agency or department specific. Responsibilities, structure, schedule, tracking, and reporting set up. For guidance, read the CMS paper "*GETTING ORGANIZED FOR HIPAA: *States' Best Practices for Scaling Mt. HIPAA"*

	Yes	No
Is an HPO established?		
Does the HPO have a written charter and a defined role?		
Does the HPO have support at the highest State executive levels?		
Is there a current Organization chart and Charter document?		

2. HIPAA Budgets, Resources, And Contracts

Resources identified and available

	Yes	No
Are the HIPAA budget requirements known in detail?		
Are the needed APDs submitted and approved for HIPAA?		
Is there a resource plan?		
Are the staffing requirements assessed for the entire project?		
Are staffing resources available when needed?		
Does the HPO have a firm commitment of resources and staff to meet the requirements?		
Are all necessary RFPs for resources and staff completed?		
Are contracts in place for additional resources and staff?		
Are contracts in place for needed software (translators, for example)?		
Are other needed services and support contracts in place?		

3. State or Agency HIPAA Plan

Overall State plan should include State agency coordination. May need sub-plans for specific areas, associated offices or subordinate departments (Project Management, Status/Tracking, Testing, Risk Management, Configuration Management, QA/QC, Contingency Planning, etc.) For help on the format and contents of system and software development related plans, see the IEEE Software Engineering Standards at WWW.IEEE.ORG. Lots of good software management related information, including Risk Management, is available from the Software Engineering Institute at WWW.SEI.CMU.EDU.

	Yes	No
Is there an overall State or Agency (or comparable) HIPAA plan?		
If needed, are there individual department plans?		
Are reasonable timelines established for critical activities?		
Are specific individuals responsible for updating the plan?		
Does the plan include outreach activities?		
Is there a plan for implementation of future HIPAA rules (NPI, Transaction Version Changes, Plan ID, Claims Attachments)?		

4. Scheduling and Tracking Project Activities

Tracking individual plans & schedules for renovation effort

	Yes	No
Do HIPAA schedules define tasks and milestones, indicating responsible entities and dependencies?		
Is there a process and tools to support maintaining HIPAA project plans and schedules?		
Do all departments, divisions, and units report to the HPO on HIPAA progress?		
Is there periodic Executive level review of progress and deadlines?		
Has a request for a one-year implementation delay been submitted (by Oct 16, 2002)?		

Part B - Definition of Covered Entity Status

5. Definition of Covered Entity Status

*Definition of Medicaid covered entity status and its relationship to other State agencies (Depts. of Health, Mental Health, Aging, etc.). For guidance, read the CMS paper "*ARE YOU A COVERED ENTITY? *And When Does Rule 1 Apply?"*

	Yes	No
Has the Medicaid State agency defined its own Covered Entity boundaries?		
Have any exempt components been identified?		
Does the agency have any components, (e.g., Provider role, Clearinghouse role, or Sponsor role) which would qualify it as another type of Covered Entity?		
Does the Medicaid agency know the Covered Entity status of the other State agencies with which it does business?		
Does the HIPAA Project Plan cover all relationships?		

Part C – Coordination of State Medicaid (or Other Agency) Enterprise

6. Outreach To Trading Partners

*Inclusion of the State Medicaid Enterprise. For guidance, see the CMS paper "*OUTREACH TO DATA TRADING PARTNERS*: "You're OK, I'm OK""*

	Yes	No
Does the agency have an Outreach Plan?		
Is the execution of the plan on schedule?		
Have issues related to testing with Partners been identified and resolved?		
Have transition issues been identified and resolved?		
Has the MHCCM (Medicaid HIPAA Compliant Concept Model) Enterprise Perspective been used to verify that all trading partners are included?		

7. Provider Survey

Provider readiness indicator

	Yes	No
Has a survey been sent to providers to determine their HIPAA readiness?		
Has the potential EDI volume been determined?		
Is the system able to handle all incoming data via all routes of data submission?		

8. Inventory Of Data Exchange Partners And Data Exchanged

All covered exchanges should be known and classified as to transaction type

	Yes	No
Was the Y2K inventory of data exchange partners and data reviewed and used as a starting point?		
Have the inventories been updated for HIPAA?		
For covered entities, have the data exchanges that require the use of standard transactions been identified?		
Is the opportunity to use any non-mandated standards (277 unsolicited, 275, 997) being considered?		

9. Trading Partner Agreements

Assuring that Trading Partner agreements are updated for HIPAA

	Yes	No
Have trading partner and Chain of Trust agreements been developed?		
Was a model agreement used?		
Was legal counsel involved in developing the contract language?		

10. Business Associate Agreements

Assuring Business Associates are doing what is needed for compliance

	Yes	No
Have all business associate contracts been examined in light of the Transaction rule?		
Are all needed parts of these contracts rewritten to ensure HIPAA compliance?		
Was a model contract used as an example?		
Was legal counsel involved in developing the contract changes?		

Part D – Impact on Medicaid (or Other Agency) Business Processes

11. Business Process Identification, Review, And Re-Engineering

Assessed for HIPAA impact, prioritized for re-engineering (requiring changes in policy, procedure, training and use of data) and for contingency planning

	Yes	No
Have the business functions been inventoried?		
Has the inventory been verified against the business functions identified in the MHCCM Operations Perspective?		
Have the business processes been assessed for HIPAA impact?		
In particular, has the electronic availability of eligibility determination been assessed to determine required changes in day-to-day operations?		
Have the processes been prioritized for re-engineering?		
Have the processes been prioritized for contingency planning?		
Are specific plans in place for critical/top priority business processes?		
Can all impacted business processes be ready by the transition date?		

12. HIPAA Standard Code Sets (Loss of Local Codes)

Identification and decisions on how to implement new standard codes, how to live without local codes, impact on systems which use local codes, impact on business processes. For guidance, see the CMS paper "DATA CONTENTS AND CODE SETS: *The Devil is in the Details"*

	Yes	No
Has the impact of the loss of local codes and adoption of standard codes on business processes been assessed?		
Has the impact of the loss of local codes and adoption of standard codes on systems been assessed?		
Can required legal and policy changes to support the loss of local codes be implemented in a timely manner?		
Have needed requests for code set changes been submitted and coordinated with the NMEH sub-workgroups (local codes, taxonomy, prior auth, EOB, etc.)?		
Is the impact that switching to standard codes will have on policies, procedures, retraining of staff, and communication with providers known?		

Part E – System Impact Assessment

13. System Assessments

Gap analysis, inventory of files, mapping of X12 transactions to internal formats, COTS analysis. See the MHCCM Toolkit for mapping and gap analysis support tools.

	Yes	No
Has a Gap Analysis been performed?		
Have mandated standard HIPAA transactions been mapped (270, 271, 276, 277, 278 request, 278 response, 820, 834, 835, 837, 837 COB)?		
Have all non-mandated X12 transactions that are planned to be implemented been mapped (e.g., 277 UNSOLICITED, 275, 997)?		
Have all affected system components been identified?		
Has system assessment been completed?		

14. Input Modes

Fax, paper, file, DDE, web-based, etc. – assure data elements available for later standard transactions, strip and store (data element storage for later use) issues

	Yes	No
Have all modes of input for all types of transactions been identified?		
Has a plan been developed to maintain or implement each type of input?		
Has the Medicaid position regarding all modes of input including DDE, web, etc. been documented?		
Have these positions and approach(es) been communicated to providers and other data trading partners?		
Has the completeness of the impact assessment been verified by using the MHCCM Operations Perspective section on Claims Submission?		

15. Systems Interfacing With The MMIS

All systems that interface with the MMIS evaluated for impact. How to merge data from new and old claims. How to handle data warehouses with mixture of data types, etc.

	Yes	No
Is there a master systems architecture diagram for the Medicaid enterprise?		
Does it include all the points of data exchange that may be impacted by HIPAA formatting or data standards?		
Have all interfacing systems been assessed for HIPAA impact?		
Are plans complete for the necessary modifications to the other systems?		

Part F- Design of System and Business Process Changes

16. Solution Designed

For MMIS and all other impacted systems – translation or clearinghouse decided upon. Access to historical claim data considered.

	Yes	No
Has an overall approach to achieving compliance been decided upon and documented?		
Has the design of the compliant system been completed?		
Have needed software and system changes been detailed?		
Has a cleanup of master files (insurance, employer, provider, patient, etc.) been planned to insure error-free conversions of the data?		
If a translator and/or a clearinghouse are part of the solution, are their roles clearly and completely defined?		
Are strip and store (data element storage for later use) needs defined?		

Part G – System Renovation

17. System and Software Solution Renovations

MMIS modifications, translator, and clearinghouse interfaces developed & installed. Other Medicaid systems and SW renovations done.

	Yes	No
Is there a schedule for design, development, and implementation?		
Are the system renovations prioritized?		
Is there a QA/QC function incorporated into the renovation process?		
Are the system renovations complete?		

Part H – Validation and Testing

18. Test Plans

Test schedule, Test environments ready. For guidance on testing, read the CMS paper "Testing! Testing! Do You Read Me?"

	Yes	No
Is there an overall plan for testing?		
Does the test plan include translator, clearinghouse, provider and all other data exchange interfaces?		
Does the test plan include a representative sample of all data exchange partners?		
Does the plan provide for preparation and scheduling of a test facility or separate test environment?		
Is there a plan to certify the correctness of input/output systems?		
Is it planned to require that EDI providers demonstrate they have successfully tested?		
Is there a plan to certify EDI submitters?		

19. Testing

Testing of Renovated Software and Business Processes

	Yes	No
Is the use of a separate testing facility planned?		
Is there a test environment separate from operations?		
Is there an automated way to generate sample test data?		
Is there an automated method for running tests?		
Does the testing process include unit, system, integration and regression tests for all system changes?		
Do the planned tests address the following 6 levels of WEDI recommended testing: 1) Integrity testing 2) Requirements testing 3) Numerical Balancing testing 4) Situation testing 5) Code Set testing 6) Type of Service/Product Type testing?		
Is there a system in place to record, prioritize and track test failures through to correction and retest?		
Is there a QA/QC function incorporated into the testing process?		

Part I – Implementation and Transition

20. Implementation Plan

Implementation of the Renovated Systems

	Yes	No
Is there a plan for implementing the renovated systems?		
If parallel operations are planned, are the resources in place?		
Are there plans to track and correct system problems identified during operations?		
Are there plans to implement modified business processes?		
Are there resources available to track process problems identified during operations?		

21. Transition Plan

Plans for the transition to HIPAA standard transactions

	Yes	No
Has phase-over or transition been planned?		
Does the plan include parallel operations?		
Have trading partners been informed of the transition plan?		
Are trading partners prepared to meet the dates in the transition plan?		
Has the plan been discussed with providers?		
Are providers prepared to meet the dates in the transition plan?		
Does the plan include enough time to test transactions thoroughly, and to phase in new standards before the beginning of the transition?		

Part J – Contingency Planning

22. Contingency Plans

Based on business continuity needs, prioritization of business functions (pay claims), risk assessments.

	Yes	No
Is there a contingency plan in case all trading partners and providers have not completed transition by the end of the transition period?		
Is there a contingency plan in case the transition is not complete by the HIPAA deadline?		
Was the contingency plan based on plans developed for Y2K?		
Does the focus of the contingency plan reflect the critical business functions?		
Does the contingency plan identify how compliance with HIPAA will be achieved for transaction types that cannot be supported before the deadline?		
Are there plans and resources to test the contingency plan?		
Have the resources needed for contingency operations been identified?		
Are contingency operations resources available?		

Attachment A

ADVANCE PLANNING DOCUMENT (APD) GUIDANCE DOCUMENT

Part I – Background

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (P.L. 104-191) as a step toward reforming health care in the United States. Title II, Subpart F of this law, titled "Administrative Simplification", requires that the Secretary of DHHS adopt standards necessary to create a national electronic health data system. Standards are required for transactions and code sets, identifiers, data security, electronic signature data, and privacy. The overall goal is to reduce administrative burdens in the health care industry by requiring and adopting the use of standardized, electronic transmission of essential administrative and financial data. Additionally, Medicaid is a health plan. As such, each state's Medicaid Management Information System (MMIS) must comply with all provisions of each HIPAA rule. The APD models (see Attachments C and D) and this Guide Document (Attachment A) have been designed to streamline the process for planning and implementing strategies for HIPAA.

Funding

The applicable regulations governing Federal Financial Participation (FFP) under title XIX are contained in 42 CFR 433.15, Subpart A. FFP is available for statewide planning, design, development and installation (DDI) of mechanized claims processing and information retrieval systems, the MMISs. FFP is available at the 90-percent rate for DDI (section 1903(a)(3)(A)(i) and 42 CFR §433.15(b)(3); and at the 75-percent rate for the continued operation of such systems, approved by CMS (see section 1903(a)(3)(B); 42 CFR §433.15(b)(4)). For further information regarding FFP, refer to the State Medicaid Manual, Part 11, sections 11276-11280.

Part II – Implementation and Planning Advance Planning Documents and Exemptions

This section provides information on two APDs that are used to provide information regarding DDI and operational phases of system developments within a state Medicaid agency. Both the Planning and Implementation APDs have similar requirements, but are used for different purposes. The following section provides information regarding the overall intent and requirements for each document.

A. Planning Advance Planning Document

The Planning APD is a brief document prepared and submitted prior to initiating planning phase activities. The purpose is not to provide needs and plans in detail, but to develop a high-level management statement of vision, needs, objectives, plans and estimated costs. The focus is on describing how planning will be accomplished and demonstrating that the state has established a plan that is reasonable for the level of effort of the project. Planning APDs that meet the standards for approval as described below will be approved in sixty days. The Planning APD has four sections: 1. Statement of Need; 2. Project Management Plan; 3. Planning Project Budget and 4. Assurances.

1. Statement of Need

This section of the Planning APD should set forth the state's information and services, "vision," including the scope and objectives of the planned information system and its interrelationships with other systems (if known). In addition, the needs statement should define the system requirements in terms of problems and needs listed. The Model HIPAA Planning APD has three components under Statement of Needs. They are:

- Statement of "Vision"[1] – The APD must identify the overall strategy for reengineering MMISs to become compliant with the Administrative Simplification provisions of HIPAA. Additional details can be provided, if necessary, to ensure that the system will become compliant by the deadline mentioned within each final rule. For example, the state may provide additional details to ensure compliance with the final rule on transactions and code sets for which the new deadline is October 16, 2003.

- New or Changed Program Requirements – All provisions of each final rule must be mentioned in the state's reengineering process. Any differences between the state's planned effort and the requirements must be explained.

- Problems or Deficiencies in Existing System – The state must identify the deficiencies within the current MMIS that prevent overall compliance with the HIPAA final rules.

2. Project Management Plan

The Project Management Plan summarizes how the states plan. The state's planning project organization is briefly described. At this point in the project, all that is required is that the state identify, by name and title, key players in the planning phase, such as the project manager and other key planning staff. This information can be depicted in an organizational chart. The Project Management Plan for planning describes how and

[1] "Vision" means the state planners' view of future program needs and the system architecture necessary to support those needs.

when the activities for the planning phase will be conducted and schedules milestones for completion of key events. This section consists of the following parts:

- Planning project organization (state and contractor) -- The state should provide a descriptive one-page chart and one-page of accompanying narratives describing the individuals working on the HIPAA project, their responsibilities, and relationships they have with state Medicaid staff and/or contractors responsible for HIPAA-related activities.

- Planning activities, products and deliverables – The state should summarize these in one page or less.

- Commitment to conduct: - Each state must check off whether they intend to conduct the following types of analyses. A statement must be provided for any "No" box that is checked explaining the rationale behind why such analyses are not being conducted.

  - ✓ Requirements Analysis (e.g. Gap Analysis) – The differences between current Medicaid systems and the HIPAA requirements. Additionally, information on the resources and time needed to remediate the MMIS must be included.
  - ✓ Alternatives Analysis – examining the potentiality of utilizing alternative methods as compared to the one chosen.
  - ✓ Cost/Benefit Analysis – analyzing the initial and long-term costs during the remediation process and comparing them to the cost benefits of alternative methods.
  - ✓ Joint Application Design (JAD) with users – whether a state will participate with the users of the MMIS in its remediation plan.
  - ✓ Functional Specification – a detailed analysis of the functionality of the MMIS under HIPAA and whether it is consistent with the requirements outlined in the HIPAA final rules.
  - ✓ Systems Design – an analysis of how the MMIS will become HIPAA compliant and what technology will be employed.
  - ✓ Impact Assessment – an analysis of how compliance efforts will affect users of the MMIS.
  - ✓ System Interrelationships (if applicable) – an analysis of the different relationships other applicable systems (e.g. IES) have with the MMIS, and how compliance efforts may affect them.

3. Planning Project Budget

This section succinctly describes in narrative form the resource needs for which funding support during the Planning Phase may be requested by the state. These needs may relate to state and contractor staff costs, computer time, hardware and commercially available software, travel space, supplies, telephones, photocopying and so forth. This section of the APD provides the budget, projected costs and time schedule for the Planning Phase.

- Anticipated state costs – The state must include documentation that anticipates all costs that would be included in both the development and implementation of the remediation method. These costs must be broken down by fiscal quarter and summarized by fiscal year, including the totals for both project planning and the program as a whole.

- Proposed time schedule – The state must include documentation on the amount of time needed for the planning phase.

4. Assurances

This section refers to the procurement of automated data processing equipment for mechanical claims processing, and whether it was procured under the appropriate requirements outlined in the Code of Federal Regulations listed, the appropriate sections of the State Medicaid Manual, and a State Medicaid Letter[2] dated December 4, 1995. This section also refers to access to records, licensing, ownership of software and the safeguarding of information contained within the system.

The state must indicate, through a check-box, whether they are compliant with the following provisions. All "No" answers must be explained with complete justification provided.

- **Procurement Standards (Competition/Sole Source)**

  Document: Title 45 Code of Federal Regulations, Part 95

  Sec. 95.613 Procurement Standards.

  (a) Procurements of ADP equipment and services are subject to the procurement standards prescribed by Subpart P of 45 CFR Part 74 regardless of any conditions for prior approval. Those standards include a requirement for maximum practical open and free competition regardless of whether the procurement is formally advertised or negotiated.
  (b) Those standards, as well as the requirement for prior approval, apply to ADP services and equipment acquired by a state or local agency, and the ADP services and equipment acquired by a state or local Central Data Processing facility primarily to support the Social Security Act programs covered by this subpart. Service agreements are exempt from these procurement standards.

  Document: State Medicaid Manual Part 11

  Section 11267 REQUIRED ASSURANCES

[2] The State Medicaid Letter, dated December 4, 1995 is attached to this Guide as ATTACHMENT E.

For 90-percent, as well as for 75-percent funding, and 50-percent FFP where the threshold amounts found at 95.611(a) are exceeded, give CMS, with respect to each RFP and/or contract entered into for a system, assurance that:

Procurements of ADP services and/or equipment for mechanized medical claims processing and information retrieval systems meet the provisions of 45 CFR 74, Administration of Grants;

Fair competition and public advertising are within Federal and state procurement standards. The Federal procurement standards are in 45 CFR 74, Subpart P and the December 4, 1995 State Medicaid Director letter (See Attachment E).

- **Access to Records**

  Document: Title 45 Code of Federal Regulations, Part 95

  Sec. 95.615 Access to systems and records.

  In accordance with 45 CFR part 74, the state agency must allow the Department access to the system in all of its aspects, including design developments, operation, and cost records of contractors and subcontractors at such intervals as are deemed necessary by the Department to determine whether the conditions for approval are being met, and to determine the efficiency, economy and effectiveness of the system.

  Document: State Medicaid Manual Part 11

  Section 11267 REQUIRED ASSURANCES

  For 90-percent, as well as for 75-percent funding, and 50-percent FFP where the threshold amounts found at 95.611(a) are exceeded, give CMS, with respect to each RFP and/or contract entered into for a system, assurance that:

  All deliverables, interim reports, data collection forms, questionnaires, and other working papers that support the final system acceptance will be made available on request to CMS. This applies to the prime contractor, any subcontractors, and other state or local agencies supplying services.

- **Software Ownership, Federal Licenses and Information Safeguarding**

  Document: Title 42 Code of Federal Regulations, Part 433

  Sec. 433.112(b) (5) – (9)

(5) The state owns any software that is designed, developed, installed or improved with 90-percent FFP.
(6) The Department has a royalty-free, non-exclusive, and irrevocable license to reproduce, publish, or otherwise use and authorize others to use, for Federal Government purposes, software, modifications to software, and documentation that is designed, developed, installed or enhanced with 90-percent FFP.
(7) The costs of the system are determined in accordance with 45 CFR 74.171.
(8) The Medicaid agency agrees in writing to use the system for the period of time specified in the APD approved by CMS, or for any shorter period of time that CMS determines justifies the Federal funds invested.
(9) The agency agrees in writing that the information in the system will be safeguarded in accordance with subpart F, part 431 of this subchapter.

- **Progress Reports**

  Document: State Medicaid Manual Part 11

  Section 11267 REQUIRED ASSURANCES

  For 90-percent, as well as for 75-percent funding and 50-percent FFP where the threshold amounts found at 95.611(a) are exceeded, give CMS, with respect to each RFP and/or contract entered into for a system, assurance that:

  Copies of progress reports, as requested, will be delivered to CMS.

In addition to the four sections of the Planning APD described above, there is an additional provision at 45 CFR § 95.605(vi), which requires a commitment to define the state's functional requirements for the purpose of evaluating the transfer of an existing system, including the transfer of another state's General Systems Design (GSD), which the state may adapt to meet state specific requirements.

B. Implementation Advance Planning Document (APD)

Implementation APDs are written plans of action that states use to request FFP in the designing, developing and implementing of the system. States are required to submit an Implementation APD prior to incurring costs for system design and development when the total project costs (including planning) are estimated to exceed the thresholds in 45 CFR § 95.61(b). The level of detail in the Implementation APD should be commensurate with the complexity and scope of the acquisition. This template provides an overview of the requirements of an Implementation APD and emphasizes the need to keep the information tightly focused on the issues below. Implementation APDs that meet the standards for approval will be approved within 60 days.

1. Statement of Needs and Objectives

In this section of the Implementation APD, the state should summarize the current environment and the new system needs, objectives, and anticipated benefits. Needs may be expressed in terms of deficiencies in existing capabilities, new or changed program requirements, or opportunities for economies or efficiencies.

- Statement of Needs and Objectives - The state must clearly state the purpose and objectives of the project to be accomplished and the necessity for the project. A basic description of the modification or system utilized in order to make the MMIS HIPAA-compliant must be included.

- Problems or deficiencies in existing system*[3] - The state must describe why the current MMIS is unable to process the new or changed requirements listed in each HIPAA final rule.

- New or changed program requirements* - The state must explain any differences between the current MMIS and the requirements listed in each HIPAA final rule.

2. Requirements Analysis, Feasibility Study, and Alternatives Analysis

The regulation at 45 CFR §95.605(2)(iii) provides for a requirements analysis, feasibility study, and alternatives analysis. The regulation does not require that a "summary" of these analyses and study be a part of the Implementation APD, nor are copies of these documents required. If the state has performed these analyses and study in the Planning APD, CMS will accept the Executive Summary of these documents as meeting the Implementation APD requirement**.**

- General Requirements – The state must submit a general requirements analysis for their compliance efforts, describing both the functional and technical needs, including system interface requirements, if applicable. It should not exceed five pages in length, and should include all analysis completed up to the point of submission of the APD.

- Alternatives Analysis – The state must briefly summarize which alternatives to the chose remediation effort were selected for evaluation of costs and benefits, and provide the rationale for selection of the chosen alternative.

3. Cost/Benefit Analysis

The state must provide a summary of the results of the cost benefit analysis. Program performance improvements, projected costs, and anticipated benefits the system is expected to deliver must be described succinctly. The narrative should address the basis,

[3] *Not required if the State has submitted a HIPAA Planning APD

assumptions, calculations and measurement plan related to performance, cost and benefit goals. The state must also indicate, through a check box, whether the following items are included with this analysis:

a. *Cost/Benefit Profile* – A brief cost-benefit profile of the chosen method for HIPAA compliance must be included;

b. *Systems Life Benefits* – A spreadsheet detailing the systems life of the chosen method of compliance must also be included.

4. Project Management Plan

The Project Management Plan summarizes the project activities, deliverables and products; project organization; state and contractor resource needs and anticipated system life. If the state has previously submitted a Planning APD, any differences from the Project Management Plan submitted in that document must be explained.

As succinctly as possible, the state must provide the following information:

- A high-level workflow addressing project activities, milestones and contractor deliverables. Relationships between activities, both sequential and parallel, must be established in the plan. Additionally, responsibilities for staff must be included as well as provisions to check progress.

- The project manager and other key staff must be identified by name and title.

- The relationship between the project team and the project steering committee must be identified (if applicable).

- Interrelationships between the user group and contractors must be identified.

- All resource needs for which funding support may be requested by the state must be identified. These needs may relate to state and contractor staff costs, computer time, hardware and commercially available software, depreciation, travel, space, supplies, telephones, photocopying, office equipment, furniture, and so forth.

- A description of the anticipated system life for the required resources must be included. This is inclusive of planning, implementation and operational phases.

5. Proposed Project Budget

The state's proposed budget, summarized in this APD, considers all costs for implementation phase activities. This might include, but is not limited to, costs associated with system software and data conversion, software development, computer capacity planning, contractor costs, supplies, training, maintenance and operations. Miscellaneous ADP costs may also be included.

A state must include a summary of **all** implementation costs, by state and Federal shares. These must be broken down by phase, category and cost amounts. Please refer to Attachment B for the sections of the State Medicaid Manual for additional guidance.

6. Assurances

Please refer to Section IV under the Planning APD subpoint for information pertaining to this section.

7. Cost Allocation

The prospective cost allocation plan is described, including procedures to identify, record, allocate, and report direct and indirect costs, partially and fully attributable to the system project.

A state must include the following:

- The rate of FFP, either enhanced or regular, by cost category per year; and
- A list of each phase of implementation, the program share of cost, the total amount, the FFP rate and the Federal/state shares.

C. EXEMPTIONS

For all systems-related activity having to do with compliance with the Administrative Simplification provisions of HIPAA, a Planning APD is not required. A state may choose to submit only an Implementation APD as long as it meets the requirements outlined in this document. Furthermore, we wish to confirm that the requirements of the Paperwork Reduction Act which, as a general matter, imposes a specific process for approval of documents requiring the collection of information, is not implicated.

Attachment B

STATE MEDICAID MANUAL, PART 11, SECTIONS 11276-11280

11276 COSTS RELATED TO MMIS DESIGN, DEVELOPMENT, INSTALLATION, OPERATION, AND ENHANCEMENT

11276.1 Introduction.

FFP is available at either 90 percent or 75 percent, but may be paid only for those functions attributable to an MMIS. For example, with respect to provider enrollment, only the costs of entering data into the computer system and processing computer exceptions are reimbursed at 75 percent FFP. Other functions, even if performed by the same unit or individuals, are reimbursable at 50 percent FFP. Appropriate costs, including overhead directly attributable to the operation of the system are also reimbursable at 75 percent FFP. (See §11276.9.)

45 CFR 74.171[1] references OMB Circular No. A-87, which defines direct costs as "those that can be identified specifically with a particular cost objective. Indirect costs are those (a) incurred for a common or joint purpose benefiting more than one cost objective, and (b) not readily assignable to the cost objectives specifically benefited, without effort disproportionate to the result achieved." As explained below, only direct costs identified specifically with the MMIS system may be claimed at the enhanced rate.

11276.2 Costs Reimbursable at 90 Percent FFP

FFP at 90 percent is available for costs directly attributable to the Medicaid program for the design, development, installation, and enhancement of mechanized claims processing and information retrieval systems. Included are resources needed for systems requirements analysis, design definition, forms development, programming, unit testing, integrated test, conversion, the use of hardware to the extent necessary for design, development, and installation, and supplies for the above. These and other direct costs including personnel costs of the State project management team specifically assigned for the development and installation effort are included. Other administrative activities are matched at 50 percent.

11276.3 Costs Reimbursable at 75 Percent FFP

FFP at 75 percent is available for MMIS operations and proprietary software.

A. MMIS Operations.

FFP at 75 percent is available for direct costs directly attributable to the Medicaid program for ongoing automated processing of claims, payments, and reports. Included are forms, use of system hardware and supplies, maintenance of software and documentation, and personnel costs of operations control clerks, suspense and/or exception claims processing clerks, data entry operators, microfilm operators, terminal operators, peripheral equipment operators, computer operators, and claims coding clerks

[1] Clarification of 45 CFR 74.171, though deleted after the SMM was issued, can be found in Attachment E of this Guidance package in a Dear State Medicaid Director's letter dated Dec. 5, 1995.

if the coded data is used in the MMIS, and all direct costs specifically identified to these cost objectives. Report users, such as staff who perform follow-up investigations, are not considered part of the MMIS.

FFP at the 75 percent level for operations does not cover clerical processing operations, except as indicated. One of the aims of system improvements is the mechanization of front-end manual editing operations to achieve greater edit reliability and the reduction of clerical workload.

B. Proprietary Software

FFP at 75 percent is available for the license fee associated with proprietary software being used to perform certain functions that are within the confines of an approved MMIS; e.g. information retrieval and report generation (See §11276.5 for Decision Support System policy).

Several regulatory factors govern such use, and are described in 45 CFR 95.617(c);

(1) Software packages sold or leased to the general public are not subject to the ownership provisions normally applied to software developed with FFP (45 CFR 95.617(a) and (b), and

(2) FFP is not available for proprietary application software developed specifically for the public assistance programs covered under this subpart, (in this case, the Medicaid Program).

Minimally, the proprietary application software must have applicability to the medical environment/community at large, and be marketed/sold within that medical environment/community at large.

HCFA will approve the use of such proprietary software which;

(a) meets the above restrictions of 45 CFR 95.617(c), and,

(b) where the vendor of the proprietary software agrees, in writing, to grant the State a perpetual license for continued use of the software should the State award a contract for a subsequent take-over of the MMIS operations by another fiscal agent/contractor.

11276.4 Costs Reimbursable at 90 and 75 Percent FFP for Equipment and Supplies Rented or Purchased

Purchase rather than rental of mechanized equipment must be justified by establishing that it is to the economic advantage of the State and Federal governments after consideration of the tangible and intangible factors involved. Included in this determination is consideration of the alternative to lease the equipment with option to purchase. Equipment cost for its use during the design, development, and installation or enhancement of an MMIS to assist in accomplishing these tasks is eligible for 90 percent FFP.

Equipment purchased for operational purposes is eligible only for FFP at 75 percent. Cost of equipment used during both implementation and operation of an MMIS is assigned by proration. Depreciation or use allowance for State charges for equipment cost is usual practice. (See 45 CFR 95, Subpart G.) Approval requirements for equipment acquisitions, when waiver is part of the APD, are found in 45 CFR 95.641.

The FFP percentage for purchase of supplies depends upon the life and use of the item. The portion of items consumed during design, development, and installation for system

test such as cards, microfilm, and forms (limited quantity) may be charged at 90 percent FFP. The portion of items not consumed and partially used during design, development, and installation may be charged at 90 percent FFP, and the remaining portion at 75 percent FFP. These same items used during system operation must be charged at 75 percent FFP.

Supplies purchased, such as disk packs and magnetic tapes, must be charged at 75 percent FFP since the intent is for use in continuous operations. (See 45 CFR 95 for standards for depreciation and use allowances.)

Costs for site preparation are operational start-up costs and matched at the 75 percent FFP rate.

11276.5 Costs Reimbursable at 75 percent FFP for MAR and SUR Activities and Decision Support Systems

Costs directly associated with personnel involved in MAR and SUR activities and the cost for operation of Decision Support Systems (DSS) generally qualify for 75 percent FFP.

A. MAR and SUR Activities

In order for cost of personnel directly associated in the production of reports for MAR and SUR activities to qualify for 75 percent FFP the personnel must routinely perform these functions (and/or SUR parameter changes) as part of their assigned responsibilities. Costs associated with the use or follow-up action of these reports are not eligible for enhanced FFP.

B. Decision Support Systems

MMIS was designed to meet operational needs through the processing and payment of claims and generation of pre-formatted management reports through the MAR and SUR functionalities. However, due to the information challenges in today's market, more flexible and timely means of obtaining and reporting information is necessary. A DSS is often a feasible means of managing data needs. DSS is a universal term describing a menu of hardware and software components which can be combined to facilitate access to data and data analysis to serve a wide range of end-users. A DSS provides a mechanism to process data in a manageable quantity and format which is easily accessed by users to manipulate data on-line. A DSS can enhance the MAR and SUR functionalities by giving States the ability to access large volumes of data to produce customized reports.

The funding levels applicable to acquisition, implementation, and operation of a DSS are listed below. These guidelines are predicated on the premise that the DSS is being procured by a State as a replacement for or a supplement to the current MAR and SUR reporting functionalities of the MMIS. A DSS procured for use with other than an MMIS would not be eligible for enhanced funding match, and depending on its relationship (or lack thereof) to the title XIX program, may (or may not) be eligible for only 50% match (or no match).

o License fee for use of the proprietary software	75% FFP
o Development of software to facilitate conversion of data format, including use of PCS, mainframe or mass storage	90% FFP
o Initial conversion* of data, including use of PCS, mainframe, or mass storage (for testing)	90% FFP

o	Repetitive cyclic conversion* of data	75% FFP
	*If the design of the operation of the DSS requires a repetitive cyclic conversion of MMIS data then such subsequent conversion costs will be funded at a 75% FFP rate.	
o	Training of users	50% FFP
o	Operation of the DSS software, including use of PCS, mainframe, or mass storage	75% FFP
o	ADP professionals**	75% FFP
o	Users**	50% FFP

**When a State employs an ADP professional to create/key-in the necessary parameters which cause the DSS to generate user-requested reports, that ADP professional is matchable at 75% FFP. However, USERS who have been trained to enter/key-in the parameters necessary to generate their own reports from the DSS are only eligible for 50% FFP match.

11276.6 Costs Reimbursable at 75 Percent FFP for MMIS-Related Clerical or Manual Processing Activities.

Although it is an objective of the MMIS to reduce manual processing (see §11276.3), some manual intervention is necessary to make any computer system perform properly. However, only those manual functions which are directly attributable to the operation of the MMIS are funded at the enhanced FFP.

11276.7 Costs Reimbursable at 75 Percent FFP for Program Management, Prior Authorization of Services, and Audit Functions.

The 75 percent FFP for MMIS operations is available for claims processing and information retrieval functions performed by the State agency or the fiscal agent. This includes the actual processing of claims as well as the production of MMIS reports. As such, the following functions must be reviewed in terms of their relationship to claims processing and information retrieval.

A. Program Management.

Although required to operate a Medicaid program, this function is not reimbursable at the MMIS FFP rate unless directly related to claims processing or information retrieval. For example, making a program management decision on a specific suspended claim is allowable at 75 percent FFP. However, the development and issuance of overall policy is excluded. The development of an edit for the claims processing system to implement a program policy (e.g., a limitation of a service) is allowable at the 75 percent rate and includes the cost of designing and implementing the edit. The cost of the program management staff that developed the policy is allowable only at the regular 50 percent rate as part of ongoing program management.

B. Prior Authorization of Services.

A program management decision on a claim entered into the system and suspended is allowable. However, prior authorization of a service such as orthodontics or elective surgery before the service is delivered is not allowable. Such a decision is based on limitations in the State plan and not directly related to the mechanized claims processing system.

C. Audit.

All State and fiscal agent audit activity is not eligible for enhanced FFP as an MMIS activity. This includes cost report audits, provider audits, and follow up investigation of claims where fraud is suspected.

11276.8 Postage Costs.

The postage necessary to mail various products stemming from the operation of an MMIS, e.g., checks, remittance advices, is not considered part of the operation of an MMIS as defined in §11110. Consequently, all postage costs associated with the operation of an MMIS are matched at the 50 percent FFP rate.

11276.9 Reimbursement of Allocated Costs.

Only direct costs allocable to the development or operation of an MMIS are eligible for reimbursement at enhanced FFP rates. Such costs include utilities, rent, telephone service, etc., necessitated by either the development or operation of an MMIS.

Costs which cannot be specifically identified with the development or operation of an MMIS are matched at the 50 percent FFP rate. Such costs are usually indirect costs including the staff costs associated with agency-wide functions such as accounting, budgeting, legal affairs, general administration, etc.

This differentiation in the funding rates for these two types of costs is not applicable to the reimbursement of fiscal agent costs.

11276.10 Costs Reimbursable at 75 Percent FFP for Fiscal Agent MMIS Operations.

A fiscal agent may perform many additional functions (see §11276.7) for the State beyond those related to MMIS operations eligible for 75 percent FFP, yet bill the State at one all inclusive rate per claim processed. If this is the case, develop a cost allocation plan through which payments to the fiscal agent are broken out for matching at the appropriate FFP rates. (See §11276.9.)

11276.11 List of Reimbursable Costs for State Systems.--

A. Introduction.

This section identifies those activities associated with the design, development, installation, enhancement, and operation of an MMIS, and the appropriate FFP matching rate for which each qualifies. These costs must be specifically identified in the APD, RFP and contract if they are to be claimed at the 90 percent rate. Only items listed for 90 percent or 75 percent rate of funding qualify for enhanced FFP as expenditures for MMIS under §1903(a)(3)of the Act.

B. List of Reimbursable Costs.--

1. Design, Development, Installation, or Enhancement of an MMIS

Item	Rate of Funding	Text Reference
Feasibility Study	50%	11275
Planning activities (e.g., preparation of an APD)	90%	11275
Preparation of an RFP for an initial or replacement MMIS	90%	11275 11269
Preparation of an RFP for an enhancement to an MMIS	90%	11275
Proposal evaluation and contractor selection	90%	11275
System and requirements analyses	90%	11110
System design, development, installation, and enhancement	90%	11275 11110
DIS	90%	11237 11275
Equipment costs only for use of such equipment in the design, development, installation, or enhancement of an MMIS	90%	11276.4
Direct personnel costs	90%	11276.2
Direct non-personnel costs	90%	11276.9
Indirect personnel and non-personnel costs	50%	11276.9
Acceptance testing	90%	11237
Supplies used during MMIS implementation	90%	11276.4
Design, development, installation, or enhancement of a proprietary system	0%	45 CFR 95.617(c)
Site preparation	75%	11276.4
Training of personnel engaged in the design, development, or installation of an MMIS	50%	42 CFR 432.50(b)

2. MMIS Operational Costs

Preparation of an APD and/or	75%	11275

Item	Rate of Funding	Text Reference
RFP directed toward the potential change of operator for an approved MMIS		
Proposal evaluation and contractor selection	75%	11275
Hardware used for MMIS operations	75%	11276.3
Supplies used in the operation of an MMIS	75%	11276.4
Claim forms (including encounter data)	75%	11276.3
Entry and maintenance of provider enrollment data	75%	11276.1
Direct costs of personnel directly associated with the operation of an approved MMIS including staff responsible for:	75%	11276.3
Data entry Operations control Exception and suspense processing (continued) Claims microfilming (continued from previous page): Peripheral equipment operations Computer operations Claims coding System documentation maintenance Software maintenance SURS parameter coding System management	75%	11276.3
Entry and maintenance of data required under HIPAA for purpose of electronic data interchange	75%	11100
Direct non-personnel costs	75%	11276.9
Indirect personnel and non-personnel costs	50%	11276.9
Publications necessary for the operation of an MMIS, such as, required claim forms	75%	11276.3
Maintenance of the system necessary to support claims processing and information retrieval functions of an MMIS	75%	11276.1 11276.3
Postage	50%	11276.8
Provider relations directly related to MMIS claims processing, such as, entry and update of provider data	75%	11276.1

MMIS Operational Costs (continued)

Item	Rate of Funding	Text Reference
MMIS production of: Checks or warrants, Remittance advices EOBs, Medical assistance ID cards, MARS and SURS reports	75%	11276.3
Operational costs of an initial or replacement MMIS until the system has been approved	50%	11255
Training of personnel directly engaged in the operation of an MMIS	75%	42CFR432.50(b)(2)

3. Other System Costs

Local ADP systems (not statewide in scope)	50%	11225
Automated administrative support systems (e.g., personnel, financial management, office automation)	50%	11276.1
Design, development, installation, enhancement, and operation of eligibility determination systems	50%	11280
Audit functions	50%	11276.7
Provider Manuals	50%	11276.9

Attachment C

MODEL HIPAA PLANNING APD

Health Insurance Portability and Accountability Act (HIPAA)

The Planning APD is a very brief document (6-10 pages) prepared and submitted *prior to initiating* Planning Phase activities. It is used to secure Federal financial participation (FFP) for the State. It is a plan to plan. The purpose is not to provide needs and plans in detail but to develop a high-level management statement of vision, needs, objectives, plans, and estimated costs. The focus is on describing how planning will be accomplished and demonstrating that the State has established a plan that is reasonable for the level of effort of the project. Planning APDs that meet the standards for approval shown in the following two pages will be approved within 60 days. The Planning APD has four sections: 1. Statement of Need 2. Project Management Plan for planning 3. Planning project budget, and 4. Assurances.

Section	Content	Description of Minimum Requirements
Statement of Need This section of the Planning APD should set forth the State's information and services "vision,"[1] including the scope and objectives of the planned information system and its interrelationships with other systems (if known). In addition, the needs statement should define the system requirements in terms of problems and needs listed in the next column.	✓ Statement of "Vision"	Reengineer Medicaid Management Information Systems to become compliant with the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act. (Please add more details if necessary)
	✓ New or changed program requirements	See Final Rule for Transactions and Code Sets published August 16, 2000. Explain any differences.
	✓ Problems or deficiencies in existing system	The current MMIS is unable to process the new or changed requirements listed above.
Project Management Plan The Project Management Plan summarizes how the State will plan. The State's planning project organization is briefly described. At this point in the project, all that is required is that the State identify key players in the planning phase, such as the project manager and other key planning staff by name and title. This information can be depicted in an organization chart. The Project Management Plan for planning describes how and when the activities for the Planning Phase will be conducted and schedules milestones for completion of key events.	✓ Planning project organization (State and contractor) – people, responsibilities and relationships	Provide descriptive one page chart and one page of accompanying narrative.
	✓ Planning activities, products and deliverables	Briefly summarize in one page or less.
	✓ Commitment to conduct : (Please provide a statement when "No" is checked)	Requirements analysis (e.g. Gap Analysis) Yes No Alternatives analysis Yes No Cost/benefit analysis Yes No JAD (joint application design sessions with users) Yes No Functional specification Yes No Systems design Yes No Impact Assessment Yes No System interrelationships (if applicable) Yes No
	✓ State/contractor needs	Briefly summarize in one page or less.
	✓ Planning project procurement activities and schedule	Briefly summarize in one page or less.

[1] "Vision" means the State planners' view of future program needs and the systems architecture necessary to support those needs.

Attachment C

Section	Content	Description of Minimum Requirements		
Planning Project Budget This section succinctly describes in narrative form the resource needs for which funding support during the Planning Phase may be requested by the State. These needs may relate to State and contractor staff costs, computer time, hardware and commercially available software, travel, space, supplies, telephones, photocopying, and so forth. This section of the APD also provides the budget and the cost allocation to be used during the Planning Phase.	✓ By categories, cost elements and amounts	Anticipated State costs Projected costs by fiscal quarter + summarized by fiscal year, including planning project total, and program totals. Proposed time schedule		
Assurances This section refers to the procurement of automated data processing equipment for mechanical claims processing, and whether it was procured under the appropriate requirements outlined in the Code of Federal Regulations (CFR) listed, the appropriate sections of the State Medicaid Manual (SMM), and a State Medicaid Letter (dated December 4, 1995). This section also refers to access to records, licensing, ownership of software and the safeguarding of information contained within the system.	✓ Procurement Standards (Competition/Sole Source)	45 CFR Part 95.613 45 CFR Part 74 SMM Section 11267 SMD Letter of Dec. 4, 1995	Yes Yes Yes Yes	No No No No
	✓ Access to Records	45 CFR Part 95.615 SMM Section 11267	Yes Yes	No No
	✓ Software Ownership ✓ Federal Licenses ✓ Information Safeguarding	42 CFR Part 433.112(b)(5) – (9)	Yes	No
	✓ Progress Reports	SMM Section 11267	Yes	No
		Explain all No answers and provide complete justification		

In addition to the four sections of the Planning APD, there is an additional provision at 45CFR § 95.605(vi), which requires a commitment to define the state's functional requirements for the purpose of evaluating the transfer of an existing system, including the transfer of another state's General Systems Design (GSD), which the state may adapt to meet state specific requirements.

Attachment D

MODEL HIPAA IMPLEMENTATION APD

Health Insurance Portability and Accountability Act (HIPAA)

Implementation APDs are written plans of action that States use to request Federal financial participation (FFP), in the designing, developing and implementing the system. States are required to submit an implementation APD prior to incurring costs for system design and development, when the total project costs (including planning) are estimated to exceed the thresholds in 45 CFR §95.611(b). The detail in the Implementation APD should be commensurate with the complexity and scope of the acquisition. This template provides an overview of the requirements of an Implementation APD and the need to keep the detail simple and focused on the issues below. Implementation APDs that meet the standards for approval shown below will be approved within 60 days.

*Not required if State has submitted a HIPAA Planning APD

Section	Content	Description of Minimum Requirements
Statement of Need and Objectives In this Section of the Implementation APD, the State should summarize the current environment and the new system needs, objectives, and anticipated benefits. Needs may be expressed in terms of deficiencies in existing capabilities, new or changed program requirements, or opportunities for economies or efficiencies.	✓ Statement of Needs and Objectives	Clearly state the purpose and objectives, including your vision of the project, to be accomplished and the necessity for the project. Include a basic description of the modification or system you seek to implement.
	✓ Problems or deficiencies in existing system*	The current MMIS is unable to process the new or changed requirements listed above
	✓ New or changed program requirements*	See Final Rule for Transactions and Code Sets published August 16, 2000. Explain any differences.
Requirements Analysis, Feasibility Study, and Alternatives Analysis The regulation at 45 CFR §95.605(2)(iii) requires that the Implementation APD shall include a requirements analysis, a feasibility study, and a statement of alternative considerations including, where appropriate, a transfer of an existing system, and an explanation of why such a transfer is not feasible, if another alternative is identified.	✓ General Requirements analysis (accomplished to date)	Provide a general requirements analysis (describing the functional and technical needs), not to exceed 5 pages in length.
	✓ Alternatives analysis (Must identify which alternatives were selected for evaluation of costs and benefits and provide the rationale for selection of the chosen alternative).	If the state has performed these analyses and study in the Planning APD, CMS will accept the Executive Summaries of these documents as meeting the Implementation APD requirement.

Attachment D

Section	Content	Description of Minimum Requirements
Cost/Benefit Analysis The State must provide a summary of the results of the cost/benefit analysis. Program performance improvements, projected costs, and anticipated benefits the system is expected to deliver must be described succinctly.	✓ By cost basis, assumptions, calculations, and measurement plan related to performance, cost and benefit goals.	Cost/Benefit Profile (show benefit detail) Yes No Systems life benefits Spreadsheet Yes No
Project Management Plan The Project Management Plan summarizes the project activities, deliverables, and products; project organization; State and Contractor resource needs; and anticipated system life.	✓ Nature, Scope, Methods, Activities, Schedule and Deliverables ✓ Project Organization and Personnel Resources ✓ State and Contractor Resource Needs ✓ System Life	As succinctly as possible, provide the following information: • Provide a high level workflow addressing project activities, milestones and contractor deliverables; • Identify the project manager and other key staff by name and title; • Identify the relationship of the project team to the project steering committee (if applicable); • Identify interrelationships with user group and contractors; • Identify the resource needs for which funding support may be requested by the State; • Describe the anticipated system life for the required resources
Proposed Project Budget This Section contains all costs for Implementation Phase activities.	✓ By phase, category and cost amounts	• A summary of all Implementation costs; by State and Federal shares (Refer to SMM, Part 11, Sections 11276-11280)
Assurances This section refers to the procurement of automated data processing equipment for mechanical claims processing, and whether it was procured under the appropriate requirements outlined in the Code of Federal Regulations (CFR) listed, the appropriate sections of the State Medicaid Manual (SMM), and a State Medicaid Letter (dated December 4, 1995). This section also refers to access to records, licensing, ownership of software and the safeguarding of information contained within the system	✓ Procurement Standards (Competition/Sole Source) ✓ Access to Records ✓ Software Ownership ✓ Federal Licenses ✓ Information Safeguarding ✓ Progress Reports	45 CFR Part 95.613 Yes No 45 CFR Part 74 Yes No SMM Section 11267 Yes No SMD Letter of Dec. 4, 1995 Yes No 45 CFR Part 95.615 Yes No SMM Section 11267 Yes No 42 CFR Part 433.112(b)(5) – (9) Yes No SMM Section 11267 Yes No Explain all "No" answers and provide complete justification

Attachment D

System	Content	Description of Minimum Requirements
Cost Allocation **T**he prospective cost allocation plan is described, including procedures to identify, record, allocate, and report direct and indirect costs, partially and fully attributable to the system project	✓ Type of FFP ✓ By phase, category and cost amounts	✓ List FFP rate (enhanced or regular) by cost category per year ✓ List phase of implementation, program share of cost, total amount, FFP rate and Federal/State shares

DEC-5-1995 **Attachment E**

Dear State Medicaid Director:

We are writing to inform you of our policy on sole source procurements and prior approval requirements for certain procurements in light of recent revisions to our Departmental regulations. On August 25, 1994 the Department of Health and Human Services (DHHS) published an interim final rule in the Federal Register which amended 45 CFR Part 74. The amendments to Part 74 contained in this rule deleted appendixes G and H, which set forth the procurement standards found in previous versions of the Office of Management and Budget (OMB) Circulars A-102, "Uniform Administrative Requirements for Grants-In-Aid To State and Local Governments" and A-110, "Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Institutions" respectively. Also deleted were many subparts of Part 74, including subpart P, which contained a provision that set forth the types of procurements that were governed by OMB Circulars A-102 and A-110.

The interim final rule incorporated into Part 74 revisions which OMB made in its Circular A-110, which governs procurements by nongovernmental grant recipients. The preamble to the rule states that, in the future, DHHS and OMB intend to propose either a separate new regulation for the entitlement programs or a complete revision of OMB Circular A-102, which contained the procurement standards for grants to State and local governments. The Department has reserved 45 CFR Part 92, subpart E, for future placement of entitlement program regulations. In the meantime, Part 74, as amended, remains applicable to the entitlement programs, including the Medicaid program.

The deletion of Appendix G removed regulatory provisions regarding procurement standards which limited the circumstances under which Federal grantor agencies could require States to secure prior approval of procurements and related procurement documents. Also eliminated was the specific provision which permitted sole source procurement only in four limited circumstances. The deletion of subpart P removed the exception to the Circular A-102 procurement standards for transactions between governmental entities. In deleting these provisions, the interim final rule did not indicate any intent to eliminate existing agency regulations or policies pertaining to these matters.

In addition, we have consulted with DHHS officials on whether our existing policies on prior approval requirements and noncompetitive procurements are affected by the removal of Appendix G and subpart P of Part 74. We were advised that existing policies of HHS awarding agencies pertaining to pre-award approval and other requirements regarding procurements remain valid unless they are specifically rescinded or amended by the awarding agencies. When the final rule is published, DHHS will include language in the preamble which will explicitly state that existing policies of awarding agencies are not invalidated by the Part 74 revisions.

While the revisions described above would also affect the rules governing managed care contracts, the Office of Managed Care in the Health Care Financing Administration (HCFA) has separately established policies and guidelines for procurements entered into under managed care arrangements, as well as those entered into under section 1915(b) freedom of choice waivers. Therefore, this letter does not affect the Federal policy regarding those procurements.
Outside of the ambit of the managed care arrangements discussed above, HCFA will maintain limited Federal oversight of State procurements. Pre-award review and approval of a State's proposed contracts and related procurement documents, such as requests for proposals and invitations for bids, will be required when any of the following conditions apply:

1. A State's procurement procedures or operations fail to comply with the procurement standards in 45 CFR Part 74.

2. The procurement is expected to exceed the small purchase threshold fixed at 41 U.S.C. 403(11) (currently $100,000) and is expected to be awarded without competition or only one bid or offer is received in response to a solicitation.

3. The procurement is expected to exceed the small purchase threshold and specifies a . "brand name" product.

4. The proposed award is over the small purchase threshold, and is to be awarded to other than the apparent low bidder under a sealed bid procurement.

5. A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount of the small purchase threshold.

While the revisions to Part 74 eliminated the provision which limited sole source procurement to specific delineated situations, the new regulations, at §74.43, retain the general requirement that all procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. Therefore, we will continue to limit the allowability of noncompetitive procurements. The circumstances under which a contract may be awarded by noncompetitive negotiation are limited to the following:

1. The item is available only from a single source;

2. Public exigency or emergency when the urgency for the requirement will not permit a delay incident to competitive solicitation; or

3. The Federal grantor agency authorizes noncompetitive negotiation; or

4. After solicitation of a number of sources, competition is determined inadequate.

We will not require prior approval for transactions between governments or agencies or instrumentalities of governments as long as there is an interagency agreement that does not provide for reimbursement above cost. We will require approval where the State Medicaid agency proposes to contract with another government or agency or instrumentality of government when there is a negotiated payment level which allows for profit.

Federal policies give States considerable latitude in procurement processes. HCFA's oversight through prior approval requirements or evaluations of State procurement processes is meant to promote the purposes of the Medicaid program in a cost effective manner. We hope that this letter clarifies HCFA's role in States' procurement transactions in light of the revisions to 45 CFR Part 74.

If you have any questions regarding this matter, please contact Ed Davies on (410) 786-3280.

/S/
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