a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice will not mandate any requirements for State, local, or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this notice under these requirements and have determined that it will not impose substantial direct requirement costs on State or local governments.

In accordance with Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Section 402 of the Social Security Act Amendments of 1967 (42 U.S.C. 1395b–1) (Catalog of Federal Domestic Assistance Program No. 93.779, Health Care Financing Research, Demonstrations and Evaluations)

Dated: March 28, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–9196 Filed 4–12–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–0007–N]

Health Insurance Reform: Standards for Electronic Transactions; Announcement of the Availability of a Model Compliance Plan

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: This notice announces the availability of instructions for, and a model of, a compliance plan that covered entities may use to request an extension to the compliance deadline for standards for electronic transactions and code sets that covered entities must use for those transactions.

FOR FURTHER INFORMATION CONTACT: Elizabeth Holland, (410) 786–1309.

SUPPLEMENTARY INFORMATION:

I. Background

On August 21, 1996 the Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104–191, which included provisions to address the need for standards for electronic health care transactions and other administrative simplification issues. Through subtitle F of this law, the Congress added to title IX of the Social Security Act (the Act) a new part C (consisting of sections 1171 through 1179 of the Act), entitled ''Administrative Simplification.'' The purpose of this part is to improve the Medicare program, the Medicaid program, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements to enable the electronic exchange of certain health information.

Section 1172 of the Act makes any standard adopted under part C of the Act applicable to the following entities as defined in section 1171 of the Act:

- All health plans.
- All health care clearinghouses.
- Any health care provider who transmits any health information in electronic form in connection with transactions referred to in section 1173(a)(1) of the Act.

Section 1175(a)(3) of the Act establishes that each person to whom a standard or implementation specification applies is required to comply with the standard no later than 24 months (or 36 months for small health plans) following its adoption. With respect to modifications to standards or implementation specifications made after initial adoption, compliance must be accomplished by a date designated by the Secretary. This date may not be earlier than 180 days after the Secretary adopts the modification.

In the August 17, 2000 **Federal Register** (65 FR 50312), we published a final rule entitled ''Health Insurance Reform: Standards for Electronic Transactions'' that implemented the provisions of sections 1171 through 1179 of the Act. These provisions established new national standards with which all covered entities must comply. The effective date of these standards for all covered entities, with the exception of small health plans is October 16, 2002, and the effective date for compliance by small health plans is October 16, 2003. In addition, the August 17, 2000 final rule established a definitions section at 45 CFR 160.103 that includes definitions for the following terms— (1) Covered entities; (2) health plans; (3) small health plans; (4) health care clearinghouses; and (5) health care providers.

However, on December 27, 2001, the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105) provided for a 1-year extension of the deadline for compliance with the electronic health care transactions standards and code sets for all covered entities, with the exception of small health plans, that request an extension on or before October 15, 2002. Covered entities that submit a request by the deadline will have until October 16, 2003 to come into compliance with the standards.

In addition, Pub. L. 107–105 required the Secretary to develop a model compliance plan by no later than March 31, 2002. In developing this model compliance plan, the Secretary consulted with organizations described in sections 1172(c)(3)(B) and (f) of the Act as organizations to be consulted in developing national electronic health care standards. One of these organizations, the Workgroup for Electronic Data Interchange (WEDI), developed a series of recommendations for the model plan. On February 7, 2002, these recommendations were discussed at a public hearing of the National Committee on Vital and Health Statistics (NCVHS).

II. Provisions of the Notice

This notice provides information to covered entities, with the exception of small health plans, that will not be compliant with the electronic health care transactions and code sets standards by October 16, 2002. As required by Pub. L. 107–105, we are providing a model compliance plan that covered entities may use to submit to request an extension. These entities may use one of the following options to file for a 1-year extension (that is, until October 16, 2003):

- Submit the on-line compliance plan, which is available on our website at *www.cms.hhs.gov/hipaa.*
- Submit a paper copy of the on-line compliance plan via mail.
- Submit their own version of a compliance plan that provides equivalent information.

The model compliance plan and instructions for its completion and submission are available via the Internet

on our website. Completion and timely submission of the model compliance plan by covered entities satisfies the ASCA requirement for requesting an extension.

A. Electronic Submissions of the Model Compliance Plan

Covered entities can submit this model compliance plan electronically via the Internet at www.cms.hhs.gov/hipaa. In order to obtain an extension, electronic submissions must be completed on or before October 15, 2002. Covered entities that complete their compliance plan electronically will receive an electronic confirmation number as their response. The confirmation number serves as the covered entity's approval notice. For additional information regarding electronic compliance plan submissions, see Appendix A of this notice. To view a copy of the electronic form, see Appendix B of this notice.

B. Paper and Alternative Submissions of a Compliance Plan

Covered entities also have the option of submitting a paper copy of the model plan. This paper submission can be a duplicate of the form in Appendix B of this notice or a printed copy of the electronic form available on our website.

In addition, a covered entity has the option to submit its own version of a compliance plan (paper copy), that must include the following:

- An analysis of the reasons for noncompliance.
- A budget for achieving compliance.
- A work plan and implementation strategy for achieving compliance.
- A decision regarding whether a contractor or vendor may be used to help achieve compliance.
- A testing timeframe that begins on or before April 16, 2003.

All paper and alternative submissions must be postmarked by October 15, 2002 and sent to the following address:

Attention: Model Compliance Plans, Centers for Medicare & Medicaid Services, PO Box 8040, Baltimore, Maryland 21244–8040.

We will not acknowledge receipt of these submissions. Therefore, we suggest that covered entities submitting their plans via mail use a method that provides proof of delivery. For additional information on paper or alternative submissions, see Appendix A of this notice.

III. Collection of Information Requirements

In accordance with section 1175(b)(1)(A) of the Act as amended by section 2 of Pub. L. 107–105, the form included as Appendix B of this notice is exempted from the requirements of the Paperwork Reduction Act of 1995. Consequently, neither the form nor the notice need to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

IV. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980 Pub. L. 96–354), section 1102 (b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any given year). We have determined that this notice is not a major rule because it does not impose an economically significant impact on covered entities or the Medicare program.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. For purposes of the RFA, most covered entities (that is, health plans, health care clearinghouses, and health care providers) are considered to be small entities, either by nonprofit status or by having revenues of $5 to $25 million or less annually. (For details, see the Small Business Administration's regulation that set forth size standards for health care industries (65 FR 69432).) Individuals and States are not included in the definition of a small entity. Covered entities will be able to assess their own progress toward HIPAA compliance and determine whether or not to request an extension. Covered entities that obtain the extension will have the added flexibility to schedule the activities needed to implement the standards and they will have additional time to conduct thorough testing with their trading partners. We are unable to quantify the impact of the 1-year extension, but we will be able to analyze the data that we receive from covered entities that submit compliance extension plans.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. Currently we are unable to quantify the impact of the provisions of this notice on small rural hospitals, but we believe that we will be better able to assess the impact of the 1-year extension through the analysis of the data submitted by covered entities requesting the extension.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice will not mandate any requirements for State, local or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this notice under these requirements and have determined that it will not impose substantial direct requirement costs on State or local governments. We also note that the option to obtain a 1-year extension will give States or local governments more flexibility in several areas which may include—(1) Additional time to conduct testing; (2) additional time for implementation; and (3) additional time to consult with vendors. In accordance with Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 1175 of the Social Security Act (42 U.S.C. 1320d–4)

Dated: April 8, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

BILLING CODE 4120–01–P

Appendix A:

Department of Health and Human Services
HIPAA Electronic Health Care Transactions and Code Sets Standards
Model Compliance Plan Instructions

Overview

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) became law. It requires, among other things, that the Department of Health and Human Services establish national standards for electronic health care transactions and code sets. October 16, 2002 was the original deadline for *covered entities* to comply with these new national standards. However, in December 2001, the Administrative Simplification Compliance Act (ASCA) extended the deadline for compliance with HIPAA Electronic Health Care Transactions and Code Sets standards (codified at 45 C.F.R. Parts 160, 162) one year – to October 16, 2003 – for all *covered entities* other than *small health plans* (whose compliance deadline is already October 16, 2003). In order to qualify for this extension, *covered entities* must submit a compliance plan by October 15, 2002. Completion and timely submission of this model compliance plan will satisfy this federal requirement, and assist us in identifying and addressing impediments to your timely and effective implementation of the HIPAA Electronic Health Care Transactions and Code Sets standards. If you are a *covered entity* other than a *small health plan* and do not submit a compliance plan, you must be compliant with the HIPAA Electronic Health Care Transactions and Code Sets standards by October 16, 2002.

You can submit this on-line model compliance plan electronically, and we will provide an on-line confirmation number as acknowledgment of your extension. This on-line compliance plan is a model only, and is provided for your information. *Covered entities* have the option of submitting their own version of a compliance plan that provides equivalent information. Refer to the "Alternative Submissions" section of these instructions for more information. For those filing electronically, your electronic confirmation number will be the only notice that you have received an extension. No other notice will be provided for electronic or paper submissions. If your paper plan consists of the equivalent information required by the statute (*covered entity* and contact information; reasons for filing for the extension; implementation budget; and the three phases of the implementation strategy) your plan is complete and you may consider your extension granted.

Completing this model compliance plan takes about 15-20 minutes. Simply answer a few questions about compliance concerns you may have, and tell us where you are in the implementation process.

The Centers for Medicare & Medicaid Services (CMS) will share information obtained from submitted compliance plans with the National Committee on Vital and Health Statistics (NCVHS) as required by the Administrative Simplification Compliance Act. The NCVHS serves as the statutory public advisory body to the Secretary of Health and Human Services in the area of health data and statistics. The NCVHS will use this information to identify barriers to compliance. All information shared with the NCVHS will have identifying information deleted.

For information on *defined terms* used in this document, refer to 45 C.F.R. 160.103 or 162.103.

Who Should File

If you are a *covered entity* and will not be compliant with the HIPAA Electronic Health Care Transactions and Code Sets standards by October 16, 2002, you must file a compliance plan in order to obtain an extension. A *covered entity* is a *health plan, a health care clearinghouse, or a health care provider* who transmits any health information in electronic form in connection with a transaction for which the Secretary has adopted standards at 45 C.F.R. Part 162. These terms are defined at 45 C.F.R. 160.103. The term *"health care provider"* includes individual physicians, physician group practices, dentists, other health care practitioners, hospitals, nursing facilities, and so on.

If you are a member of a group practice, the extension will be granted to all physicians/practitioners who are members of that practice. It is not necessary to file separate compliance plans for each physician in the practice if the practice files all claims on your behalf. However, if you submit claims for payment outside of the group's claims processing system, you need to file your own compliance plan.

You do not have to file a compliance plan if you will be compliant by October 16, 2002 but one or more of your trading partners is not yet HIPAA compliant. But remember that you/your organization must be HIPAA compliant by this date (or by October 16, 2003 if you are filing a compliance plan) for all transactions that apply to you.

When to File

Compliance plans must be submitted electronically no later than October 15, 2002. Paper submissions should be postmarked no later than October 15, 2002. Compliance plans filed electronically and paper submissions received or postmarked after this date will not qualify for the extension.

How to File

Electronic submission is the fastest, easiest way to file your compliance plan. Just complete the model compliance plan on-line, click "Submit" at the end, and it will be on its way to us electronically. For those filing electronically, your electronic confirmation number will be the only notice that you have received an extension. No other notice will be provided for electronic or paper submissions. If your paper plan consists of the equivalent information required by the statute (*covered entity* and contact information; reasons for filing for the extension; implementation budget; and the three phases of the implementation strategy) your plan is complete and you may consider your extension granted.

Please do NOT electronically submit AND mail paper copies of this model compliance plan. One submission per *covered entity*, either electronically OR paper, will suffice.

Alternative Submissions

Covered entities that use the model compliance plan provided on our website, www.cms.hhs.gov/hipaa can file electronically. If you cannot submit your compliance plan electronically via our website, or you want to submit your own version of a compliance plan

that provides equivalent information, it must be printed and mailed to us. Please send paper submissions of your compliance plan postmarked no later than October 15, 2002 to:

Attention: Model Compliance Plans
Centers for Medicare & Medicaid Services
P.O. Box 8040
Baltimore, MD 21244-8040

CMS will not acknowledge receipt of paper submissions. For proof of delivery, we suggest you use the U.S. Postal Service.

Section A: *Covered Entity* and Contact Information

(1) Name of *Covered Entity*. Please enter the name of the *covered entity* for which you are filing this compliance plan. See "Who Must File" above for more information.

If you are filing for multiple related *covered entities* that are operating under a single implementation plan, list their names, tax identification numbers and Medicare identification numbers. Compliance plans for unrelated multiple *covered entities* or for related *covered entities* that are not included under the same implementation plan must be filed separately. Are you filing for a health plan, health care clearinghouse or other health care organization that has multiple components? If they are operating under the same implementation plan, then you can file one compliance plan on their behalf. If not, then you must file separate compliance plans for each entity. See also (5) "Authorized Person" for more information.

(2) Tax Identification Number. Enter each *covered entity's* IRS Employer Identification Number (EIN). If there is no EIN, enter the *covered entity's* Social Security Number. While an EIN or Social Security Number is not required, this information will facilitate ensuring that the correct *covered entity* obtains the extension.

(3) Medicare Identification Number.

Please enter the identification number that applies to each *covered entity* listed.

- If you are a Medicare physician or physician group, enter your UPIN number.
- If you are a supplier of durable medical equipment, enter your NSC number. If you have multiple locations under one EIN, just report the initial location's number (a 6-digit number followed by 0001)
- If you are an institution, enter your OSCAR number. This is your 6-digit Medicare billing number.

If you are not a Medicare provider, you need not enter any identification number in (3).

(4) Type of *Covered Entity*. Tell us which *covered entity* category applies to your organization. Check all boxes that apply.

(5) Authorized Person. Provide the name of a person who is authorized to request the extension and provide the information. This might be the individual physician, business/practice

manager, a corporate officer, chief information officer or other individual who is responsible for certifying that the information provided is accurate and correct. (You may include a title, e.g., Dr.). If filing for multiple *covered entities*, this person should be authorized to request the extension for all the listed *covered entities*. Otherwise, a separate compliance plan must be filed to indicate the authorized person for each respective *covered entity*.

(6) Title. Provide the title for the person shown in (5).

(7) Street. Enter the street mailing address/post office box for the person shown in (5)

(8) City/State/Zip. Enter this information for the person's address as shown in (5).

(9) Telephone Number: Enter the telephone number (including area code) for the person shown in (5).

Section B: Reason for Filing for This Extension

(10) Please let us know the reason(s) why you will not be in compliance with the HIPAA Electronic Health Care Transactions and Code Sets standards (45 C.F.R. Parts 160, 162) by October 16, 2002. Check all boxes that apply. If the reason you will not be compliant is not shown, check "Other" and briefly specify the reason for non-compliance.

Section C: Implementation Budget

This question asks about the estimated financial impact of HIPAA compliance on your organization. Please respond to (11) by indicating on the drop-down menu which category most closely reflects your estimate of your HIPAA compliance costs. If you're not sure, check "Don't Know."

Section D: Implementation Strategy

This section asks about overall awareness of the HIPAA Transactions and Code Set Standards, Operational Assessment, and Development and Testing. These are collectively referred to as the Implementation Strategy.

Implementation Strategy Phase One -- HIPAA Awareness

If you have completed this Awareness phase of the Implementation Strategy, check YES (12) and skip to (14), indicating your completion date for this phase. Then proceed to Phase Two – Operational Assessment. If you answer (12) NO, answer (13) and (14).

To complete this Awareness phase you should

- obtain information regarding HIPAA Electronic Transactions and Code Sets Standards;
- discuss this information with your vendors; and
- conduct preliminary staff education.

Tell us when you started or plan to start this activity (13), and when you completed or plan to complete activity for this Awareness phase of the Implementation Strategy (14).

Implementation Strategy Phase Two -- Operational Assessment

If you have completed this Operational Assessment phase of the Implementation Strategy, check YES (15) and skip to (20), indicating your completion date for this phase. Then proceed to Phase Three – Development and Testing. If you answer (15) NO, answer all questions (16) through (20).

To complete this Operational Assessment phase you should

- inventory the HIPAA gaps in your organization;
- identify internal implementation issues and develop a workplan to address them; and
- consider and decide whether or not to use a vendor or other contractor to assist you in becoming compliant with the HIPAA Electronic Health Care Transactions and Code Sets standards.

Indicate your progress for tasks (16) through (18), and projected/actual start and completion dates for this phase in the boxes provided (19) and (20).

Implementation Strategy Phase Three -- Development and Testing

If you have completed this Development and Testing phase, check YES (21) and skip to (26), indicating your completion date. If you answer (21) NO, answer all questions (22) through (26).

To complete this Development and Testing phase, you should

- finalize development of applicable software and install it;
- complete staff training on how to use the software; and
- start and finish all software and systems testing.

Show your progress for tasks (22) and (23) for resolving computer software conversion to a HIPAA compliant system and training your staff. Indicate your projected/actual development start dates (24), projected/actual initial internal software testing date (25) and final testing completion date (26).

The model compliance plan is now complete. You may click on "Clear Plan" to delete your entries and revise your information, or "Submit Electronically" to electronically submit this model compliance plan; or print it and follow the instructions for paper submissions in the "How to File" section of these instructions.

Appendix B:

Department of Health and Human Services

Health Insurance Portability and Accountability Act of 1996

Electronic Health Care Transactions and Code Sets Standards Model Compliance Plan

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) became law. It requires, among other things, that the Department of Health and Human Services establish national standards for electronic health care transactions and code sets. October 16, 2002 was the original deadline for *covered entities* to comply with these new national standards. However, in December 2001, the Administrative Simplification Compliance Act (ASCA) extended the deadline for compliance with HIPAA Electronic Health Care Transactions and Code Sets standards (codified at 45 C.F.R. Parts 160, 162) one year – to October 16, 2003 – for all *covered entities* other than *small health plans* (whose compliance deadline is already October 16, 2003). In order to qualify for this extension, *covered entities* must submit a compliance plan by October 15, 2002. Completion and timely submission of this model compliance plan will satisfy this federal requirement, and assist us in identifying and addressing impediments to your timely and effective implementation of the HIPAA Electronic Health Care Transactions and Code Sets standards. If you are a *covered entity* other than a *small health plan* and do not submit a compliance plan, you must be compliant with the HIPAA Electronic Health Care Transactions and Code Sets standards by October 16, 2002.

For general information about HIPAA and instructions on how to complete this compliance plan, refer to our website, www.cms.hhs.gov/hipaa. You can go to the website and submit this on-line compliance plan electronically, and we will provide an on-line confirmation number as acknowledgment of your extension. This on-line compliance plan is a model only, and is provided for your information. *Covered entities* have the option of submitting their own version of a compliance plan that provides equivalent information. Refer to the instructions on our website for information on how to file alternative submissions. For those filing electronically, your electronic confirmation number will be the only notice that you have received an extension. No other notice will be provided for electronic or paper submissions. If your paper plan consists of the equivalent information required by the statute (*covered entity* and contact information; reasons for filing for the extension; implementation budget; and the three phases of the implementation strategy) your plan is complete and you may consider your extension granted.

For information on *defined terms* used in this document, refer to 45 C.F.R. 160.103 or 162.103.

Section A: *Covered Entity* and Contact Information

1. Name of *Covered Entity*	2. Tax Identification Number	3. Medicare Identification Number(s)

4. Type of C*overed Entity* (Check all that apply from these drop-down menus)

☐ *Health Care Clearinghouse* ☐ *Health Plan* ☐ *Health Care Provider*

Dentist
DME Supplier
Home Health Agency
Hospice
Hospital
Nursing Home
Pharmacy
Physician/Group Practice
Other

5. Authorized Person _____ 6. Title _____

7. Street
8. City State Zip
9. Telephone Number

Section B: Reason for Filing for This Extension

10. Please check the box next to the reason(s) that you do not expect to be compliant with the HIPAA Electronic Health Care Transactions and Code Sets standards (45 C.F.R. Parts 160, 162) by October 16, 2002. Multiple boxes may be checked.

- ☐ Need more money
- ☐ Need more staff
- ☐ Need to buy hardware
- ☐ Need more information about the standards
- ☐ Waiting for vendor(s) to provide software
- ☐ Need more time to complete implementation
- ☐ Waiting for clearinghouse/billing service to update my system
- ☐ Need more time for testing
- ☐ Problems implementing code set changes
- ☐ Problems completing additional data requirements
- ☐ Need additional clarification on standards
- ☐ Other

Section C: Implementation Budget

This question relates to the general financial impact of the HIPAA Electronic Health Care Transactions and Code Sets standards (45 C.F.R. Parts 160,162) on your organization.

11. Select from the drop-down menu the range of your estimated cost of compliance with the HIPAA Electronic Health Care Transactions and Code Sets standards (45 C.F.R. Parts 160, 162):

Less than $10,000
$10,000 - $100,000
$100,000 - $500,000
$500,000 - $1 million
Over $1 million
Don't know

Section D: Implementation Strategy

This Implementation Strategy section encompasses HIPAA Awareness, Operational Assessment, and Development and Testing. For more details on completing each of these subsections, refer to the model compliance plan instructions at www.cms.hhs.gov/hipaa.

Implementation Strategy Phase One -- HIPAA Awareness

These questions relate to your general understanding of the HIPAA Electronic Health Care Transactions and Code Sets standards (45 C.F.R. Parts 160, 162).

12. Please indicate whether you have completed this Awareness phase of the Implementation Strategy.
☐ Yes ☐ No

If yes, skip to (14), and then to Phase Two – Operational Assessment. If no, please answer both (13) and (14). Have you determined a:

13. Projected/Actual Start Date: (select month/year from this drop-down menu) ☐ ☐

14. Projected/Actual Completion Date: (select month/year from this drop-down menu) ☐ ☐

Implementation Strategy Phase Two -- Operational Assessment

These questions relate to HIPAA operational issues and your progress in this area.

15. Please indicate whether you have completed this Operational Assessment phase of the Implementation Strategy.
☐ Yes ☐No

If yes, proceed to (20) and then Phase Three – Development and Testing. If no, please answer all the following questions. Have you:

16. Reviewed current processes against HIPAA Electronic Health Care Transactions and Code Sets standards (45 C.F.R. Parts 160, 162) requirements?
☐ Yes ☐No ☐Initiated But Not Completed

17. Identified internal implementation issues and developed a workplan?
☐ Yes ☐No ☐Initiated But Not Completed

18. Do you plan to or might you use a contractor/vendor to help achieve compliance?
☐ Yes ☐No ☐Undecided

19. Projected/Actual Start Date: (select month/year from this drop-down menu) ☐ ☐

20. Projected/Actual Completion Date: (select month/year from this drop-down menu) ☐ ☐

Implementation Strategy Phase Three --- Development and Testing

These questions relate to HIPAA development and testing issues. ASCA legislation requires that testing begin no later than April 16, 2003. For more details, refer to the model compliance plan instructions at www.cms.hhs.gov/hipaa.

21. Please indicate whether you have completed this Development and Testing phase of the Implementation Strategy.

☐ Yes ☐ No

If yes, proceed to (26). If no, please answer all the following questions. Have you:

22. Completed software development/installation?

☐ Yes ☐ No ☐ Initiated But Not Completed

23. Completed staff training?

☐ Yes ☐ No ☐ Initiated But Not Completed

24. Projected/Actual Development Start Date: (select month/year from this drop-down menu) ☐ ☐

25. Projected/Actual Initial Internal Software Testing Start Date: (select month/year from this drop-down menu) ☐ ☐

26. Projected/Actual Testing Completion Date: (select month/year from this drop-down menu) ☐ ☐

CLICK HERE TO SUBMIT ELECTRONICALLY

CLICK HERE TO CLEAR PLAN

FOR PAPER SUBMISSIONS:

Please mail paper versions of this model compliance plan to:

Attention: Model Compliance Plans
Centers for Medicare & Medicaid Services
P.O. Box 8040
Baltimore, MD 21244-8040

CMS will not provide an acknowledgment of receipt of paper submissions of this model compliance plan. For proof of delivery, we suggest that you use the U.S. Postal Service.

[FR Doc. 02–9197 Filed 4–12–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0276]

Agency Information Collection Activities; Announcement of OMB Approval; Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods with Vinclozolin Residues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods with Vinclozolin Residues'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 23, 2001 (66 FR 53614), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0484. The approval expires on March 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: April 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–9097 Filed 4–12–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety Research; Availability of Cooperative Agreements; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), in this request for applications (RFA), is announcing the availability of approximately $750,000 in research funds for fiscal year (FY) 2002. These funds will be used to support collaborative research efforts between the Center for Food Safety and Applied Nutrition (CFSAN) and scientists and to complement and accelerate ongoing research in five project areas in order to reduce the incidence of foodborne illness and to protect the nations's food supply, food additives, and dietary supplements.

DATES: Submit applications by May 30, 2002.

ADDRESSES: Submit completed applications to Maura Stephanos, Grants Management Specialist, Grants Management Staff (HFA–520), Division of Contracts and Procurement Management, Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7183, FAX 301–827–7106, e-mail: mstepha1@oc.fda.gov. Application forms are available either from Maura Stephanos (address above) or on the Internet at http://grants.nih.gov/grants/funding/phs398/phs398.html. NOTE: Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH).

FOR FURTHER INFORMATION CONTACT: Regarding the administrative and financial management aspects of this notice: Maura Stephanos (address above).

Regarding the programmatic aspects of this notice: John W. Newland, Microbial Research Coordinator, Office of Science (HFS–06), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1915, e-mail: john.newland@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to reducing the incidence of foodborne illness to the greatest extent feasible and to protecting the integrity of the nation's food supply. Research in food safety seeks to reduce the incidence of foodborne illness by improving our ability to detect and quantitate foodborne pathogens, toxins and chemicals that could jeopardize the security of the food supply, and to find new and improved ways to control these agents. CFSAN supports multiyear cooperative agreements intended to help achieve these research goals of reducing the incidence of foodborne illness and ensuring the integrity of foods, food additives, and dietary supplements. This extramural program supports novel collaborative research efforts between CFSAN and scientists and leverages expertise not found within CFSAN to complement and accelerate ongoing research. Collaborations such as these provide information critical to food safety guidance and policymaking, and stimulate fruitful interactions between FDA scientists and those within the greater research community.

In continuation of this effort, CFSAN will provide FY 2002 funds to be used for research to help enhance the following capabilities of the agency: The ability to detect and control the presence of human pathogens, food allergens, toxins, and other bioactive compounds that may be present in FDA-regulated products; and the development of a framework by which the possible risk posed by potential high threat agents that might be used to adulterate particular foods, food additives, and dietary supplements can be ranked and systematically evaluated.

FDA is announcing the availability of research funds for FY 2002 to support research in the following five project categories: (1) Development and implementation of a risk-ranking framework to evaluate potential high threat microbiological agents, toxins, and chemicals in food; (2) practical application of laboratory based biosensor detection technology to detect and analyze microbiological agents, food allergens, toxins, and other bioactive compounds in foods, food additives, and dietary supplements; (3) multi-residue capillary gas chromatographic/mass spectrometric (GC/MS) technique for the detection of chemicals that may be present as contaminants in foods, food additives, and dietary supplements; (4) evaluation of the efficacy of multiple heat treatments used during the production of dairy products relative to the inactivation of bacterial spores; and (5) development of a bioinformatic approach, using predictive algorithms and protein sequence databases (structural proteomics), to identify the potential allergenicity of food proteins. Approximately $750,000 will be available in FY 2002. Of this amount,