information and data which should be included in a 510(k) submission for the washers and washer-disinfectors intended to process reusable medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1252 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' will be available at ''http://www.fda.gov/cdrh/ode/Ed☒dn.HTML''.

IV. Comments

Interested persons may, on or before February 3, 1999, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 8, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–29565 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Collection # HCFA-R–265]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHSS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 C.F.R. Part 1320. We cannot reasonably comply with the normal clearance procedures because of the statutory requirement to implement section 4016 of Balanced Budget Act of 1997.

We are requesting OMB review and approval of this collection within 11 working days, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below, within 10 working days of the publication of this notice in the **Federal Register**. During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 C.F.R. section 1320.5.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection summarized and discussed below.

Type of Information Collection Request: New collection;

Title of Information Collection: Medicare Coordinated Care Demonstration Project and Request for Information on Potential Best Practices of Coordinated Care;

Form/Collection No.: HCFA-R–265;

Use: Section 4016 of the Balanced Budget Act of 1997 (Public Law 105–33) requires the Secretary of Health and Human Services (the Secretary) to evaluate best practices in the private sector for methods of coordinated care. The statute also directs the Secretary to design a demonstration project for the Medicare fee-for-service population based on such evaluation.

The purpose of the demonstration is to evaluate models of coordinated care that improve the quality of services provided to beneficiaries who have a chronic illness and reduce expenditures under Parts A and B of the Medicare program.

We competitively awarded a task order to Mathematica Policy Research, Inc. (MPR) to conduct a review of best practices in coordinating care and provide a recommendation of demonstration design options. We will perform the final assessment of best practices and select the demonstration design.

We will publish a notice to announce our intent to conduct the Medicare Coordinated Care Demonstration and inform interested parties of the opportunity to submit information on potential best practices of coordinated care, as well as comment on potential aspects of the overall demonstration. We will solicit information on successful models of coordinated care, disease management, or case management that are appropriate for the Medicare fee-for-service population.

In the notice we will request that any person or organization submit information about successful programs; however, the information must provide evidence of success in sufficient detail to be useful. Thus, operators of programs may be in the best position to submit information regarding their approach. We are interested in the following items of information:

- The name and address of the program.
- The name, address, telephone number, facsimile number, and E-mail address of a contact person.
- Background information on the program (including goals, history, relationship to larger organization(s), number of clients served, and length of time the program has been in operation).
- Special or innovative features of the program.
- Size and composition of the staff (number of registered nurses and number of social workers performing case management).
- Referral sources, targeting criteria, and selection criteria, if any, for participants.
- Information on the patients the program serves, including age ranges, diagnoses or conditions, and/or functional impairments.
- Program intervention and how services differ from the usual care the patient would have received.
- How care plans are developed and monitored for each patient.
- Patient education efforts, if any.
- Patient monitoring efforts, if any.
- Feedback to providers, if any.
- Average length of time patient is in program.
- Funding source(s) for the program.
- Financial incentives, if any, for providers and patients to participate.
- Outcome measures by which the program's performance is evaluated (including clinical, utilization, client-reported, and financial measures used).
- Program impacts on these measures.
- Cost savings due to the program (total and per person served per month).
- How the program impacts and cost savings were calculated (i.e., method of estimating reduction in use and costs, such as comparison to control group or prior year experience).
- Costs of operating the program (average per patient, per month costs).
- Adaptability of the program to the Medicare fee-for-service setting.
- Program brochures or published articles, if any.

We are also interested in comments on potential aspects of the overall demonstration. Specifically, we are interested in comments that discuss and distinguish program characteristics known to be essential for positive outcomes in a fee-for-service setting from characteristics of lesser or unknown importance. Commenters may also wish to address the types of providers, organizations, or entities that are capable of, and qualified to provide, coordinated care or case management services. Other topics of importance include, but are not limited to:

- The relationship of the case management entity with other providers.
- The potential role of the case manager in authorizing and/or providing services beyond coordinating and educational activities.
- Appropriate incentives for the case management entity, beneficiaries, and other providers.
- Appropriate payment methodology.
- Potential risk bearing arrangements for the case management entity.

In addition, we will seek comments regarding challenges to, and potential solutions for, implementing a coordinated care demonstration in rural sites.

Frequency: One time;

Affected Public: Business or other for-profit, not-for-profit institutions;

Number of Respondents: 1,000;

Total Annual Responses: 1,000;

Total Annual Hours: 10,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, and HCFA form number referenced above, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection requirements must be mailed and/or faxed within 10 working days of the publication of this notice in the **Federal Register** to the designee referenced below:

Health Care Financing Administration, Office of Information Services, Standards and Security Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Attn: Dawn Willinghan, HCFA–R–265, Fax Number: (410) 786–0262 and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Eydt, HCFA Desk Officer. *Fax Number:* (202) 395–6974 or (202) 395–5167.

Datedd: October 30, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–29677 Filed 11–4–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program generally, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005, (202) 219–9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8A46, Rockville, MD 20857, (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated her responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table