

Medicare Advantage and 1876 Cost Plan Expansion Application; *Use*: The information will be collected under the solicitation of Part C applications from MA, EGWP Plan, and Cost Plan applicants and will be used to ensure that applicants meet our requirements and support the determination of contract awards. Participation in all programs is voluntary in nature; only organizations that are interested in participating in the program will respond to the solicitation. The MA-PDs that voluntarily participate in the Part C program must submit a Part D application and successful bid. The package has been revised subsequent to the publication of the 30-day **Federal Register** notice (July 11, 2014; 79 FR 40105). *Form Number*: CMS-10237 (OMB control number: 0938-0935); *Frequency*: Yearly; *Affected Public*: Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents*: 566; *Total Annual Responses*: 566; *Total Annual Hours*: 22,625. (For policy questions regarding this collection contact Melissa Staud at 410-786-3669).

2. *Type of Information Collection Request*: Reinstatement without change of a previously approved collection; *Title of Information Collection*: Letter Requesting Waiver of Medicare/Medicaid Enrollment Application Fee; Submission of Fingerprints; Submission of Medicaid Identifying Information; Medicaid Site Visit and Rescreening; *Use*: Section 6401 of the Affordable Care Act (ACA) establishes a number of important payment safeguard provisions. The provisions are designed to improve the integrity of the Medicare, Medicaid, and Children's Health Insurance Programs (CHIP) so as to reduce fraud, waste and abuse. The provisions include the following:

- *Medicare Enrollment Application Fee Waiver Request*: Certain providers and suppliers enrolling in Medicare will be required to submit a fee with their application. Under 42 CFR 424.514, if the applicant believes it has a hardship that justifies a waiver of the application fee, it may submit a letter describing said hardship.

- *Fingerprints*: Certain providers and suppliers enrolling in Medicare, Medicaid, and CHIP will be required to submit fingerprints—either digitally or via the FD-258 standard fingerprint card—of their owners.

- *Suspension of Medicaid Payments*: A State Medicaid agency shall suspend all Medicaid payments to a provider when there is a pending investigation of a credible allegation of Medicaid fraud against an individual or entity, unless it has good cause not to suspend payments

or to suspend payment only in part. The State Medicaid agency may suspend payments without first notifying the provider of its intention to suspend such payments. A provider may request, and must be granted, administrative review where State law so requires.

- *Collection of Social Security Numbers (SSNs) and Dates of Birth (DOB) for Medicaid and CHIP Providers*: The State Medicaid agency or CHIP agency must require that all persons with an ownership or control interest in a Medicaid or CHIP provider submit their SSNs and DOBs.

- *Site Visits for Medicaid-only or CHIP-only providers*: A State Medicaid agency or CHIP agency must conduct on-site visits for providers it determines to be “moderate” or “high” categorical risk.

- *Rescreening of Medicaid and CHIP Providers Every 5 Years*: A State Medicaid agency or CHIP agency must screen all providers at least every 5 years. This is consistent with the Medicare requirement in current 42 CFR 424.515 that providers and suppliers revalidate their enrollment information at least every 5 years.

Form Number: CMS-10357 (OMB control number: 0938-1137); *Frequency*: On occasion; *Affected Public*: Private sector—Business or for-profit and Not-for-profit institutions and State, Local, or Tribal Governments; *Number of Respondents*: 960,981; *Total Annual Responses*: 960,981; *Total Annual Hours*: 1,248,082. (For policy questions regarding this collection contact Frank Whelan at 410-786-1302).

3. *Type of Information Collection Request*: New collection (Request for a new OMB control number); *Title of Information Collection*: Public Health Agency/Registry Readiness to Support Meaningful Use; *Use*: The Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs provide incentives for the meaningful use of Certified Electronic Health Record Technology (CEHRT). We defined meaningful use as a set of objectives and measures in either Stage 1 or Stage 2 depending on how long an eligible provider has participated in the program. Both Stage 1 (3 objectives) and Stage 2 (5 objectives) of meaningful use contain objectives and measures that require eligible providers to determine the readiness of public health agencies and registries to receive electronic data from CEHRT. Public comments on the notice of proposed rulemaking for Stage 2 of meaningful use (77 FR 13697) asserted that the burden for each individual eligible provider to determine the readiness of multiple public health agencies and registries

could be nearly eliminated if we were to maintain a database on the readiness of public health agencies and registries. In the final rule for Stage 2 of meaningful use (77 FR 53967), we agreed that the burden on eligible providers, public health agencies and registries would be greatly reduced and established that we would create such a database and it would serve as the definitive information source for determining public health agency and registry readiness to receive electronic data associated with the public health meaningful use objectives. The information will be made publicly available on the CMS Web site (www.cms.gov/EHRincentiveprograms) in order to provide a centralized repository of this information to eligible providers and eliminate there multiple individual inquiries to multiple public health agencies and registries. *Form Number*: CMS-10499 (OMB control number: 0938—New); *Frequency*: Yearly; *Affected Public*: Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents*: 250; *Total Annual Responses*: 250; *Total Annual Hours*: 83. (For policy questions regarding this collection contact Kathleen Connors de Laguna at 410-786-2256).

Dated: September 30, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Reunification Procedures for Unaccompanied Alien Children.
OMB No.: 0970-0278.

Description: Following the passage of the 2002 Homeland Security Act (Pub. L. 107-296), the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is charged with the care and placement of unaccompanied alien children in Federal custody, and implementing a policy for the release of these children, when appropriate, upon the request of suitable sponsors while awaiting immigration proceedings. In order for ORR to make determinations regarding the release of these children, the

potential sponsors must meet certain conditions pursuant to section 462 of the Homeland Security Act and the *Flores v. Reno* Settlement Agreement No. CV85-4544-RJK (C.D. Cal. 1997).

The proposed information collection requests information to be utilized by

ORR for determining the suitability of a sponsor/respondent for the release of a minor from ORR custody. The proposed instruments are the Family Reunification Application, the Family Reunification Checklist for Sponsors,

and the Authorization for Release of Information.

Respondents: Sponsors requesting release of unaccompanied alien children to their custody.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Family Reunification Application	55,200	1	.25	13,800
Family Reunification Checklist for Sponsors	55,200	1	.75	41,400
Authorization for Release of Information	55,200	1	.25	13,800

Estimated Total Annual Burden Hours: 69,000.

ORR has requested emergency processing for this information collection for a period of 90 days from the October 31, 2014 expiration date of these instruments.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 3, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0303. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Records; Electronic Signatures—(OMB Control Number 0910-0303)—Extension

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the Agency has stated its ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require the following standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The Agency anticipates the use of electronic media will substantially reduce the paperwork