

changes to the CMS EHR Incentive Programs and the 2014 Edition Certification Criteria for EHR technology.

The information collection requirements contained in this information collection request are needed to implement the HITECH Act. In order to avoid duplicate payments, all EPs are enumerated through their National Provider Identifier (NPI), while all eligible hospitals and CAHs are enumerated through their CMS Certification Number (CCN). State Medicaid agencies and CMS use the provider's tax identification number and NPI or CCN combination in order to make payment, validate payment eligibility and detect and prevent duplicate payments for EPs, eligible hospitals and CAHs. *Form Number:* CMS-10336 (OCN: 0938-1158). *Frequency:* Occasionally; *Affected Public:* Private sector. *Number of Respondents:* 214, 694; *Total Annual Responses:* 214,694. *Total Annual Hours:* 2,034,740.16. (For policy questions regarding this collection contact Travis Broome at 214-767-4450. For all other issues call 410-786-1326.)

9. Type of Information Collection Request: Reinstatement with change of a previously approved collection; *Title of Information Collection:* Security Consent and Surrogate Authorization Form; *Use:* The primary function of the Medicare enrollment application is to obtain information about the Provider or supplier and whether they meet the Federal and/or State qualifications to participate in the Medicare program. In addition, the Medicare enrollment application gathers information regarding the provider or supplier's practice location, the identity of the owners of the enrolling organization, and information necessary to establish the correct claims payment.

Enrollees have the option of submitting either a CMS 855 form, or submitting information via a web based process. In establishing a web based application process, we allow providers and suppliers the ability to enroll in the Medicare program, revalidate their enrollment and make changes to their enrollment information via Internet-based Provider Enrollment, Chain and Ownership System (PECOS). Individual providers/suppliers (hereinafter referred to as "Individual Providers") log into Internet-based PECOS using their User IDs and passwords established when they applied on-line to the National Plan and Provider Enumeration System (NPPES) for their National Provider Identifiers (NPIs). Authorized Officials (AOs) of the provider or supplier organizations (hereinafter referred to as

"Organizational Providers") must register for a user account and authenticate their identity and connection to the organization they represent before being able to log into Internet-based PECOS. Once authenticated, AOs for Organizational Providers, receive complete access to their enrollment information via Internet-based PECOS. Individuals and AOs of Organizational Providers are not required to submit a Security Consent and Surrogate Authorization Form to enroll, revalidate or make changes to their Medicare enrollment information.

Individual and Organizational Providers may complete their Medicare enrollment responsibilities on their own or elect to delegate this task to a Surrogate. A Surrogate is an individual or organization identified by an Individual or Organizational Provider as someone authorized to access CMS computer systems, such as Internet-based PECOS, National Provider Plan and Enumeration System (NPPES) and the Medicare and Medicaid Electronic Health Records (EHR) Incentive Program Registration and Attestation System (HITECH), on their behalf and to modify or view any information contained therein that the Individual or Organizational Provider may have permission or right to access in accordance with Medicare statutes, regulations, policies, and usage guidelines for any CMS system. Surrogates may consist of administrative staff, independent contractors, 3rd party consulting companies or credentialing departments. In order for an Individual or Organizational Provider to delegate the Medicare credentialing process to a Surrogate to access and update their enrollment information in the above mentioned CMS systems on their behalf, it is required that a Security Consent and Surrogate Authorization Form be completed, or Individual and Organizational Providers use an equivalent online process via the PECOS Identity and Access Management (I&A) system. The Security Consent and Surrogate Authorization form replicates business service agreements between Medicare providers, suppliers or both and Surrogates providing enrollment services.

We are proposing one version of the Security Consent and Surrogate Authorization Form. The form, once signed, mailed and approved, grants a Surrogate access to all current and future enrollment data for the Individual or Organization Provider. *Form Number:* CMS-10220 (OCN: 0938-1035). *Frequency:* Occasionally. *Affected Public:* Individuals and Private

Sector; *Number of Respondents:* 88,650; *Total Annual Responses:* 88,650; *Total Annual Hours:* 22,162. (For policy questions regarding this collection contact Alisha Banks at 410-786-0671. For all other issues call 410-786-1326.)

10. Type of Information Collection Request: Reinstatement with change of a previously approved collection; *Title of Information Collection:* Certification Statement for Electronic File Interchange Organizations; *Use:* Health care providers can currently obtain a National Provider Identifier (NPI) via a paper application or over the Internet through the National Plan and Provider Enumeration System (NPPES). These applications must be submitted individually, on a per-provider basis. The Electronic File Interchange (EFI) process allows provider-designated organizations (EFIOs) to capture multiple providers' NPI application information on a single electronic file for submission to NPPES. This process is also referred to as bulk enumeration. To ensure that the EFIO has the authority to act on behalf of each provider and complies with other federal requirements, an authorized official of the EFIO must sign a certification statement and mail it to us. *Form Number:* CMS-10175 (OCN: 0938-0984). *Frequency:* Occasionally. *Affected Public:* Private Sector; *Number of Respondents:* 25; *Total Annual Responses:* 25; *Total Annual Hours:* 75. (For policy questions regarding this collection contact Leslie Jones at 410-786-6599. For all other issues call 410-786-1326.)

Dated: June 4, 2013.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10309, CMS-10475, CMS-R-5 and CMS-R-234]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the

Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by July 8, 2013.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs,
Attention: CMS Desk Officer,
Fax Number: (202) 395-6974 OR
Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:
Reports Clearance Office at (410) 786-1326

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or

requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection. *Title of Information Collection:* Grandfathering Provisions of the Medicare DMEPOS Competitive Bidding Program. *Use:* Section 1847(a)(4) of the Social Security Act (the Act) requires (in the case of covered durable medical equipment (DME) items for which payment is made on a rental basis under section 1834(a) of the Act and in the case of oxygen for which payment is made under section 1834(a)(5) of the Act) that the Secretary will establish a grandfathering process by which covered items and supplies that were rented by suppliers before the implementation of a competitive bidding program may be continued.

We established the grandfathering process in the April 10, 2007 final rule for competitive bidding (72 FR 17992) for rented DME and oxygen and oxygen equipment when these items are included under the Medicare DMEPOS Competitive Bidding Program. This process only applies to suppliers that rented DME and oxygen and oxygen equipment to beneficiaries who maintain a permanent residence in a competitive bidding area (CBA) before the implementation of the competitive bidding program.

The competitive bidding program will require some beneficiaries to change their suppliers. To avoid a beneficiary being without medically necessary equipment we believe it is necessary to establish this notification process. The notification to the beneficiaries is a beneficiary protection that will keep them informed of whether or not they can continue to rent an item from their current supplier or go to a contract supplier. The notification will also provide information to the beneficiary as to how to find a contract supplier in their CBA. In the event that the beneficiary must go to a contract supplier, the notification will identify the procedure for the pick-up of their current equipment and delivery of new equipment. *Form Number:* CMS-10309

(OCN: 0938-1079). *Frequency:* Once; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 2,697; *Total Annual Responses:* 536,667; *Total Annual Hours:* 65. (For policy questions regarding this collection contact Michael Keane at 410-786-4495. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* New collection (request for a new OMB control number). *Title of Information Collection:* Hospice Experience of Care Survey; *Use:* This survey supports the National Quality Strategy that was called for under the Affordable Care Act to create national aims and priorities to guide local, state, and national efforts to improve the quality of health care. This strategy has established six priorities that support a three-part aim focusing on better care, better health, and lower costs through improvement. Because the hospice survey focuses on experiences of care, implementation of the survey supports the following national priorities for improving care: Engaging patients and families in care and promoting effective communication and coordination. In addition, upon national implementation and public reporting of hospice survey results, the survey will provide data on experiences with hospice care that enable consumers to make meaningful comparisons between hospices across the nation. *Form Number:* CMS-10475 (OCN: 0938-New); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 730; *Total Annual Responses:* 730. *Total Annual Hours:* 185. (For policy questions regarding this collection contact Lori Teichman at 410-786-6684. For all other issues call 410-786-1326.)

3. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection. *Title of Information Collection:* Physician Certification/Recertification in Skilled Nursing Facilities (SNFs) Manual Instructions and Supporting Regulation in 42 CFR 424.20; *Use:* The Medicare program requires, as a condition for Medicare Part A payment for post-hospital SNF services that a physician must certify and periodically recertify that a beneficiary requires a SNF level of care. The physician certification and recertification is intended to ensure that the beneficiary's need for services has been established and then reviewed and updated at appropriate intervals. The documentation is a condition for Medicare Part A payment for post-hospital SNF care. *Form Number:* CMS-R-5 (OCN: 0938-0454). *Frequency:*

Occasionally; *Affected Public*: Private sector (business or other for-profit and not-for-profit institutions); *Number of Respondents*: 1,796,502; *Total Annual Responses*: 1,796,502; *Total Annual Hours*: 559,713. (For policy questions regarding this collection contact Kia Sidbury at 410-786-7816. For all other issues call 410-786-1326.)

4. Type of Information Collection Request: Extension without change of a currently approved collection; **Title of Information Collection:** Subpart D—Private Contracts and Supporting Regulations Contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455. **Use:** Section 4507 of Balancing Budget Act (BBA) 1997 amended section 1802 of the Social Security Act to permit certain physicians and practitioners to opt-out of Medicare and to provide (through private contracts) services that would otherwise be covered by Medicare. Under such contracts the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. Subpart D and the supporting regulations counters the effect of certain provisions of Medicare law that, absent section 4507 of BBA 1997, preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to

Medicare limits. Physicians and/or practitioners use these information collection requirements to comply with the law. In addition, Medicare carriers use this information to determine if benefits should be paid or continued. **Form Number:** CMS-R-234 (OCN 0938-0730); **Frequency:** Biennially; **Affected Public:** Private sector (business or other for-profits); **Number of Respondents:** 26,820. **Total Annual Responses:** 26,820. **Total Annual Hours:** 7,197. (For policy questions regarding this collection contact Fred Grabau at 410-786-0206. For all other issues call 410-786-1326.)

Dated: June 4, 2013.

Martique Jones,
Deputy 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

Submission for OMB Review; Comment Request

Title: Guidance for Tribal TANF.

OMB No.: 0970-0157.

Description

42 U.S.C. 612 (Section 412 of the Social Security Act) requires each Indian Tribe that elects to administer and operate a Temporary Assistance for Needy Families (TANF) program to submit a TANF Tribal Plan. The TANF Tribal Plan is a mandatory statement submitted to the Secretary by the Indian Tribe, which consists of an outline of how the Indian Tribes TANF program will be administered and operated. It is used by the Secretary to determine whether the plan is approvable and to determine that the Indian Tribe is eligible to receive a TANF assistance grant. It is also made available to the public.

Respondents

Indian Tribes applying to operate a TANF program.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Request for State Data Needed to Determine the Amount of a Tribal Family Assistance Grant	23	1	68	1564

Estimated Total Annual Burden Hours: 1,564.

Additional Information

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent

directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
[FR Doc. 2013-13536 Filed 6-6-13; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0179]

Guidance for Industry and Food and Drug Administration Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled "Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products," dated June 2013. The final guidance document provides technical and scientific