Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10225, CMS–10502, CMS–10503, CMS–10504 and CMS–10506]

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 April 9, 2014.

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) 395–5806, *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 the 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© 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:* Revision of a currently approved collection; *Title of Information Collection:* Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership; *Use:* There is no Medicare prohibition against physician investment in a hospital or critical access hospitals (CAH). Likewise, there is no Medicare requirement that a hospital or CAH have a physician on-site at all times; although, there is a requirement that they be able to provide basic elements of emergency care to their patients. Medicare quality and safety standards are designed to provide a national framework that is sufficiently flexible to apply simultaneously to hospitals of varying sizes, offering varying ranges of services in differing settings across the nation. At the same time, however, patients might consider an ownership interest by their referring physician, the presence of a physician on-site or both to be important factors in their decisions about where to seek hospital care. A well-educated consumer is essential to improving the quality and efficiency of the healthcare system. Accordingly, patients should be made aware of the physician ownership of a hospital, whether or not a physician is present in the hospital at all times, and the hospital's plans to address patients' emergency medical conditions when a physician is not present. The intent of the disclosures is to increase the transparency of the hospital's ownership and operations to patients as they make decisions about receiving care at the hospital. Please note that the associated information collection request has been revised subsequent to the publication of the 60-day **Federal Register** notice (78 FR 75925, December 13, 2013.). *Form Number:* CMS–10225 (OCN: 0938–1034); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 2,597; *Total Annual Responses:* 30,654,968; *Total Annual Hours:* 261,447. (For policy questions regarding this collection contact Teresa Walden at 410–786–3755).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Long Term Care Hospital Quality Reporting Program: Program Evaluation; *Use:* Section 3004(a) of the Affordable Care Act (ACA) mandated that we establish a quality reporting program for Long Term Care Hospitals (LTCHs). Specifically, section 3004(a) added section 1886(m)(5) to the Social Security Act (the Act) to establish a quality reporting program for LTCHs. This program requires that quality data be submitted by LTCH providers in a time, form and manner specified by the Secretary.

We are interested in exploring how LTCH providers are responding to the new quality reporting program (QRP) and its measures. We believe that it is important to understand early trends in outcomes, to make adjustments as needed to enhance the effectiveness of the program, and to seek opportunities to minimize provider burden, and ensure the QRP is useful and meaningful to providers. The methodology employed in the evaluation is the utilization of qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, we have decided that at this juncture it would be meaningful to use a rich, contextual approach to evaluation the process and success of the QRP initiative.

The decision to pursue this quantitative methodology in 2013, in which we learned that providers are anxious to have their voice heard, but that they did not feel comfortable expressing themselves fully in public open door forums. Providers desired some level of confidentiality, which this methodology affords. The intended use of the information collected is to help inform us about CMS providers' experiences related to the QRPs, such as program impact related to quality improvement, burden, process-related issues, and education. This will also inform future measurement development for the LTCH QRP, future steps related to data validation, as well as future monitoring and evaluation. General findings may be used to discuss our future efforts in the QRP. *Form Number:* CMS–10502 (OCN: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit organizations; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 71. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Inpatient Rehabilitation Facilities Quality Reporting Program: Program Evaluation; *Use:* Section 3004 of the Affordable Care Act (ACA) mandated that we establish a quality reporting program for Inpatient Rehabilitation Facilities (IRFs). Specifically, section 3004(a) added section 1886(j)(7) to the Social Security Act (''the Act'') to establish a quality reporting program (QRP) for IRFs. This program requires IRFs to submit quality data in a time, form and manner specified by the Secretary.

We are interested in exploring how IRF providers are responding to the new QRP and its measures. We believe that it is important to understand early trends in outcomes, to make adjustments as needed to enhance the effectiveness of the program, and to seek opportunities to minimize provider burden, and ensure the quality reporting program is useful and meaningful to the providers. The methodology employed in the evaluation is the utilization of qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, we have decided that at this juncture it would be meaningful to use a rich, contextual approach to evaluation the process and success of the QRP initiative. The decision to pursue this quantitative methodology in 2013, in which we learned that providers are anxious to have their voice heard, but that they did not feel comfortable expressing themselves fully in public open door forums. Providers desired some level of confidentiality, which this methodology affords.

The intended use of the information collected is to help inform CMS providers' experiences related to the QRPs, such as program impact related to quality improvement, burden, process-related issues, and education. This will also inform future measurement development for the IRF QRP, future steps related to data validation, as well as future monitoring and evaluation. General findings may be used to discuss our future efforts in the QRP. *Form Number:* CMS–10503 (OCN: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit organizations; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 71. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

4. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Hospice Quality Reporting Program: Program Evaluation; *Use:* Section 3004(c) of the Affordable Care Act (ACA) mandated that we establish a quality reporting program (QRP) for hospices. Specifically, section 3004(c) added section 1814(i)(5) to the Social Security Act (the Act) to establish a quality reporting program for hospices. This program requires that quality data be submitted by hospices providers in a time, form and manner specified by the Secretary.

We are interested in exploring how hospice providers are responding to the new QRP and its measures. We believe that it is important to understand early trends in outcomes, to make adjustments as needed to enhance the effectiveness of the program, and to seek opportunities to minimize provider burden, and ensure the quality reporting program is useful and meaningful to the providers. The methodology employed in the evaluation is the utilization of qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, we have decided that at this juncture it would be meaningful to use a rich, contextual approach to evaluation the process and success of the QRP initiative. The decision to pursue this quantitative methodology in 2013, in which we learned that providers are anxious to have their voice heard, but that they did not feel comfortable expressing themselves fully in public open door forums. Providers desired some level of confidentiality, which this methodology affords.

The intended use of the information collected is to help inform CMS providers' experiences related to the QRPs, such as program impact related to quality improvement, burden, process-related issues, and education. This will also inform future measurement development for the hospice QRP, future steps related to data validation, as well as future monitoring and evaluation. General findings may be used to discuss our future efforts in the QRP. *Form Number:* CMS–10504 (OCN: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit organizations; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 71. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

5. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Conditions of Participation for Community Mental Health Centers and Supporting Regulations in 42 CFR 485; *Use:* On June 17, 2011, we proposed for the first time new conditions of participation (CoPs) for community mental health centers (CMHCs). We finalized nd were finalized in the final rule that published October 29, 2013 (78 FR 64604), with an effective date 12-months after publication of the final rule. These CoPs which are based on criteria prescribed in law and are standards designed to ensure that each facility has properly trained staff to provide the appropriate safe physical environment for patients. These particular standards reflect comparable standards developed by industry organizations such as the Joint Commission. The primary users of this information will be State agency surveyors, CMS and CMHCs for the purpose of ensuring compliance with Medicare CoPs as well as ensuring the quality of care provided by CMHCs to patients. *Form Number:* CMS–10506 (OCN: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit organizations; *Number of Respondents:* 130; *Total Annual Responses:* 79,530; *Total Annual Hours:* 2,060,342. (For policy questions regarding this collection contact Mary Rossi-Coajou at 410–786–6051.)

Dated: March 5, 2014.

Martique Jones,

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

[FR Doc. 2014–05104 Filed 3–7–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0768]

Determination That ZEFAZONE (Cefmetazole Sodium) Injection, Equivalent to 1 Gram Base/Vial and Equivalent to 2 Gram Base/Vial, and ZEFAZONE (Cefmetazole Sodium) Intravenous Solution, Equivalent to 20 Milligrams Base/Milliliter and Equivalent to 40 Milligrams Base/Milliliter, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ZEFAZONE (cefmetazole sodium) Injection, equivalent to (EQ) 1 gram (g) base/vial and EQ 2 g base/vial, and ZEFAZONE (cefmetazole sodium) Intravenous (IV) Solution, EQ 20 milligrams (mg) base/milliliter (mL) and EQ 40 mg base/mL, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, and ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and 40 mg base/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kathy Schreier, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993–0002, 301–796–3432.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the Orange Book. Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, is the subject of NDA 50–637, held by Pharmacia & Upjohn, Inc., which was initially approved on December 11, 1989; and ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, is the subject of NDA 50–683, held by Pharmacia & Upjohn, Inc., which was initially approved on December 29, 1992. ZEFAZONE is a semisynthetic cephem antibiotic that is indicated for treatment of urinary tract infections, lower respiratory tract infections, skin and skin structure infections, and intra-abdominal infections.

In a letter dated August 1, 2000, Pharmacia & Upjohn, Inc., notified FDA that ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, and ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, were no longer being marketed and requested withdrawal of NDA 50–637 and NDA 50–683. FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book and, in the **Federal Register** of August 16, 2001 (66 FR 43017), announced that it was withdrawing approval of NDA 50–637 and NDA 50–683 effective September 17, 2001.

Salus Pharma LLC submitted a citizen petition dated June 17, 2013 (Docket No. FDA–2013–P–0768), under 21 CFR 10.30, requesting that the Agency determine whether ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not request that we determine whether ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, approved under NDA 50–683, was withdrawn for safety or effectiveness, that product also has been discontinued. On our own initiative, we have also determined whether ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, and ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, and ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, and ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, and ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons