DEPARTMENT OF HEALTH & HUMAN SERVICES
200 Independence Avenue, SW
Washington, DC 20201

CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF THE ADMINISTRATOR

Date: August 2, 2016

To: Howard Shelanski
Administrator, OIRA

From: Andrew M. Slavitt
Acting Administrator

SUBJECT: Request for Emergency Clearance Under the Paperwork Reduction Act – Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium (CMS-10629; OMB 0938-New)

Justification

The Centers for Medicare & Medicaid Services (CMS) is requesting that this information collection request (ICR), for providers and suppliers requesting a waiver to enroll in Medicare/Medicaid CHIP in a moratoria area, be processed under the emergency PRA clearance process. We believe this process is warranted under 5 CFR 1320.13(a)(2)(i).

More specifically, with the approval of CMS-6059-N5, the extension of the State Moratorium, expanding to state-wide for Home Health Agencies, Home Health Sub-Units, and Non-Emergency Ambulance suppliers, on July 29, 2016, an access to beneficiary care may result.

Background

The Affordable Care Act provided CMS with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and CHIP, including the authority to place a temporary moratorium on provider enrollment in these programs. CMS first used its moratoria authority on July 30, 2013, to prevent enrollment of new HHAs in the Chicago, IL and Miami, FL areas, as well as Part B non-emergency ground ambulance suppliers in the Houston, Texas area. CMS exercised this authority again on January 30, 2014, to extend the existing moratoria and expand them to include HHAs in Fort Lauderdale, Florida, Detroit, Michigan and Houston, Texas, and Dallas, Texas as well as Part B non-emergency ground ambulance suppliers in Philadelphia, Pennsylvania and nearby New Jersey counties. The moratoria have since been extended at six month intervals and to date, remain in place in all of the above-mentioned locations.
The Provider Enrollment Moratoria Geographic/Access Waiver Demonstration will support an expansion to state-wide moratoria by addressing the operational concerns that have surfaced throughout the moratoria and providing possible exceptions to the moratoria to ensure that beneficiary access to care is not adversely impacted. Authorization of an exception would be based primarily on beneficiary access to care but would also depend upon passing the enhanced screening measures. The demonstration includes a provision restricting newly enrolling providers to a specific county-based geographical area, based on beneficiary need. Under the proposed demonstration, and sections 1879 (a)(2) and (b) of the Social Security Act, claims

outside of the provider's or supplier's service area will be denied and the provider or supplier may not bill beneficiaries for services outside of the approved service area. This will limit financial liability of Medicare beneficiaries and protect them from costs associated with claims submitted by providers and suppliers who are not eligible to provide services in that geographic location. Additionally, providers seeking to enroll as part of the demonstration will be subject to heightened screening requirements. Should the demonstration prove to be a beneficial tool, CMS would consider expanding this demonstration to other states with instances of high fraud and would initiate rulemaking to continue the heightened level of scrutiny and oversight the demonstration provides.

Timeline

July 22, 2016

- Target submission date for emergency justification to OMB.

July 25, 2016

- Target approval date for emergency justification.

July 29, 2016

- Target date display date for the emergency *Federal Register notice* for this collection.
- Start of 2-week public comment period.

August 3, 2016

- Target publication date for the emergency Federal Register notice.
- Target date for submitting the ICR to OMB.

August 12, 2016

- End of two week public comment period.
- CMS will respond to public comments (if applicable).
- Start of OMB review period.

August 17, 2016

- Requested OMB approval date.
- Approved collection is posted.

Supporting Statement for Paperwork Reduction Act Submissions

Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium
(CMS-10629/OMB: 0938-NEW)

A. BACKGROUND

On July 30, 2013, CMS implemented moratoria to prevent enrollment of new home health agencies (HHAs) in the Chicago, Illinois and Miami, Florida areas, as well as Part B ground ambulance suppliers in the Houston, Texas area. CMS exercised this authority again on January 30, 2014, to extend the existing moratoria and expand them to include HHAs in the metropolitan areas of Fort Lauderdale, Florida; Detroit, Michigan; Houston, Texas; and Dallas, Texas, as well as Part B ground ambulance suppliers in Philadelphia, Pennsylvania and nearby New Jersey counties. The moratoria have since been extended at 6-month intervals and to date, remain in place in all of the above-mentioned locations.

Since implementation of the moratoria, CMS has been able to evaluate the moratoria and identified several operational concerns. Because the current moratoria are geographically defined by county, they do not prohibit providers and suppliers from opening new locations or creating a new enrollment and moving it into a moratorium area. Moreover, CMS is unable to prevent existing providers and suppliers from outside of a moratoria area from servicing beneficiaries within that area. In fact, CMS has analyzed data showing that providers and suppliers who are located several hundred miles outside of a moratorium area are billing for services provided to beneficiaries located within that moratorium area. The ability of providers and suppliers to circumvent the moratoria undermines the effectiveness of the moratoria in protecting the integrity of the Medicare, Medicaid, and CHIP programs.

In order to mitigate the vulnerabilities that have been observed in the current moratoria, CMS is expanding the moratoria on Medicare Part B, Medicaid, and CHIP non-emergency ambulance suppliers and Medicare, Medicaid, and CHIP HHA providers to statewide as announced in a Federal Register document which posted on July 29, 2016.

The Provider Enrollment Moratoria Access Waiver demonstration will support an expansion to state-wide moratoria (FR citation) by addressing the operational concerns that have surfaced throughout the moratoria and providing possible exceptions to the moratoria to ensure that beneficiary access to care is not adversely impacted. Authorization of an exception would be based primarily on beneficiary access to care but would also depend upon passing the enhanced screening measures which are discussed in (FR citation). The demonstration includes a provision that will restrict the billing of newly enrolling providers to a specific county-based geographical area, based on beneficiary need. Under the proposed demonstration, and 1879 (a)(2) and (b) of the Social Security Act, claims outside of the provider's or supplier's service area will be denied and the provider or supplier may not bill beneficiaries for services outside of the approved service area. This will limit financial liability of Medicare beneficiaries and protect them from costs associated with claims submitted by providers and suppliers who are not eligible to provide services in that geographic location. Additionally, providers seeking to enroll as part

of the demonstration will be subject to heightened screening requirements.

The Provider Enrollment Moratoria Access Waiver Application, named the "Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium" has been created to collect that data, which will be completed by providers and suppliers to apply for a waiver in Moratoria locations.

Goals of the enrollment form

The goal of the Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium is to provide a uniform application process that all providers and suppliers may follow so that CMS is able to administer the Medicare, Medicaid or Children's Health Insurance Program moratorium process in a standardized and repeatable manner. This form creates a standardized process so that decisions to grant exceptions from the moratoria are being made with the same criteria each time.

The demonstration Federal Register document (CMS-6073-N) is posting on July 29, 2016. Because CMS does not have a current form approved that will allow us to address access to care issues in the moratoria areas, we are requesting expedited OMB approval with an abbreviated emergency two-week comment period which will begin on the date of display (July 29, 2016). Without the ability to collect access to care information immediately as well screening information, we will be unable to implement the demonstration authority which allows us to accommodate access to care issues, which could result in serious beneficiary access to care concerns. OMB will review the form after the two-week comment period and if approved, it will be valid for no more than 6 months. CMS will publish a 60-day Federal Register notice immediately following approval of the emergency OMB request.

JUSTIFICATION

1. Need and Legal Basis

This demonstration, in conjunction with an expansion of the existing provider enrollment moratoria, will allow CMS to mitigate known vulnerabilities within the existing moratoria and will lead to increased investigations of fraud. Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-l(a)(l)(J)) permits the Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act." In addition to the development and demonstration of improved methods for investigations, CMS will utilize this demonstration to address beneficiary access to care issues.

2. Information Users

The form may be used by newly enrolling Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agency Providers in Moratoria Designated Geographic Locations, seeking a waiver for enrollment.

3. Use of Information Technology

This form lends itself to email or hardcopy submission ONLY. The form may be emailed to providerenrollmentmoratoria@cms.gov and paper submissions will be mailed to CMS Central Office, Center for Program Integrity. CMS is also requiring that providers and suppliers submitting the enrollment wavier form also submit CMS-855 by email. The purpose of this request is to limit the amount of additional information that we are requiring on the waiver application.

4. Duplication of Efforts

There is no duplicative information collection instrument or process.

5. Small Business

This form may affect small businesses; however, CMS does not have the regulatory authority to exclude small business from state-implemented moratoria, nor does CMS have the authority to require the submission of less information in order to reduce the burden to small business.

6. Less Frequent Collection

This information is collected on an as needed basis, as defined by state Medicaid and CHIP programs.

7. Special Circumstances

This is a special circumstance because this form only lends itself to email or hardcopy submission. The form can be requested via the email providerenrollmentmoratoria@cms.gov, completed, and emailed back to the same address or mailed back in a paper submission to CMS Central Office, Center for Program Integrity.

8. Federal Register Notice/Outside Consultation

A Notice (CMS-6073-N) is scheduled to display on July 29, 2016 at the Office of the Federal Register. The notice will announce an emergency comment period. The two-week comment period will begin from the date of display. No individuals outside the Agency were consulted on either the data collection or analysis associated with this collection activity.

9. Payment/Gift to Respondents

No payments or gifts will be provided to respondents.

10. Confidentiality

CMS will comply with all Privacy Act, Freedom of Information laws and regulations that apply to this collection. Privileged or confidential commercial or financial information is protected from public disclosure by Federal law 5 U.S.C. 522(b)(4) and Executive Order 12600.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimate (Hours and Wages)

A. Paperwork Burden Estimate (hours)

The provider and supplier burden associated with completion of this form is estimated at six hours per form. This will include the following time burden per form:

- 2 hours for completion of fingerprint-based criminal background check (FCBC)
- 2 hours for completion of access to care assessment
- 1.5 hours for completion of form
- 0.5 hours for completion of other miscellaneous administrative activities

There will be variation to this estimate based on proximity to a fingerprinting offices as well as the complexity of the data that the provider or suppliers elects to submit. To assist with completion of access to care assessment, CMS has HHA and ambulance saturation data available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-22.html.

CMS expects an estimate of 800 new applicants[1] requesting waiver for a total of 4,800 burden hours annually. Additionally, the provider will have the additional burden associated with completion of the CMS-855, which is required for enrollment into Medicare. This burden is covered under OMB control number 0938-0685.

A. Paperwork Burden Estimate (cost)

This form will be completed by provider and suppliers seeking a waiver to enroll in a Moratoria area. The cost burden is estimated at $26.00 ($13.00 base pay) an hour for completion of access to care analysis and miscellaneous administrative activities, totaling $65.00 per application, equaling $52,000 annually. The cost burden is estimated at $178.70 ($89.35 base pay) an hour for the owner to obtain fingerprints and waiver form totaling $625.45 per application, equaling $500,360 annually. Estimated annual burden for 800 newly enrolling applicants totals $552,360.To derive average costs, we used date from the Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm#31-0000 for healthcare support occupations and http://www.bls.gov/oes/current/oes111011.htm for chief executives.) Hourly wage rates include the costs of fringe benefits (calculated at 100 percent of salary) and the adjusted hourly wage.

[1]800 applicants is an estimate based upon the number of new enrollments plus the number of denials due to moratoria in all moratoria states.

13. Capital Cost

There is no capital cost associated with this collection.

14. Cost to Federal Government

There is no additional cost to the Federal government. Applications will be processed in the normal course of Federal duties.

15. Changes to Burden

This is a new collection of information.

16. Publication/Tabulation Dates

There are no plans to publish or tabulate the information collected.

17. Expiration Date

The expiration date and OMB control number will be displayed on each data collection form.