Supporting Statement for Paperwork Reduction Act Submissions

Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium
(CMS-10629/OMB control number: 0938-1313)

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. On August 3, 2016 (81 FR 51120), CMS extended the current moratoria for an additional 6 months and expanded them to statewide for the enrollment of new HHAs in Florida, Illinois, Michigan, and Texas, and Part B non-emergency ambulance suppliers in New Jersey, Pennsylvania, and Texas. Our August 3, 2016 publication also announced the lifting of temporary moratoria for all Part B emergency ambulance suppliers. On January 9, 2017 (82 FR 2362) and July 28, 2017 (82 FR35122), CMS again issued a document to extend the temporary moratoria for a period of 6 months. On September 1, 2017, CMS lifted the statewide temporary moratorium on the enrollment of new Medicare Part B non-emergency ground ambulance suppliers in Texas under the authority of .42 C.F.R. § 424.570(d). CMS most recently extended the remaining moratoria for an additional 6 months on January 30, 2018 and they apply to Medicare, Medicaid, and CHIP.

In imposing these enrollment moratoria, CMS considered both qualitative and quantitative factors that suggest a high risk of fraud, waste, or abuse. CMS relied on law enforcement's longstanding experience with ongoing and emerging fraud trends and activities through civil, criminal, and administrative investigations and prosecutions. CMS' assessment of a high risk of fraud, waste, or abuse in the provider and supplier types within these geographic locations was then confirmed by CMS data analysis, which relied on factors the agency identified as strong indicators of risk. For a more detailed explanation of this determination process and use of these authorities, see the July 31, 2013 Federal Register document (78 FR 46339) or February 4, 2014 Federal Register document (79 FR 6475)). Since implementation of the moratoria, CMS has been able to evaluate the moratoria and identified several operational concerns. Because the moratoria prior to statewide implementation was geographically defined by county, they did 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. Additionally, at the time of the decision to implement the moratoria statewide, CMS saw areas of saturation that exceeded the national average in moratoria states. In the Federal Register document published on February 4, 2014 (79 FR 6475) initially imposing the temporary moratorium on enrollment of HHAs in Broward County, Florida, CMS stated that "it is not necessary to extend the moratorium to the other counties that border Broward because of the

state's home health licensing rules that prevent providers enrolling in these counties from serving the beneficiaries in Broward." However, through data analytics, we determined that these state licensure restrictions are not adequate deterrents to prevent a provider from enrolling in one county and servicing beneficiaries in other counties. In some cases, CMS observed providers who were servicing beneficiaries located over 300 miles from their practice location. This 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.

The Provider Enrollment Moratoria Access Waiver Demonstration (Demonstration) supports state-wide moratoria (81 FR 51120) 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 is based primarily on beneficiary access to care but also depends upon passing the enhanced screening measures which are discussed in (81 FR 51116). The Demonstration includes a provision that restricts the billing of newly enrolling providers to a specific county-based geographical area, based on beneficiary need. Under the Demonstration, and 1879 (a)(2) and (b) of the Social Security Act, claims outside of the provider's or supplier's service area are be denied and the provider or supplier may not bill beneficiaries for services outside of the approved service area. This limits financial liability of Medicare beneficiaries and protects 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 waiver 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 original Demonstration information collection received emergency Office of Management and Budget (OMB) approval on August 19, 2016, under OMB control number 0938-1313. On October 21, 2016, CMS published a 60-day Notice in the Federal Register (81 FR 75408) to begin the normal OMB clearance process.

JUSTIFICATION

1. Need and Legal Basis

Section 402(a)(l)(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". This demonstration, in conjunction with the existing statewide provider enrollment moratoria, allows CMS to mitigate known vulnerabilities within the existing moratoria and leads to increased investigations of fraud. Additionally, CMS utilizes this demonstration to address beneficiary access to care issues.

2. Information Users

The provider enrollment moratoria access waiver application is being utilized to support the Demonstration. The criteria for enrollment under the Demonstration include an access to care issue in the geographic area where the individual or entity proposes to service beneficiaries and passing heightened screening requirements. The waiver application form collects information so that CMS may perform heightened screening and will impact newly enrolling Part B non-emergency ground ambulance suppliers and home health agency providers in moratoria designated geographic locations. The following areas are currently impacted by moratoria: Part B non-emergency suppliers in New Jersey and Pennsylvania, and HHA providers in Florida, Illinois, Michigan, and Texas.

As part of the Demonstration, CMS evaluates several criteria in order to complete heightened screening, including:

- License verification
- Site visits
- Ownership interest verification in LexisNexis and state databases
- Fingerprint-based background checks
- Evaluation of past behavior in public programs
- Federal debt review
- Credit history review
- Background investigations including evaluation of affiliations

CMS currently evaluates three of these criteria for both HHAs and ambulance suppliers during the routine application process. However, through the Demonstration CMS has added new requirements, including fingerprinting of all applicants in order to perform thorough background checks. In order to support the Demonstration CMS also added additional criteria, including evaluation of past behavior in public programs, Federal debt, and the individual or entities credit history to determine whether there is evidence of behavior that poses an undue risk of fraud, waste, or abuse to the Medicare program. Finally, CMS performs an evaluation of the applicant’s affiliations in order to evaluate programmatic risk.

In order to evaluate affiliations, CMS requires the submission of affiliation with entities and individuals that: (1) currently have uncollected debt to Medicare, Medicaid, or CHIP; (2) have been or are subject to a payment suspension under a federal health care program or subject to an Office of Inspector General (OIG) exclusion; or (3) have had their Medicare, Medicaid, or CHIP

enrollment denied or revoked. For the context of this demonstration CMS defines an affiliation as:

- 5 percent greater direct or indirect ownership interest that an individual or entity has in another organization;
- A general or limited partnership interest that an individual or entity has in another organization; an interest in which an individual or entity exercises operational or managerial control over another organization; and
- An interest where an individual or entity directly or indirectly conducts the day-to-day operations of another organization.

The above relationships must be disclosed regardless of whether:

- The relationship is contractual or through some other arrangement;
- The managing individual or entity is a W-2 employee of the organization;
- An interest in which an individual is acting as an officer or director of a corporation; or
- It is a reassignment relationship.

In addition to evaluation disclosed affiliations, CMS performs research in order to independently determine or verify whether an affiliation exists. This review may include evaluation of Provider Enrollment Chain and Ownership System (PECOS) records, the System for Award Management (SAM) Database, the OIG exclusion database, and LexisNexis, among other resources.

Should an affiliation be disclosed or discovered independently by CMS, we evaluate that affiliation to determine whether it poses an undue risk of fraud, waste, or abuse to the Medicare program. Among other things, CMS reviews the duration of the applicant's relationship with the affiliated provider or supplier, determines whether the affiliation still exists or how long ago it ended, evaluates the degree and extent of the affiliation, and reason for termination of the affiliation if applicable. Additionally, CMS determines whether the provider or supplier is currently revoked under a different name, numerical identifier, or business identity.

CMS may deny a provider's or supplier's Demonstration waiver application if CMS determines through heightened screening that enrolling the applicant would pose an undue risk of fraud, waste, or abuse to the Medicare program.

CMS completes a thorough review and renders a decision for each application within 90 days of receipt. Any application that meets the waiver criteria is forwarded to the Medicare Administrative Contractor (MAC) for further processing. The MAC processes the application and determines whether enrollment is appropriate based on all current enrollment policies and procedures.

3. Use of Information Technology

This form lends itself to email or hardcopy submission ONLY. The form may be found at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/

MedicareProviderSupEnroll/ProviderEnrollmentMoratorium.html. 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.

7. Special Circumstances

This is a special circumstance because this form only lends itself to email or hardcopy submission. The form can be found at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/ProviderEnrollmentMoratorium.html or 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 60-day Notice published in the Federal Register on October 31, 2016 (81 FR 75408). Several comments were received from the Illinois Homecare and Hospice Council (IHHC). Comments have been addressed in Appendix A. A 30-day Notice published February 17, 2017 (82 FR 11037). No comments were received in response to the 30-day notice.

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. Payment will be allowed if the applicant's waiver is approved.

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.

The SORN title is Medicare Supplier Enrollment Application – Number: 9-70-0532.

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-sheetsitems/2016-02-22.html.

CMS expects an estimate of 30 new applicants[1] requesting waiver for a total of 1804 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.

[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.

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 $26.84 ($13.42 base pay) an hour for completion of access to care analysis and miscellaneous administrative activities, totaling $67.10 per application, equaling $2,013.00 annually. The cost burden is estimated at $186.88 ($93.44base pay) an hour for the owner to obtain fingerprints and waiver form totaling $654.08 per application, equaling $19,622.40 annually. Estimated annual burden for 30 newly enrolling applicants totals $21,635.40. To derive average costs, we used data from the Bureau of Labor Statistics' May 2016 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.

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

The change to cost burden is derived from the Bureau of Labor Statistics' of May 2016. The previous cost burden was estimated at $26.00 and updated to $26.84 ($13.42 base pay) an hour for completion of access to care analysis and miscellaneous administrative activities, previously totaling $65.00 updated to $67.10 per application, previously equaling $1,950.00 updated to $2,013.00 annually. The previous cost burden was estimated at $178.70 and updated to $186.88 ($93.44base pay) an hour for the owner to obtain fingerprints and waiver form previously totaling $625.45 updated to $654.08 per application, previously equaling $18,763.50 updated to $19,622.40 annually. Previous estimated annual burden for 30 newly enrolling applicants totals $20,713.50 updated to $21,635.40. There are no changes to burden with this request to reinstate the 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. (See top right corner of each page).