



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Parts 405, 424, and 455

[CMS-6073-N]

### **Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Provider Enrollment Moratoria Access Waiver Demonstration of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Moratoria-Designated Geographic Locations**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Implementation of the waiver demonstration.

**SUMMARY:** This notice announces the Provider Enrollment Moratoria Access Waiver Demonstration of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in 6 states. The demonstration is being implemented in accordance with section 402 of the Social Security Amendments of 1967 and gives CMS the authority to grant waivers to the statewide enrollment moratoria on a case-by-case basis in response to access to care issues, and to subject providers and suppliers enrolling via such waivers to heightened screening, oversight, and investigations.

**DATES:** Effective July 29, 2016.

**FOR FURTHER INFORMATION CONTACT:** Jung Kim, (410) 786-9370.

News media representatives must contact CMS' Public Affairs Office at (202) 690-6145 or email them at [press@cms.hhs.gov](mailto:press@cms.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

The Affordable Care Act provided CMS with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), including the authority to implement a temporary moratorium on provider enrollment in these programs. CMS uses quantitative and qualitative data to determine whether there is a need for a moratorium, such as reviewing provider and supplier saturation data for the area under consideration for a moratorium and whether such area has significantly higher than average billing per beneficiary or provider per beneficiary ratios. CMS first used its moratoria authority on July 30, 2013, 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 locations previously noted.

Since implementation of the moratoria, CMS has been able to evaluate the moratoria and has identified several limitations. 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 outside the moratorium area 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 some

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 elsewhere in this issue of the **Federal Register**.

## **II. Demonstration Design and Duration**

CMS is implementing the "Provider Enrollment Moratoria Access Waiver Demonstration" (PEWD), as authorized by section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)), concurrently with the announcement of the statewide expansion of temporary moratoria on the enrollment of non-emergency ambulance suppliers and home health agencies in Medicare, Medicaid, and CHIP in six states elsewhere in this issue of the **Federal Register**. CMS is implementing this statewide expansion in order to address a high incidence of fraud in the moratoria areas without adversely affecting beneficiary access to care. This demonstration will permit a provider or supplier subject to the moratoria to submit a PEWD application that, if approved, will exempt the provider or supplier from the statewide moratorium in designated geographic areas. Additionally, it will implement a process for heightened review and investigations for such providers and suppliers enrolling pursuant to such waivers.

In order to qualify for a waiver of the moratoria restrictions, a provider or supplier must demonstrate that an access to care issue exists, and will be subject to heightened screening

measures. If the provider or supplier receives a waiver, restrictions will be implemented on the provider's or supplier's service area to limit the provider or supplier to the area with access to care issues and prevent it from furnishing services in locations that are already oversaturated with that provider or supplier type. This restriction will be based on the saturation of providers or suppliers and the number of beneficiaries in the counties where the provider or supplier proposes to operate. Extensive evaluations of providers and suppliers seeking to enroll through this demonstration will be coupled with proactive reviews of submitted claims beginning within the first 60 days of enrollment, as well as increased investigations with referral to law enforcement as appropriate, for newly enrolled and existing providers.

Under the demonstration, claims submitted for services furnished outside of the provider's or supplier's approved service area will be denied and the provider or supplier may not bill beneficiaries for such services provided. This will limit the financial liability of Medicare, Medicaid, and CHIP 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.

For the same reasons that we implementing this demonstration in Medicare, CMS will also implement the demonstration in Medicaid and CHIP, as authorized by section 402 of the Social Security Amendments of 1967.

#### A. Medicare Implementation

The CMS Center for Program Integrity (CPI) will perform all PEWD application reviews and make the relevant access to care determinations.

CMS is currently engaged in the process to seek OMB approval of a PEWD application form under the Paperwork Reduction Act of 1995. Upon approval of this form, providers and

suppliers should complete the form and submit it, with all required documentation, to the designated mailbox: [ProviderEnrollmentMoratoria@cms.hhs.gov](mailto:ProviderEnrollmentMoratoria@cms.hhs.gov). Upon receipt of the application, required documentation, and payment of the application fee, CPI will review for completeness and, within 30 days, will respond with confirmation of receipt or in the case of an incomplete application, rejection. Application submission will require full disclosure of affiliations as outlined in the March 1, 2016 proposed rule (81 FR 10720) titled “Medicare, Medicaid, and Children’s Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process” (hereinafter referred to as the March 1, 2016 proposed rule). Although this is a proposed rule, we are adopting the proposed procedures for disclosing affiliations for purposes of this demonstration. Should we receive more than one application for a particular geographical area, the applications will be prioritized by order of receipt. An application will not be considered received until it is complete, including fingerprints. A more detailed discussion regarding these requirements may be found later in this section of this document. Subsequently, CMS will have 90 days from initial receipt to review each application and communicate a decision to the provider or supplier.

Once a complete application is received, the primary determining factor for PEW approval under this demonstration, and the first step in application review, will be a determination regarding beneficiary access to care. This determination will be primarily based upon an evaluation of provider and supplier saturation, provider or supplier to beneficiary ratios, and claims data; this review will be supplemented with the access to care information that the provider or supplier has provided. As a requirement of the application, the provider or supplier will be required to submit detailed access to care information that demonstrates whether an access to care issue exists in the counties where the provider or supplier is attempting to enroll.

In 2016, we publicly released moratoria-related saturation data. This data set, located at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-22.html>, includes national and state, and county level, saturation data that identifies states that are currently impacted by moratorium. This data gives both states and the public detailed information relevant for an access to care justification. Additionally, we expect applicants to submit data to support that an access to care issue exists, which should not subject applicants to unnecessary burdens of performing extensive analyses. CMS will evaluate the provider- or supplier-generated information and compare it with statistical analysis data that is generated internally by CMS to determine whether an access to care issue exists in the identified area.

If we determine that a beneficiary access to care issue does not exist in the counties where the provider or supplier proposes to operate, the application will be rejected and the application fee will be refunded. A provider or supplier whose application has been rejected may submit a new application at any time. If any subsequent application demonstrates an access to care issue, then we may move forward with processing the application.

When we determine that beneficiary access to care is limited in the counties where the provider or supplier has proposed to enroll, we will continue to the next step in processing the application. We will utilize the ownership information in the submitted CMS-855, in conjunction with the information on the PEWD application, to perform the following screening measures:

- License verification.
- Background investigations including evaluation of affiliations as outlined in the

March 1, 2016 proposed rule.

- Federal debt review.
- Credit history review.
- Fingerprint-based criminal background checks (FCBC) of persons with a 5 percent or greater direct or indirect ownership interest, partners and managing employees.
- Enhanced site visits.
- Ownership interest verification in LexisNexis and state databases.
- Evaluation of past behavior in other public programs.

Providers and suppliers who do not pass these heightened screening requirements will receive a letter stating that their application has been denied and indicating the specific reason(s) for denial. Should it choose to do so, a provider or supplier whose application has been denied may submit an appeal to CMS within 15 days of denial. The appeal must specifically address the reason(s) for denial and detail the action(s) taken to resolve any deficiency. We will evaluate the appeal and process, or deny, the application as appropriate. If a provider or supplier's application is denied because the provider or supplier has not passed the heightened screening requirements, the application fee will not be refunded. Further, if a provider or supplier is denied for a reason under § 424.530(a), the provider or supplier may not reapply under the Provider Enrollment Waiver (PEW). Additional information about submitting an appeal may be found on the provider enrollment moratoria website at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/ProviderEnrollmentMoratorium.html>.

If CMS determines that a provider or supplier meets the requirements of the PEWD, it will forward the provider or supplier's CMS 855 application to the Medicare Administrative Contractor (MAC) for further processing. The MAC will process the application and determine whether enrollment is appropriate based on all current enrollment policies and procedures.

In addition to the heightened screening measures previously described , providers or suppliers that enroll via this demonstration will also be subject to a 1-year period of enhanced oversight as authorized by section 1866(j)(3)(A) of the Social Security Act (the Act). As part of this oversight, providers or suppliers that enroll through the demonstration will be limited to furnishing services within a specific geographic area based on beneficiary access to care determinations. Providers and suppliers submitting a PEWD application will specify a requested geographic area. However, this area may be further restricted or expanded based upon CMS's determination regarding the scope of the access to care issue. Claims for services furnished outside of the approved service area will be denied and the provider or supplier may not bill beneficiaries for services outside of the approved service area.

Another aspect of our enhanced oversight during this demonstration will be to closely monitor the billing patterns of providers and suppliers through the Fraud Prevention System (FPS). Any abuse of billing privileges may result in revocation of Medicare enrollment. All applicants who are enrolled through the PEWD will be subject to all Medicare policies and regulations, including the requirement of revalidation of their Medicare enrollment within five years of initial enrollment, in addition to the heightened oversight that is implemented through the demonstration.

If CMS determines there is a beneficiary access to care issue, we will utilize tools that CMS already has in place to facilitate care. Both the regional offices and 1-800-MEDICARE have experience and valuable tools in resolving beneficiary access to care issues, including Home Health Compare and similar provider and supplier locator resources. As current practice dictates, the beneficiary will also be assisted with widening his search, if appropriate, and can be given additional means to assist in finding care, including utilizing the Senior Health Insurance

Program (SHIP), an organization that is very experienced in addressing such issues. In the event that the beneficiary is a Medicare Advantage enrollee, then their plan would be contacted and responsible for providing a resolution to their access to care issue.

#### B. Increased Investigation and Prosecution

Throughout the course of the demonstration, CMS will work with all of its state, federal and law enforcement partners to identify fraudulent providers and suppliers and will take administrative action to remove such providers and suppliers from the Medicare program. For example, within 60 days of a provider or supplier's enrollment pursuant to the PEW, we will perform proactive monitoring and oversight of such provider or supplier, including proactive examination of claims data and investigation of billing anomalies. Further, we will prioritize PEWD-related investigations and will make referrals to appropriate law enforcement partners, including Department of Justice (DOJ), Office of Inspector General (OIG), and state law enforcement agencies, for prosecution of fraud.

#### C. Medicaid and CHIP Implementation

In addition to the Medicare program, this demonstration will also apply to Medicaid and CHIP. The states will administer the Medicaid and CHIP PEWD and will independently evaluate access to care. If a state determines that a statewide expansion of temporary moratoria would pose unique access to care concerns as compared with more geographically limited moratoria, then the state may elect to lift the moratoria after notifying the Secretary. However, we anticipate that, in the majority of cases, states will be able to use the flexibilities afforded by PEWD to address access to care concerns.

All PEWD-related processes, including but not limited to heightened screening, enrollment, denials, and appeals will be operationalized by the state Medicaid and CHIP

agencies in accordance with Federal and State regulations and guidance. The states will make recommendations to CMS regarding when a provider should be enrolled based on access to care, and must wait for CMS concurrence prior to enrolling a provider under the PEWD. CMS will evaluate all recommendations within 30 days of receipt and will advise the state as to whether or not CMS concurs with the recommendation to move forward in the enrollment process. States will not be required to seek approval from CMS to deny a PEWD application. If a provider or supplier receives an enrollment waiver from Medicare, the provider or supplier will be eligible to enroll in Medicaid or CHIP without further review by the states or further concurrence by CMS. However, if a provider or supplier receives a Medicaid or CHIP waiver, the provider or supplier must separately apply for a waiver with Medicare.

#### D. Demonstration Conclusion

CMS will utilize the PEWD as an opportunity to observe the statewide moratoria and heightened application review effectiveness until the moratoria are lifted, or for a total of 3 years, whichever comes first. Should the PEWD prove to be a useful tool, we will explore options for continuing and expanding the most successful aspects outside of the context of a demonstration. The enhanced oversight exercised as part of the demonstration will also allow us to identify trends and vulnerabilities in the moratoria states and make program adjustments to address fraud schemes as they transform over time.

At the conclusion of the demonstration, those enrollments that occurred as part of the PEWD will be converted to standard enrollments without geographical billing restrictions.

#### E. Duration of the Demonstration

The PEWD will begin concurrently with statewide expansion of moratoria of HHAs and ambulance suppliers in 6 states (which will be in place for 6 months with the potential for

extensions in 6-month increments) and will commence on July 29, 2016. This demonstration will last until the statewide moratoria are lifted, or for a total of 3 years through (concluding on July 28, 2019), whichever comes first.

#### **IV. Collection of Information Requirements**

##### A. Background

In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) we requested emergency review under 5 CFR 1320.13(a)(2)(i) because public harm is reasonably likely to result if the regular clearance procedures were followed. Interested parties may comment on the collection of information requirements during a 2-week comment period beginning on July 29, 2016. Those comments will be reviewed prior to OMB action. Once approved, any information collection will be active for no more than 6 months.

Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day and 30-day notice in the **Federal Register** concerning each proposed collection of information requirements. To comply with the PRA, CMS will publish the 60-day **Federal Register** notice immediately following OMB approval of the emergency information collection requirement (ICR).

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on the ICRs outlined as follows.

## B. Burden Estimate (Hours and Wages)

### 1. 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<sup>1</sup> 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.

### 2. Paperwork Burden Estimate (cost)

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<sup>1</sup>800 applicants is an estimate based upon the number of new enrollments plus the number of denials due to moratoria in all moratoria states.

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 data 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](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.

### C. Response to Comments

We welcome comments on all burden estimates contained in the collection of information section of this notice. If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, (CMS-10629)

Fax: (202) 395-6974; or

Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov)

### **V. Waiver Authority**

Under section 402(b) of Pub. L. 90-248 (42 U.S.C. 1395b-1(b)), certain requirements of the Act and implementing regulations will be waived in order to implement this demonstration.

Specifically, CMS will waive the following authorities in Florida, Illinois, Michigan, New Jersey, Pennsylvania, and Texas:

- Waiver of § 424.518(c) and (d) and 455.434(a) which describe the fingerprinting rules for enrollment in Medicare, Medicaid and CHIP.<sup>2</sup> This waiver involves expanding the existing regulatory authority in two ways: (1) to include ambulance suppliers requesting a PEW waiver within the categories of providers and suppliers to which the FCBC requirements apply; and (2) to include managing employees within the associated individuals subject to an FCBC when the provider or supplier seeks to enroll according to the PEW. Additionally, we intend to modify the authority which currently requires denial or revocation of providers or suppliers who fail to submit fingerprints, to instead specify that a PEWD application will be rejected if the provider or supplier fails to submit the required fingerprints within 30 days.

- Waiver of section 1866(j)(3)(B) of the Act, which requires program instruction or regulatory interpretation in order to implement section 1866(j)(3) of the Act for the provisional period of enhanced oversight for new providers of services and suppliers. We intend to implement the requirements of section 1866(j)(3) of the Act for purposes of this demonstration and in the absence of regulation or other instruction in order to allow for a 1-year period of enhanced oversight of newly enrolling providers and suppliers under this demonstration.

- Waiver of § 424.545, Part 498 Subparts D and E, and § 405.803(b) of the regulations, as well as section 1866(j)(8) of the Act which allow a provider or supplier the right to request a hearing with an administrative law judge and the Department Appeals Board in the case of denial

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<sup>2</sup> According to § 457.990, the enrollment screening requirements applicable to providers enrolling in Medicaid apply equally to those enrolling in CHIP.

of an enrollment application. Denials of enrollment pursuant to this demonstration will be appealable only to CMS, and any applicant to the PEWD will waive their right to further appeal.

- Waiver of section 1866(j)(7) of the Act and §§ 424.570 and 455.470 of the regulations which specify that the moratoria must be implemented at a provider- or supplier-type level, in order to allow a case-by-case exception process to moratoria.

Dated: July 26, 2016

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**Andrew M. Slavitt**

Acting Administrator,

Centers for Medicare & Medicaid Services.

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