

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.² 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 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.

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

Dated: July 26, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 424 and 455

[CMS-6059-N5]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Implementation and Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations and Lifting of the Temporary Moratoria on Enrollment of Part B Emergency Ground Ambulance Suppliers in All Geographic Locations

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

ACTION: Extension, implementation, and lifting of temporary moratoria.

SUMMARY: This document announces the extension of temporary moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance suppliers and Medicare home health agencies (HHAs), subunits, and branch locations in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. It also announces the implementation of temporary moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance suppliers and Medicare HHAs, subunits, and branch locations in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey on a statewide basis. In addition, it announces the lifting of the moratoria on all Part B emergency ground ambulance suppliers. These moratoria, and the changes described in this document, also apply to the enrollment of HHAs and non-emergency ground ambulance suppliers in Medicaid and the Children's Health Insurance Program.

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.

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS' Implementation of Temporary Enrollment Moratoria

Under the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively known as the Affordable Care Act), the Congress provided the Secretary with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Section 6401(a) of the Affordable Care Act added a new section 1866(j)(7) to the Social Security Act (the Act) to provide the Secretary with authority to impose a temporary moratorium on the enrollment of new Medicare, Medicaid or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. Section 6401(b) of the Affordable Care Act added specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any moratorium imposed by the Secretary unless the State determines that the imposition of such moratorium would adversely impact Medicaid beneficiaries' access to care. Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to provide that all of the Medicaid provisions in sections 1902(a)(77) and 1902(kk) are also applicable to CHIP.

In the February 2, 2011 **Federal Register** (76 FR 5862), CMS published a final rule with comment period titled, "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers," which implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under § 424.570(a)(2)(i) and (iv), CMS, or CMS in consultation with the Department of Health and Human Services' Office of Inspector General (HHS-OIG) or the Department of Justice (DOJ), or both, may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type, or particular geographic locations, or both. At § 424.570(a)(1)(ii), CMS stated that it would announce any temporary moratorium in a **Federal Register**

document that includes the rationale for the imposition of such moratorium. This document fulfills that requirement.

In accordance with section 1866(j)(7)(B) of the Act, there is no judicial review under sections 1869 and 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. A provider or supplier may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium; however the scope of any such appeal is limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial. Under § 424.570(c), CMS denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. If the provider or supplier was required to pay an application fee, the application fee will be refunded if the application was denied as a result of the imposition of a temporary moratorium (see § 424.514(d)(2)(v)(C)).

Based on this authority and our regulations at § 424.570, we initially imposed moratoria to prevent enrollment of new HHAs, subunits, and branch locations¹ (hereafter referred to as HHAs) in Miami-Dade County, Florida and Cook County, Illinois, as well as surrounding counties, and Medicare Part B ground ambulance suppliers in Harris County, Texas and surrounding counties, in a notice issued on July 31, 2013 (78 FR 46339). We exercised this authority again in a notice published on February 4, 2014 (79 FR 6475) when we extended the existing moratoria for an additional 6 months and expanded them to include enrollment of HHAs in Broward County, Florida; Dallas County, Texas; Harris County, Texas; and Wayne County, Michigan and surrounding counties, and enrollment of ground ambulance suppliers in Philadelphia, Pennsylvania and surrounding counties. Then, we further extended these moratoria in documents issued on August 1, 2014 (79 FR 44702), February 2, 2015 (80 FR 5551), July 28, 2015 (80 FR 44967), and February 2, 2016 (81 FR 5444).

B. Determination of the Need for Moratoria

In imposing these enrollment moratoria, CMS considered both

qualitative and quantitative factors suggesting 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' determination of a high risk of fraud, waste, or abuse in these 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 of these authorities, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475)).

Because fraud schemes are highly migratory and transitory in nature, many of CMS' program integrity authorities and anti-fraud activities are designed to allow the agency to adapt to emerging fraud in different locations. The laws and regulations governing CMS' moratoria authority give us flexibility to use any and all relevant criteria for future moratoria, and CMS may rely on additional or different criteria as the basis for future moratoria.

1. Application to Medicaid and the Children's Health Insurance Program (CHIP)

The February 2, 2011 final rule also implemented section 1902(kk)(4) of the Act, establishing new Medicaid regulations at § 455.470. Under § 455.470(a)(1) through (3), the Secretary may impose a temporary moratorium, in accordance with § 424.570, on the enrollment of new providers or provider types after consulting with any affected State Medicaid agencies. The State Medicaid agency must impose a temporary moratorium on the enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program unless the State determines that the imposition of such moratorium would adversely affect Medicaid beneficiaries' access to medical assistance and so notifies the Secretary. The final rule also implemented section 2107(e)(1)(D) of the Act by providing, at § 457.990 of the regulations, that all of the provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act, as well as the implementing regulations, also apply to CHIP.

Section 1866(j)(7) of the Act authorizes imposition of a temporary enrollment moratorium for Medicare, Medicaid, and/or CHIP, "if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such

program." While there may be exceptions, CMS believes that generally, a category of providers or suppliers that poses a risk to the Medicare program also poses a similar risk to Medicaid and CHIP. Many of the new anti-fraud provisions in the Affordable Care Act reflect this concept of "reciprocal risk" in which a provider that poses a risk to one program poses a risk to the other programs. For example, section 6501 of the Affordable Care Act titled, "Termination of Provider Participation under Medicaid if Terminated Under Medicare or Other State Plan," which amends section 1902(a)(39) of the Act, requires State Medicaid agencies to terminate the participation of an individual or entity if such individual or entity is terminated under Medicare or any other State Medicaid plan. Additional provisions in title VI, Subtitles E and F of the Affordable Care Act also support the determination that categories of providers and suppliers pose the same risk to Medicaid as to Medicare. Section 6401(a) of the Affordable Care Act required us to establish levels of screening for categories of providers and suppliers based on the risk of fraud, waste, and abuse determined by the Secretary. Section 6401(b) of the Affordable Care Act required State Medicaid agencies to screen providers and suppliers based on the same levels established for the Medicare program. This reciprocal concept is also reflected in the Medicare moratoria regulations at § 424.570(a)(2)(ii) and (iii), which permit CMS to impose a Medicare moratorium based solely on a State imposing a Medicaid moratorium. Accordingly, CMS has determined that there is a reasonable basis for concluding that a category of providers or suppliers that poses a risk to Medicare also poses a similar risk to Medicaid and CHIP, and that a moratorium in all of these programs is necessary to effectively combat this risk.

2. Consultation With Law Enforcement

In consultation with the HHS Office of Inspector General (OIG) and the Department of Justice (DOJ), CMS previously identified two provider and supplier types in nine geographic locations that warrant a temporary enrollment moratorium. For a more detailed discussion of this consultation process, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475).

3. Data Analysis

In addition to consulting with law enforcement, CMS also analyzed its own data to identify specific provider and

¹ As noted in the preamble to the final rule with comment period implementing the moratorium authority (February 2, 2011, CMS-6028-FC (76 FR 5870), home health agency subunits and branch locations are subject to the moratoria to the same extent as any other newly enrolling home health agency.

supplier types within geographic locations with significant potential for fraud, waste or abuse, therefore warranting the imposition of enrollment moratoria.

Four of the six states subject to the temporary enrollment moratoria for HHAs and Part B non-emergency ground ambulance suppliers have counties that contain or are adjacent to HEAT Medicare Fraud Strike Force locations, with the exception of Pennsylvania and New Jersey. All six states are also consistently ranked near the top for the identified metrics among counties with at least 200,000 Medicare beneficiaries in 2012.

4. Beneficiary Access to Care

Beneficiary access to care in Medicare, Medicaid, and CHIP is of critical importance to CMS and its State partners, and CMS carefully evaluated access for the target moratorium locations with every imposition and extension of the moratoria. Prior to imposing these moratoria, CMS reviewed Medicare data for these areas and found no concerns with beneficiary access to HHAs or ground ambulance suppliers. CMS also consulted with the appropriate State Medicaid Agencies and with the appropriate State Departments of Emergency Medical Services to determine if the moratoria would create access to care concerns for Medicaid and CHIP beneficiaries in the targeted locations and surrounding counties. All of CMS' State partners were supportive of CMS' analysis and proposals, and together with CMS, determined that these moratoria would not create access to care issues for Medicaid or CHIP beneficiaries.

5. When a Temporary Moratorium Does Not Apply

Under § 424.570(a)(1)(iii), a temporary moratorium does not apply to changes in practice locations, changes to provider or supplier information such as phone number, address, or changes in ownership (except changes in ownership of HHAs that require initial enrollments under § 424.550). Also, in accordance with § 424.570(a)(1)(iv), the moratorium does not apply to an enrollment application that a CMS contractor has already approved, but has not yet entered into the Provider Enrollment Chain and Ownership System (PECOS) at the time the moratorium is imposed.

6. Lifting a Temporary Moratorium

In accordance with § 424.570(b), a temporary enrollment moratorium imposed by CMS will remain in effect for 6 months. If CMS deems it

necessary, the moratorium may be extended in 6-month increments. CMS will evaluate whether to extend or lift the moratorium before the end of the initial 6-month period and, if applicable, any subsequent moratorium periods. If one or more of the moratoria announced in this document are extended, CMS will publish a document regarding such extensions in the **Federal Register**.

As provided in § 424.570(d), CMS may lift a moratorium at any time if the President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, if circumstances warranting the imposition of a moratorium have abated, if the Secretary has declared a public health emergency, or if, in the judgment of the Secretary, the moratorium is no longer needed.

Once a moratorium is lifted, the provider or supplier types that were unable to enroll because of the moratorium will be designated to CMS' high screening level under §§ 424.518(c)(3)(iii) and 455.450(e)(2) for 6 months from the date the moratorium was lifted.

II. Lifting of Moratorium on New Part B Emergency Ambulance Suppliers in All Geographic Locations

CMS previously imposed moratoria on the enrollment of new Part B ground ambulance suppliers in the Texas counties of Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller; the Pennsylvania counties of Bucks, Delaware, Montgomery, and Philadelphia; and the New Jersey counties of Burlington, Camden, and Gloucester. These moratoria became effective upon publication of the notice in the **Federal Register** on July 31, 2013 (78 FR 46339) and the moratoria document on February 4, 2014 (79 FR 6475), and were subsequently extended by documents published in the **Federal Register** on August 1, 2014 (79 FR 44702), February 2, 2015 (80 FR 5551), and July 28, 2015 (80 FR 44967), and February 2, 2016 (81 FR 5444).

Throughout the duration of the temporary moratoria on newly enrolling Part B ground ambulance providers, CMS has evaluated the risk to the Medicare program of separate categories of ambulance suppliers. This evaluation has shown that the primary risk to the program comes from the non-emergency ambulance supplier category. Additionally, we have observed potential access to care related issues for emergency ambulance services in some areas. As a result, CMS is not extending the temporary moratoria on the

enrollment of Part B emergency ground ambulance suppliers in any geographic locations in the states of New Jersey, Pennsylvania, or Texas. However, we will continue to evaluate all ambulance services for indicators of fraud, waste, and abuse and will evaluate the need for future moratoria based on these indicators. The lifting of the moratorium on new Part B emergency ambulance suppliers in all geographic locations also applies to Medicaid and CHIP. New Part B suppliers of emergency ambulance services will be permitted to enroll as of July 29, 2016. Any such suppliers that enroll within 6 months of that date will be included in the "high" risk screening category, as provided in § 424.518(c)(3). New emergency ambulance suppliers that furnish both emergency and non-emergency services will only be able to bill for emergency transportation services.

III. Extension of Home Health and Ambulance Moratoria—Geographic Locations

CMS previously imposed moratoria on the enrollment of new HHAs in the Florida counties of Broward, Miami-Dade, and Monroe; the Illinois counties of Cook, DuPage, Kane, Lake, McHenry, and Will; the Michigan counties of Macomb, Monroe, Oakland, Washtenaw, and Wayne; and the Texas counties of Brazoria, Chambers, Collin, Fort Bend, Galveston, Dallas, Harris, Liberty, Denton, Ellis, Kaufman, Montgomery, Rockwall, Tarrant, and Waller. Further, we previously imposed moratoria on the enrollment of new ground ambulance suppliers in the Texas counties of Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller; the Pennsylvania counties of Bucks, Delaware, Montgomery, and Philadelphia; and the New Jersey counties of Burlington, Camden, and Gloucester. These moratoria became effective upon publication of the notice in the **Federal Register** on July 31, 2013 (78 FR 46339) and the moratoria document on February 4, 2014 (79 FR 6475), and were subsequently extended by documents published in the **Federal Register** on August 1, 2014 (79 FR 44702), February 2, 2015 (80 FR 5551), July 28, 2015 (80 FR 44967), and February 2, 2016 (81 FR 5444).

As provided in § 424.570(b), CMS may deem it necessary to extend previously-imposed moratoria in 6-month increments. Under this authority, CMS is extending the temporary moratoria on the Medicare enrollment of HHAs and Part B non-emergency ground ambulance suppliers in the geographic locations discussed herein. Under regulations at § 455.470 and

§ 457.990, these moratoria also apply to the enrollment of HHAs and non-emergency ground ambulance suppliers in Medicaid and CHIP. Under § 424.570(b), CMS is required to publish a document in the **Federal Register** announcing any extension of a moratorium, and this extension of moratoria document fulfills that requirement.

CMS consulted with the HHS–OIG regarding the extension of the moratoria on new HHAs and Part B non-emergency ground ambulance suppliers in all of the moratoria counties, and HHS–OIG agrees that a significant potential for fraud, waste, and abuse continues to exist regarding those provider and supplier types in these geographic areas. The circumstances warranting the imposition of the moratoria have not yet abated, and CMS has determined that the moratoria are still needed as we monitor the indicators and continue with administrative actions to combat fraud and abuse, such as payment suspensions and revocations of provider/supplier numbers. (For more information regarding the monitored indicators, see the February 4, 2014 moratoria document (79 FR 6475)).

Based upon CMS' consultation with the relevant State Medicaid agencies, CMS has concluded that extending these moratoria will not create an access to care issue for Medicaid or CHIP beneficiaries in the affected counties at this time. CMS also reviewed Medicare data for these areas and found there are no current problems with access to HHAs or ground ambulance suppliers. Nevertheless, the agency will continue to monitor these locations to make sure that no access to care issues arise in the future.

Based upon our consultation with law enforcement and consideration of the factors and activities described previously, CMS has determined that the temporary enrollment moratoria should be extended for an additional 6 months.

IV. Implementation of New Home Health and Part B Non-Emergency Ambulance Moratoria—Geographic Locations

1. Geographic locations affected by implementation.

CMS has determined that the factors initially evaluated to implement the temporary moratoria show that a high risk of fraud, waste, and abuse exists beyond the current moratoria areas, which may suggest that a high risk of fraud, waste, or abuse exists due largely to circumvention of the moratoria by

some providers and suppliers. The primary means of circumvention includes enrolling a new practice location outside of a moratorium area and servicing beneficiaries within the moratorium area. Additionally, CMS has continued to see areas of saturation that exceed the national average in the moratoria states. As a result, CMS, in consultation with the OIG, has determined that it is necessary to expand the temporary moratoria on a statewide basis, by implementing temporary moratoria on all newly enrolling HHAs in the remaining counties in Florida, Illinois, Michigan, and Texas, and on all newly enrolling Part B non-emergency ground ambulance suppliers in the remaining counties in Texas, New Jersey, and Pennsylvania, in order to combat fraud, waste, or abuse in those states. CMS has determined that these moratoria will also apply to Medicaid and CHIP in each state, although states continue to have the ability to opt out if they determine that the imposition of such moratorium would adversely impact Medicaid beneficiaries' access to care.

In the 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 beneficiaries in Broward.” However, through data analytics, we have 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 has observed that providers are servicing beneficiaries located over 300 miles from their practice location.

As a result of this and other data analyses, CMS has determined that it is necessary to expand these moratoria to be statewide. Accordingly, beginning on the effective date of this document, no new HHAs will be enrolled in Medicare, Medicaid, or CHIP with a practice location in Florida, Illinois, Michigan, or Texas unless their enrollment application has already been approved but not yet entered into PECOS for Medicare or the State Provider/Supplier Enrollment System for Medicaid and CHIP as of the effective date of this document. Additionally, no new Part B non-emergency ground ambulance supplier will be enrolled into Medicare, Medicaid, or CHIP with a practice location in Texas, New Jersey, or Pennsylvania unless their enrollment

application has already been approved but not yet entered into PECOS for Medicare or the State Provider/Supplier Enrollment System for Medicaid and CHIP as of the effective date of this document.

2. Beneficiary Access to Care

Beneficiary access to care in Medicare, Medicaid, and CHIP is of critical importance to CMS and its State partners, and CMS carefully evaluated access for the target moratorium locations. CMS recognizes the increased risk of beneficiary access to care issues when implementing statewide moratoria. In order to address this issue, we have performed a detailed access to care analysis for all moratoria states, and identified the counties with lower saturation of home health and Part B ground ambulance providers or suppliers.² These data include an evaluation of provider and supplier saturation, provider or supplier to beneficiary ratios, and claims data in the Medicare program. Beneficiary access to care is a primary concern for CMS, and we will continue to utilize these data to address the lowest saturation areas. As a continual measure, CMS will update and evaluate these data to monitor attrition of home health and Part B ground ambulance providers or suppliers from Medicare and make certain that beneficiaries in counties with lower provider or supplier saturation are not negatively impacted by the moratoria or related enforcement activities. Any beneficiary that experiences access to care issues may report them to 1–800–MEDICARE or their state’s Quality Improvement Organization (QIO) for resolution.

CMS does not currently have the regulatory authority to implement an exception process to respond to beneficiary access to care issues; therefore, concurrently with the statewide moratoria implementation, CMS is announcing a demonstration under the authority provided in Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1(a)(1)(J)) that waives certain authorities and allows for such exceptions. The demonstration will, among other things, allow for access to care-based exceptions to the moratoria in certain limited circumstances. This will allow enrollment of a provider or supplier after a heightened review of that provider has been conducted.

CMS has determined that this exception process will also apply to

²Data related to HHAs and Part B non-emergency ambulance suppliers may be viewed at <https://data.cms.gov/moratoria-data>.

Medicaid and CHIP providers in each state. CMS will work collaboratively with states to implement this demonstration in a way that accommodates the access to care needs of beneficiaries in each state.

Details of the demonstration may be found at elsewhere in this issue of the **Federal Register**.

V. Summary of the Moratoria Locations

CMS is executing its authority under sections 1866(j)(7), 1902(kk)(4), and 2107(e)(1)(D) of the Act to extend and implement temporary enrollment moratoria on HHAs for all counties in Florida, Illinois, Michigan, and Texas, as well as Part B non-emergency ground ambulance suppliers for all counties in New Jersey, Pennsylvania, and Texas.

VI. Clarification of Right to Judicial Review

Section 1866(j)(7)(B) of the Act states that there shall be no judicial review under section 1869, section 1878, or otherwise, of a temporary moratorium imposed on the enrollment of new providers of services and suppliers if the Secretary determines that the moratorium is necessary to prevent or combat fraud, waste, or abuse. Accordingly, our regulations at 42 CFR 498.5(l)(4) state that for appeals of denials based on a temporary moratorium, the scope of review will be limited to whether the temporary moratorium applies to the provider or supplier appealing the denial. The agency's basis for imposing a temporary moratorium is not subject to review. Our regulations do not limit the right to seek judicial review of a final agency decision that the temporary moratorium applies to a particular provider or supplier. In the preamble to the February 2, 2011 (76 FR 5918) final rule with comment period establishing this regulation, we explained that "a provider or supplier may administratively appeal an adverse determination based on the imposition of a temporary moratorium up to and including the Department Appeal Board (DAB) level of review." We are clarifying that providers and suppliers that have received unfavorable decisions in accordance with the limited scope of review described in § 498.5(l)(4) may seek judicial review of those decisions after they exhaust their administrative appeals. However, we reiterate that section 1866(j)(7)(B) of the Act precludes judicial review of the agency's basis for imposing a temporary moratorium.

VII. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VIII. Regulatory Impact Statement

CMS has examined the impact of this document as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major regulatory actions with economically significant effects (\$100 million or more in any 1 year). This document will prevent the enrollment of new home health providers and Part B non-emergency ground ambulance suppliers in Medicare, Medicaid, and CHIP. Though savings may accrue by denying enrollments, the monetary amount cannot be quantified. After the imposition of the initial moratoria on July 31, 2013, 889 HHAs, and 19 ambulance companies in all geographic areas affected by the moratoria had their applications denied. We have found the number of applications that are denied after 60 days declines dramatically, as most providers and suppliers will not submit applications during the moratoria period. Therefore, this document does not reach the economic threshold, and thus is not considered a major action.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most

hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. CMS is not preparing an analysis for the RFA because it has determined, and the Secretary certifies, that this document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if an action may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area (MSA) for Medicare payment purposes and has fewer than 100 beds. CMS is not preparing an analysis for section 1102(b) of the Act because it has determined, and the Secretary certifies, that this document will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any regulatory action whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately \$146 million. This document will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Because this document does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.

Dated: July 13, 2016.

Andrew M. Slavitt,
Acting Administrator, Centers for Medicare & Medicaid Services.

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