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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-6059-N4]**

### **Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extended Temporary Moratoria on Enrollment of Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations**

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

**ACTION:** Extension of temporary moratoria.

**SUMMARY:** This document announces the extension of temporary moratoria on the enrollment of new Medicare Part B ground ambulance suppliers and Medicare home health agencies, 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. These moratoria also apply to the enrollment of home health agencies and ground ambulance suppliers in Medicaid and the Children's Health Insurance Program.

**DATES: Effective Date:** January 29, 2016.

**FOR FURTHER INFORMATION CONTACT:** Belinda Gravel, (410) 786-8934. 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**

###### **A. CMS' Imposition of Temporary Enrollment Moratoria**

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 Children's Health Insurance Program (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. For a more detailed explanation of these authorities, please see the July 31, 2013 notice (78 FR 46339) that first established temporary moratoria in certain geographic locations, or the February 4, 2014 (79 FR 6475) document that extended and expanded such moratoria (hereinafter referred to as the February 4, 2014 moratoria document).

Based on this authority and our regulations at § 424.570, we initially imposed moratoria to prevent enrollment of new home health agencies, subunits, and branch locations<sup>1</sup> (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 document published on February 4, 2014 (79 FR 6475) when we extended the existing moratoria for an additional 6 months and expanded it 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), and July 28, 2015 (80 FR 44967).

#### B. Determination of the Need for Moratoria

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<sup>1</sup> 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.

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)).

#### 1. Consultation with Law Enforcement

In consultation with the HHS Office of Inspector General (OIG) and the Department of Justice (DOJ), CMS 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).

#### 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. 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.

### 3. 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 any subsequent moratorium periods. If one or more of the moratoria announced in this document are extended or lifted, CMS will publish a document to that effect in the **Federal Register**.

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 is lifted.

## **II. Extension of Home Health and Ambulance Moratoria – Geographic Locations**

As noted earlier, we 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), and July 28, 2015 (80 FR 44967).

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 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 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 ground ambulance suppliers in all of the moratoria counties, and the HHS OIG agrees that a significant potential for fraud, waste, and abuse continues to exist 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, 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.

### III. 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 the enrollment moratoria in the following counties for HHAs and ground ambulance suppliers:

**Table 1--HHA Moratoria**

<b>State</b>	<b>City/Metropolitan Area</b>	<b>Counties</b>
FL	Fort Lauderdale	Broward
FL	Miami	Monroe Miami-Dade
IL	Chicago	Cook DuPage Kane Lake McHenry Will
MI	Detroit	Macomb Monroe Oakland Washtenaw Wayne
TX	Dallas	Collin Dallas Denton Ellis Kaufman Rockwall Tarrant
TX	Houston	Brazoria Chambers Fort Bend Galveston

State	City/Metropolitan Area	Counties
		Harris Liberty Montgomery Waller

**Table 2—Ground Ambulance Moratoria**

State	City/Metropolitan Area	Counties
PA/NJ	Philadelphia	Bucks Burlington (NJ) Camden (NJ) Delaware Gloucester (NJ) Montgomery Philadelphia
TX	Houston	Brazoria Chambers Fort Bend Galveston Harris Liberty Montgomery Waller

#### **IV. 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(1)(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. We reiterate, however, that section 1866(j)(7)(B) of the Act precludes judicial review of the agency’s basis for imposing a temporary moratorium.

## **V. 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.).

## **VI. 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 one year). This document will prevent the enrollment of new home health providers and ground ambulance suppliers in Medicare and new home health providers and ground ambulance suppliers in 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, 848 HHAs and 14 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 \$7.0 million to \$35.5 million in any one 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 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 one year of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately \$144 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, the Office of Management and Budget reviewed this document.

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and  
44 U.S.C. Chapter 35.

Dated: December 7, 2015.

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**Andrew M. Slavitt**

Acting Administrator,

Centers for Medicare & Medicaid Services.

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