



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

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

#### **42 CFR Part 424**

**[CMS-6059-N7]**

### **Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency 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 statewide temporary moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance providers and suppliers and Medicare home health agencies, subunits, and branch locations in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey, as applicable, to prevent and combat fraud, waste, and abuse. This extension also applies to the enrollment of new non-emergency ground ambulance suppliers and home health agencies, subunits, and branch locations in Medicaid and the Children's Health Insurance Program in those states.

**DATES:** Applicable July 29, 2017.

#### **FOR FURTHER INFORMATION CONTACT:**

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## **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 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

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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, 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.

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).<sup>2</sup> 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). On August 3, 2016 (81 FR 51120), we 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.<sup>3</sup> On January 9, 2017, CMS again issued a document to extend the temporary moratoria for a period of 6 months (82 FR 2363).

## B. Determination of the Need for Moratoria

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<sup>2</sup> CMS has identified an error in the provider and beneficiary saturation data described in our July 31, 2013 **Federal Register** notice (78 FR 46339). We have subsequently revised the methodology by which we determine provider and beneficiary saturation. Following these revisions to the methodology, we simulated application of our current 2016 methodology to the 2013 data, and determined that the 2013 decision to impose the moratorium would not have been impacted had the revised methodology been applied. Provider saturation remains one of the criteria used to determine whether to implement a moratorium. CMS has made market saturation data publicly available at <https://data.cms.gov/market-saturation>.

<sup>3</sup> CMS also concurrently announced 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 allows for access to care-based exceptions to the moratoria in certain limited circumstances after a heightened review of that provider has been conducted. This exception process also applies to Medicaid and CHIP providers in each state. This announcement may be found in the **Federal Register** document issued on August 3, 2016 (81 FR 51116).

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

## 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 and extending 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. All of CMS' State partners were supportive of CMS' analysis

and proposals, and together with CMS, determined that continuation of 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 any of the following: (1) changes in practice location (2) changes in provider or supplier information, such as phone number or address; or (3) changes in ownership (except changes in ownership of HHAs that require initial enrollment under § 424.550). Also, in accordance with § 424.570(a)(1)(iv), a temporary moratorium does not apply to any enrollment application that a Medicare 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. Extension of Home Health and Ambulance Moratoria – Geographic Locations**

CMS currently has in place moratoria on newly enrolling HHAs in Florida, Illinois, Michigan, and Texas and Part B non-emergency ambulance suppliers in New Jersey, Pennsylvania, and Texas.

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 providers and suppliers in the geographic locations discussed herein. Under the regulations at § 455.470 and § 457.990, these moratoria also apply to the enrollment of HHAs and non-emergency ground ambulance providers and suppliers in Medicaid and CHIP in those locations. 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 providers and suppliers in all of the moratoria states, 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 states at this time. CMS also reviewed Medicare data for these states and found there are no current problems with access to HHAs or ground ambulance providers or 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 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 providers and suppliers for all counties in New Jersey, Pennsylvania, and Texas.

### **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(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.

#### **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 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 in certain states. Though savings may accrue by denying enrollments, the monetary amount cannot be quantified. Since the imposition of the initial moratoria on July 31, 2013, more than 1184 HHAs and 23 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 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 (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 2017, that threshold is approximately \$148 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.

CMS-6059-N7

Dated: July 14, 2017

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**Seema Verma**

Administrator,

Centers for Medicare & Medicaid Services.

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