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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6077–N]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Decision To Lift the Temporary Moratorium on Enrollment of Non-Emergency Ground Ambulance Suppliers in Texas

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

ACTION: Lifting of temporary enrollment moratorium on non-emergency ground ambulance suppliers in Texas.

SUMMARY: This document announces that on September 1, 2017, the statewide temporary moratorium on the enrollment of new Medicare Part B non-emergency ground ambulance suppliers in Texas was lifted. This announcement also applies to the temporary moratorium on enrollment of non-emergency ground ambulance suppliers in Medicaid and the Children's Health Insurance Program in Texas.

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

The Social Security Act (the Act) provides the Secretary with tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). In particular, section 1866(j)(7) of the Act provides 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 such a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. Regarding Medicaid, section 1902(kk)(4) of the Act requires States to comply with any moratorium imposed by the Secretary unless the State determines that the imposition of such temporary moratorium would adversely impact Medicaid beneficiaries' access to care. In addition, section 2107(e)(1)(F) of the Act provides that the Medicaid provisions in 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.

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 [1] (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). These moratoria also applied to Medicaid and CHIP. 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 moratoria for an additional 6 months and expanded them to statewide for enrollment of HHAs in Florida, Illinois, Michigan, and Texas, and non-emergency ground ambulance suppliers in New Jersey, Pennsylvania, and Texas. We also announced the lifting of temporary moratoria for all Part B emergency ambulance suppliers as well as emergency ambulance providers in Medicaid and CHIP.[2] Finally, on January 29, 2017 (82 FR 2363) and again on July 28, 2017 (82 FR 35122), we extended the statewide moratoria of HHAs in Florida, Illinois, Michigan, and Texas, and Part B non-emergency ground ambulance suppliers in New Jersey, Pennsylvania, and Texas for additional 6 month periods. These extensions also applied to such providers in Medicaid and CHIP.

II. Lifting a Temporary Moratorium

CMS has authority under § 424.570(d) to lift a temporary moratorium at any time in specified situations, including if the President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act. On August 25, 2017, the President of the United States signed the Presidential Disaster Declaration for several counties in the State of Texas. As a result of the President's declaration, CMS carefully reviewed the potential impact of continued moratoria in Texas, and decided to lift the temporary enrollment moratorium on Medicare Part B non-emergency ground ambulance suppliers in Texas in order to aid in the disaster response to Hurricane Harvey. This lifting of the moratorium also applied to Medicaid and CHIP in Texas. A notification that CMS lifted the moratorium was published at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/ProviderEnrollmentMoratorium.html* and became effective on September 1, 2017. In accordance with § 424.570(d), CMS is also publishing this document in the **Federal Register** to announce this action. Non-emergency ground ambulance suppliers that were previously unable to enroll in Medicare, Medicaid or CHIP in Texas

[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.

[2] CMS also concurrently announced a demonstration under the authority provided in section 402(a)(l)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–l(a)(l)(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 demonstration 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).

because of the moratorium will be able to apply for enrollment and will be designated to the ''high'' screening level in accordance with §§ 424.518(c)(3)(iii) and 455.450(e)(2) if such supplier applies at any time within 6 months from the date the moratorium was lifted.

III. Clarification of Right to Judicial Review

Section 1866(j)(7)(B) of the Act provides 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.

IV. 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.*).

V. 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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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 announces CMS's decision to lift the moratorium on new enrollment of non-emergency ground ambulance suppliers in Medicare Part B, Medicaid, and CHIP in Texas. Though costs may result from allowing non-emergency ambulance enrollment in Texas, the monetary amount cannot be quantified. After the imposition of the initial moratoria on July 31, 2013, specifically to the non-emergency ambulance suppliers, a total of 24 ambulance companies in all geographic areas affected by the moratoria had their applications denied. Since the moratorium was lifted on September 1, 2017, we have had two ambulance enrollments in Texas, and we have seen no evidence that there will be a large surge in applications in the immediate future. 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 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 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

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 substantial 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: October 27, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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