developmental disabilities; (9) collaborates with international organizations in developing strategies for the prevention of developmental disabilities; (10) disseminates findings of research through direct contact with health authorities, publication and distribution of special reports, publication in scientific and technical journals, conference presentations, and other appropriate means; and (11) provides training in the epidemiology of developmental disabilities to professionals throughout the United States and abroad.

Delete in its entirety the title and function statement for the *Epidemiology and Surveillance Branch (CUBDB)* and insert the following:

Epidemiology and Surveillance Branch (CUBDB). (1) Provides scientific leadership in the design and implementation of monitoring systems as well as designs and conducts epidemiologic and genetic research to identify causes, risk factors and complications of blood disorders in affected populations; (2) designs and manages surveillance systems to evaluate the incidence, morbidity, and mortality associated with blood diseases and disorders; (3) plans, develops and coordinates special surveys and populations studies to monitor and assess the complications of blood disorders; (4) designs and implements studies using surveillance data to identify risk factors for the complications of blood disorders, and evaluating the effectiveness of the prevention activities; (5) provides epidemiologic and medical consultation and technical assistance, including epidemic aids to state and local health departments, other governmental agencies, and other public and private institutions in the investigation of blood disorders and related complications; (6) designing and implements studies to evaluate the effectiveness of implemented prevention strategies in the treatment centers, (7) works closely with internal and external organizations in applying prevalence and incidence data to target and evaluate programs to prevent the complications of blood diseases and chronic hereditary disorders, (8) publishes findings and advances arising out of surveillance and epidemiologic research to the scientific and public health communities; (9) provides training services to states, localities, and other countries in investigation, diagnosis, prevention, and control of blood diseases and chronic hereditary disorders; (10) assists in designing, implementing, and evaluating prevention and counseling programs for persons and their families with chronic blood diseases and selected chronic hereditary disorders; (11) designs, implements and coordinates the prevention and surveillance activities of specialized federally funded prevention centers organized to prevent the complications of blood diseases and chronic hereditary disorders; (12) conducts and supports both qualitative and quantitative research to expand the knowledge base related to blood disorders across the lifespan; (13) collaborates with hemostasis laboratory branch and incorporates the findings of these branches' activities which leads to prevention of complications of blood disorders; (14) supports public health analysis to include facilitating data collection, data management, data manipulation, analysis, project reporting and presentation; and (15) conducts applied research to develop, evaluate, improve and standardize public information systems and educational modules which support the prevention of complications from blood disorders.

Delete in its entirety the title and function statement for the *Laboratory Research Branch (CUBDC)* and insert the following:

Hemostasis Laboratory Branch (CUBDC). (1) Identifies new genetic markers of risk factors and clotting defects for affected groups; (2) provides reference laboratory diagnosis for multi-site epidemiologic and surveillance studies; (3) develops techniques and interpretation methods to improve molecular and coagulation diagnosis; (4) provides diagnostic support for epidemiologic studies and epidemic aids on emerging blood disorders and chronic hereditary disorders; (5) determines the mechanisms of pathogenesis and complications of blood disorders and chronic hereditary disorders;

(6) conducts research and providing reference services on diagnostic techniques for blood disorders and chronic hereditary disorders; (7) conducts research to improve laboratory methodologies and materials; (8) where appropriate, maintains the national reference laboratory for blood disorders and chronic hereditary disorders; (9) works closely with entities and organizations within the agency and organizations external to the agency to provide laboratory services in support of projects whose primary aim is to prevent and reduce complications associated with blood disorders and chronic hereditary disorders; and (10) publishes findings and advances arising out of surveillance and epidemiologic research to the scientific and public health communities.

Delete in its entirety the title and function statement for the *Prevention Research and Informatics Branch (CUBDD).*

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2016–01833 Filed 2–1–16; 8:45 am]

BILLING CODE 4160–18–P

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.*

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 [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). 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

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

[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.

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

State	City/metropolitan area	Counties
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.
		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(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. 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.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–01835 Filed 1–29–16; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3323–N]

Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs; Extension of Comment Period

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

ACTION: Request for information; extension of comment period.

SUMMARY: This document extends the comment period for the December 31, 2015 request for information entitled ''Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs'' (80 FR 81824) (referred to in this document as December 31 RFI). The comment period for the December 31 RFI, which would have ended on February 1, 2016, is extended for 15 days.

DATES: The comment period is extended to February 16, 2016. To be assured consideration, written or electronic comments on the December 31 RFI must be received at one of the addresses provided below no later than February 16, 2016.

ADDRESSES: In commenting on the December 31 RFI, please refer either to file code CMS–3323–NC and comment as indicated in that document (80 FR 81824) or file code CMS–3323–N and comment as provided in this document. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3323–N, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3323–N, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments. Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through