Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October through December 2014)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the October through December 2014 quarter.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6059–N2]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extended Temporary Moratoria on Enrollment of 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 ambulance suppliers and home health agencies (HHAs) in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse.

DATES: *Effective Dates:* January 29, 2015.

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 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) or February 4, 2014 extension and establishment of a temporary moratoria document (hereinafter referred to as the February 4, 2014 moratoria document or notice) (79 FR 6475).

Based on this authority and our regulations at § 424.570, we have implemented three phases of the moratoria to date. In the notice issued on July 31, 2013 (78 FR 46339), we imposed moratoria on the enrollment of home health agencies in Miami-Dade County, Florida and Cook County, Illinois and surrounding counties and on the enrollment of ground ambulance suppliers in the Harris County, Texas area and surrounding counties. Then, in the notice published on February 4, 2014 (79 FR 6475), we extended the initial moratoria and imposed moratoria on the enrollment of home health agencies in Broward County, Florida, Dallas County, Texas, Harris County, Texas and Wayne County, Michigan and surrounding counties and on the enrollment of ground ambulance suppliers in Philadelphia, PA and surrounding counties. In the notice published on August 1, 2014 (79 FR 44702), CMS extended all of the above-mentioned moratoria.

B. Determination of the Need for Extending a Moratorium

In extending 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 and extending these moratoria, CMS consulted with the appropriate State Medicaid Agencies and with the appropriate State Department of Emergency Medical Services to determine if the moratoria would create an access to care issue 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 will not create access to care issues for Medicaid or CHIP beneficiaries. CMS also reviewed Medicare data for these areas and found there are no current problems with access to HHAs or ground ambulance suppliers.

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. (For a more detailed explanation of how CMS can lift a temporary moratorium, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475)). 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 was 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 Broward county, Miami-Dade and Monroe in Florida, 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 and 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 in the **Federal Register** of a notice on July 31, 2013 (78 FR 46339), a moratoria notice on February 4, 2014 (79 FR 6475) and a moratoria notice on August 1, 2014 (79 FR 44702).

In accordance with § 424.570(b), CMS may deem it necessary to extend previously-imposed moratoria in 6-month increments. Under its authority at § 424.570(b), 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 both the HHS–OIG and DOJ regarding the extension of the moratoria on new HHAs and ground ambulance suppliers in all of the moratoria counties, and both HHS–OIG and DOJ agree 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 ensure 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 these moratoria in the following counties for these providers and suppliers:

TABLE 1—HHA MORATORIA

State	City/Metro 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—PART B AMBULANCE MORATORIA

State	City/Metro 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.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

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 ambulance suppliers in Medicare, and new home health providers and ambulance suppliers in Medicaid and CHIP. Though savings may accrue by denying enrollments, the monetary amount cannot be quantified. After the imposition of the moratoria on July 31, 2013, 231 HHAs and 7 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 regulations 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 2014, that threshold is approximately $141 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. Since 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; Sec. 1103 of the Social Security Act (42 U.S.C. 1302).

Dated: December 19, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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