ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Medical/Clinical Laboratory Technologist.	Hemovigilance Module Annual Survey.	500	1	2	1,000
Medical/Clinical Laboratory Technologist.	Hemovigilance Module Monthly Reporting Plan.	500	12	1/60	100
Medical/Clinical Laboratory Technologist.	Hemovigilance Module Monthly Reporting Denominators.	500	12	1	6,000
Medical/Clinical Laboratory Technologist.	Hemovigilance Adverse Reaction	500	48	15/60	6,000
Medical/Clinical Laboratory Technologist.	Hemovigilance Incident	500	10	10/60	833
Staff RN	Patient Safety Component—Annual Facility Survey for Ambulatory Surgery Center (ASC).	5,000	1	5/60	417
Staff RN	Outpatient Procedure Component—Monthly Reporting Plan.	5,000	12	15/60	15,000
Staff RN	Outpatient Procedure Component Event.	5,000	25	40/60	83,333
Staff RN	Outpatient Procedure Component—Monthly Denominators and Summary.	5,000	12	40/60	40,000
Registered Nurse (Infection Preventionist).	Outpatient Dialysis Center Practices Survey.	6,500	1	2.0	13,000
Staff RN	Dialysis Monthly Reporting Plan	6,500	12	5/60	6,500
Staff RN	Dialysis Event	6,500	60	25/60	162,500
Staff RN	Denominators for Dialysis Event Surveillance.	6,500	12	10/60	13,000
Staff RN	Prevention Process Measures Monthly Monitoring for Dialysis.	1,500	12	1.25	22,500
Staff RN	Dialysis Patient Influenza Vaccination.	325	75	10/60	4,063
Staff RN	Dialysis Patient Influenza Vaccination Denominator.	325	5	10/60	271
Total	.....	.....	.....	.....	4,861,542

Maryam I. Daneshvar,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–16028 Filed 6–29–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare and Medicaid Services

Notice of Hearing: Reconsideration of Disapproval Texas Medicaid State Plan Amendment (SPA) 14–25

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

ACTION: Notice of Hearing: Reconsideration of Disapproval.

SUMMARY: This notice announces an administrative hearing to be held on August 6, 2015, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children's Health, Dallas Regional Office, 1301 Young Street, Room 714, Dallas, TX 75202, to reconsider CMS' decision to disapprove Texas' Medicaid SPA 14–25.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by July 15, 2015.

FOR FURTHER INFORMATION CONTACT: Benjamin R. Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244; Telephone: (410) 786–3169.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS' decision to disapprove Texas' Medicaid SPA 14–25, which was submitted to the Centers for Medicare and Medicaid Services (CMS) on August 26, 2014 and disapproved on April 7, 2015. In part, this SPA requested CMS approval to revise the methodology for calculating the hospital-specific limit for the Disproportionate Share Hospital (DSH) program. Specifically, SPA 14–25 proposed to exclude from the calculation, the portion of a Medicare payment for an individual who is dually-eligible for Medicare and Medicaid that exceeds the Medicaid allowable cost for the service provided to the recipient. This exclusion would permit the state to make Medicaid DSH payments that are above and beyond hospitals' reported uncompensated costs of providing services to Medicaid and uninsured individuals.

The issue to be considered at the hearing is:

- Whether Texas SPA 14–25 is inconsistent with Medicaid DSH requirements of sections 1902(a)(13)(A)(iv) and 1923 of the Social Security Act (Act) because it would provide for payment to disproportionate share hospitals of amounts that exceed the hospital's uncompensated costs which cannot be considered consistent with DSH requirements pursuant to the hospital-specific limit under section 1923(g)(1) of the Act.

Section 1116 of the Act and federal regulations at 42 CFR part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. CMS is required to publish a copy of the notice

to a state Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Texas announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Kay Ghahremani
State Medicaid/CHIP Director
Health and Human Services Commission
Post Office Box 13247
Mail Code H100
Austin, TX 78711

Dear Ms. Ghahremani:

I am responding to your request for reconsideration of the decision to disapprove Texas' State Plan amendment (SPA) 14–25, which was submitted to the Centers for Medicare & Medicaid Services (CMS) on August 26, 2014, and disapproved on April 7, 2015. I am scheduling a hearing on your request for reconsideration to be held on August 6, 2015, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid & Children's Health, Dallas Regional Office, 1301 Young Street, Room 714, Dallas, TX 75202.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements present any problems, please contact Mr. Cohen at (410) 786–3169. In order to facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. If the hearing date is not acceptable, Mr. Cohen can set another date mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR part 430.

In part, this SPA requested CMS approval to revise the methodology for calculating the hospital-specific limit for the Disproportionate Share Hospital (DSH) program. Specifically, SPA 14–25 proposed to exclude from the calculation, the portion of a Medicare payment for an individual who is dually-eligible for Medicare and Medicaid that exceeds the Medicaid allowable cost for the service provided to the recipient. This exclusion would permit the state to make Medicaid DSH payments that are above and beyond hospitals' reported uncompensated costs of providing services to Medicaid and uninsured individuals.

The issue to be considered at the hearing is:

• Whether Texas SPA 14–25 is inconsistent with Medicaid DSH requirements at sections 1902(a)(13)(A)(iv) and 1923 of the Social Security Act (Act) because it would provide for payment to disproportionate share hospitals of amounts that exceed the hospital's uncompensated costs which cannot be considered consistent with DSH requirements pursuant to the hospital-specific limit under section 1923(g)(1) of the Act.

In the event that CMS and the State come to agreement on resolution of the issues which formed the basis for disapproval, this SPA may be moved to approval prior to the scheduled hearing. I am responding to your request for reconsideration of the decision to disapprove Texas' Medicaid state plan amendment (SPA) 14–025, which was submitted to the Centers for Medicare and Medicaid Services (CMS) on August 26, 2014, and disapproved on April 7, 2015. I am scheduling a hearing on your request for reconsideration to be held on August 6, 2015, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children's Health, Dallas Regional Office, 1301 Young Street, Room 714, Dallas, TX 75202.

Sincerely,

Andrew M. Slavitt

cc: Benjamin R. Cohen

Section 1116 of the Social Security Act (42 U.S.C. 1316; 42 CFR 430.18) (Catalog of Federal Domestic Assistance program No. 13.714. Medicaid Assistance Program.)

Dated: June 24, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–16098 Filed 6–29–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0161]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Export Certificates for Food and Drug Administration Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Export Certificates for FDA Regulated Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 10, 2015, the Agency submitted a proposed collection of information entitled, ''Export Certificates for FDA Regulated Products'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0498. The approval expires on March 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16023 Filed 6–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0025]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Food Labeling; Declaration of Certifiable Color Additives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 30, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of