DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9996–N3]

Early Retiree Reinsurance Program

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

ACTION: Notice.

SUMMARY: This notice establishes a timeframe by which plan sponsors participating in the Early Retiree Reinsurance Program (ERRP) are expected to use ERRP reimbursement funds. Sponsors are expected to use such funds as soon as possible, but not later than December 31, 2014.

DATES: *Effective Date:* This notice is effective March 16, 2012.

FOR FURTHER INFORMATION CONTACT: David Mlawsky, (410) 786–6851.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010) (the Affordable Care Act), included a provision that established the temporary Early Retiree Reinsurance Program (ERRP) which provides reimbursement to eligible sponsors of employment-based plans for a portion of the costs of providing health coverage to early retirees (and eligible spouses, surviving spouses, and dependents of such retirees), during the period beginning on the date on which the program is established, and ending on January 1, 2014. Section 1102(a)(l) of the Affordable Care Act required the Secretary to establish the program within 90 days of enactment of the law (by June 21, 2010). In the May 5, 2010 **Federal Register** (75 FR 24450), we published an interim final regulation with comment period, implementing the program as of June 1, 2010. Section 1102(e) of the Affordable Care Act appropriates funding of $5 billion for the temporary program.

Consistent with section 1102(c)(4) of the Affordable Care Act, the rule at 45 CFR 149.200 states:

> A sponsor must use the proceeds under this program to—(1) reduce the sponsor's health benefit premiums or health benefit costs, (2) reduce health benefit premium contributions, copayments, deductibles, coinsurance, or other out-of-pocket costs, or any combination of these costs, for plan participants, or (3) reduce any combination of the costs in (a)(1) and (a)(2) of this section. Proceeds under this program must not be used as general revenue for the sponsor.

We have published several guidance documents that further clarify this section of the rule (see the *Guidance on Complying with the Prohibition on Using Early Retiree Reinsurance Program Reimbursements as General Revenue* under the Regulations and Guidance section of *www.errp.gov,* and the Common Questions under the Use of Reimbursement section at *www.errp.gov*).

We have provided the available ERRP funds to reimburse plan sponsors' eligible early retiree health care costs with the expectation that plan sponsors will use the funds in an allowable manner, as outlined in 45 CFR 149.200, as soon as possible after receiving ERRP funds. In February 2012, we released Common Question 800–13, which provided the date, December 31, 2014, by which plan sponsors are expected to use the received funds.

II. Provisions of This Notice

Section 1102(c)(4) of the Affordable Care Act, immediately following its discussion of how ERRP reimbursements may be used, states: ''The Secretary shall develop a mechanism to monitor the appropriate use of such payments by such entities.'' We believe that one necessary component of such a mechanism is a deadline by when plan sponsors are expected to use ERRP reimbursements. Thus, one of the Common Questions we have published to clarify the ERRP rule at 45 CFR 149.200 sets forth our expectation as to when a plan sponsor that has received ERRP reimbursement will use that reimbursement (Common Question 800–13). This notice reiterates and formalizes our expectation that a sponsor will use ERRP reimbursement funds as soon as possible, but not later than December 31, 2014. We believe this deadline is consistent with the January 1, 2014 statutory end date of the ERRP, and also affords plan sponsors the flexibility and time they may need in order to appropriately use ERRP reimbursement.

Common Question 800–13 also states, and we reiterate in this notice, that a sponsor is not required to use ERRP reimbursement funds by the end of the plan year in which they are received. Sponsors may use ERRP reimbursement funds in a manner permitted under the statute, regulation, and other ERRP program guidance.

III. Collection of Information Requirements

This document does not impose any new 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. However, the information collection requirements associated with the ERRP are currently approved under OMB control number 0938–1087, with an expiration date of September 30, 2014.

Authority: Sections 1102(a)(l) and 1102(c)(4) of the Affordable Care Act (42 U.S.C. 18002(a)(l) and(c)(4)).

Dated: March 13, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Standards for Private Laboratory Analytical Packages and Introduction to Laboratory Related Portions of the Food Modernization Safety Act for Private Laboratory Managers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meetings.

The Food and Drug Administration (FDA) is announcing two meetings entitled ''Standards for Private Laboratory Analytical Packages and Introduction to Laboratory Related Portions of the Food Modernization Safety Act for Private Laboratory Managers.'' The topic to be discussed is the quality standards expected in all analytical packages and an introduction to sections of the Food Safety Modernization Act of January 6, 2011, that affect laboratories.

Date and Time: The meetings will be held on April 3, 2012, from 1 p.m. to 4:30 p.m. in Bothell, WA, and on April 5, 2012, from 1 p.m. to 4:30 p.m. in Oakland, CA.

Location: The meeting in Bothell, WA, will be held at the FDA Seattle District Office, 22201 23rd Dr. SE., Bothell, WA 98021. The Oakland, CA, meeting will be held in the R. Dellums Federal Building, Conference Room A/B, 2nd Floor North, 1301 Clay St., Oakland, CA 94612.

Contact: R.V. Asmundson, Food and Drug Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612–5217, 510–287–2715, FAX: 510–287–3739, email: *rod.asmundson@fda.hhs.gov.*

Registration: Send registration information (including name, title, firm