Fairness Enforcement Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts, and equity). The agency believes that this reclassification action is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, this final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule action will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis pursuant to section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information to the public.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 884.2730 is added to subpart C to read as follows:

§ 884.2730 Home uterine activity monitor.

(a) *Identification.* A home uterine activity monitor (HUAM) is an electronic system for at home antepartum measurement of uterine contractions, data transmission by telephone to a clinical setting, and for receipt and display of the uterine contraction data at the clinic. The HUAM system comprises a tocotransducer, an at-home recorder, a modem, and a computer and monitor that receive, process, and display data. This device is intended for use in women with a previous preterm delivery to aid in the detection of preterm labor.

(b) *Classification.* Class II (special controls); guidance document (Class II Special Controls Guidance for Home Uterine Activity Monitors).

Dated: January 31, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–5813 Filed 3–8–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 8931]

RIN 1545–AW02

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2590

RIN 1210–AA77

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

45 CFR Part 146

RIN 0938–AI08

Interim Final Rules for Nondiscrimination in Health Coverage in the Group Market

AGENCIES: Internal Revenue Service, Department of the Treasury; Pension and Welfare Benefits Administration, Department of Labor; Health Care Financing Administration, Department of Health and Human Services.

ACTION: Interim final rules; delay of effective date and conforming amendments.

SUMMARY: Consistent with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan,'' published in the **Federal Register** on January 24, 2001 (66 FR 7702), this action delays for 60 days the effective date for the rules entitled ''Interim Final Rules for Nondiscrimination in Health Coverage in the Group Market,'' published in the **Federal Register** on January 8, 2001 (66 FR 1378). This document also makes conforming amendments to reflect the delay in effective date.

DATES: The effective date of the Interim Final Rules amending 26 CFR Part 54, 29 CFR Part 2590, and 45 CFR Part 146, published in the **Federal Register** on January 8, 2001, at 66 FR 1378, is delayed for 60 days, from March 9, 2001, until May 8, 2001. The conforming amendments in this document are effective May 8, 2001.

FOR FURTHER INFORMATION CONTACT: Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; Amy J. Turner, Pension and Welfare Benefits Administration,

Department of Labor, at (202) 219–7006; or Ruth A. Bradford, Health Care Financing Administration, Department of Health and Human Services, at (410) 786–1565.

SUPPLEMENTARY INFORMATION: Consistent with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan,'' published in the **Federal Register** on January 24, 2001 (66 FR 7702), this action delays for 60 days the effective date and, for consistency, certain applicability dates for the rules entitled ''Interim Final Rules for Nondiscrimination in Health Coverage in the Group Market,'' published in the **Federal Register** on January 8, 2001 (66 FR 1378). These rules implement statutory provisions prohibiting discrimination based on a health factor by group health plans and issuers offering health insurance coverage in connection with a group health plan. The rules implement changes made to the Internal Revenue Code of 1986, the Employee Retirement Income Security Act of 1974, and the Public Health Service Act, enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and most of the guidance contained in these rules remains applicable for plan years beginning on or after July 1, 2001. This document also makes conforming amendments to reflect the delay in effective date.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(3)(A). Alternatively, the Departments' implementation of this rule without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(3)(B) and 553(d)(3), in that seeking public comment is impracticable, unnecessary, and contrary to the public interest. The 60-day delay in effective date is necessary to give Department officials the opportunity for further review and consideration of new regulations, consistent with the Assistant to the President's memorandum of January 20, 2001. Given the imminence of the effective date, seeking prior public comment on this delay would have been impractical, unnecessary, and contrary to the public interest in the orderly promulgation and implementation of regulations. Because the delay is only for 60 days, a 30-day comment period before the delay could be effective would exhaust a substantial amount of time that group health plans, health insurance issuers, and State insurance commissioner's offices could otherwise use to review their plan documents, insurance policies, and State laws for purposes of the orderly implementation of the interim regulations. In addition, it would create confusion among State agencies, employers, plan administrators, issuers, and third party administrators as to the effective date of certain provisions, impeding their compliance and enforcement efforts.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Employee benefit plans, Employee Retirement Income Security Act, Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Conforming Amendments to the Regulations

Internal Revenue Service

26 CFR Chapter I

Accordingly, the publication on January 8, 2001 of the temporary and final rules, 26 CFR Part 54, is amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 54.9802–1 [Amended]

Par. 2. Section 54.9802–1 is amended by removing the date ''March 9, 2001'' in each place it appears in paragraph (i)(1) and adding in its place ''May 8, 2001''.

§ 54.9802–1T [Amended]

Par. 3. Section 54.9802–1T is amended by:

1. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in paragraph (i)(1).

2. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in paragraph (i)(3)(ii)(A) introductory text.

3. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in paragraph (i)(3)(ii)(C) *Example 2* (ii).

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: March 2, 2001.

Pamela F. Olsen,

Deputy Assistant Secretary of the Treasury.

Pension and Welfare Benefits Administration

29 CFR Chapter XXV

For the reasons set forth above, the publication on January 8, 2001 of the interim final rule, 29 CFR Part 2590, is amended as follows:

PART 2590—RULES AND REGULATIONS FOR HEALTH INSURANCE PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

Paragraph 1. The authority citation for part 2590 continues to read as follows:

Authority: Secs. 107, 209, 505, 701–703, 711–713, and 731–734 of ERISA (29 U.S.C. 1027, 1059, 1135, 1171–1173, 1181–1183, and 1191–1194), as amended by HIPAA (Public Law 104–191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104–204, 110 Stat. 2935), and WHCRA (Public Law 105–277, 112 Stat. 2681–436), section 101(g)(4) of HIPAA, and Secretary of Labor's Order No. 1–87, 52 FR 13139, April 21, 1987.

§ 2590.702 [Amended]

Par. 2. Section 2590.702 is amended by:

1. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in the heading to paragraph (i)(1).

2. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in paragraph (i)(1).

3. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in paragraph (i)(3)(ii)(A) introductory text.

4. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in paragraph (i)(3)(ii)(C) *Example 2* (ii).

Signed at Washington, DC this 16th day of February, 2001.

Alan D. Lebowitz,

Acting Assistant Secretary, Pension and Welfare Benefits Administration, Department of Labor.

Health Care Financing Administration

45 CFR Subtitle A

For the reasons set forth above, the publication on January 8, 2001 of the interim final rule, 45 CFR part 146, is amended as follows:

PART 146—RULES AND REGULATIONS FOR HEALTH INSURANCE PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

Paragraph 1. The authority citation for part 146 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791 and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92 as amended by HIPAA (Public Law 104–191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104–204, 110 Stat. 2935), and WHCRA (Public Law 105–277, 112 Stat. 2681–436), and section 102(c)(4) of HIPAA.

§ 146.121 [Amended]

Par. 2. Section 146.121 is amended by:

1. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in the heading to paragraph (i)(1).

2. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in paragraph (i)(1).

3. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in paragraph (i)(3)(ii)(A) introductory text.

4. Removing the date ''March 9, 2001'' and adding in its place ''May 8, 2001'' in paragraph (i)(3)(ii)(C) *Example 2* (ii).

Dated: February 20, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

Approved: March 5, 2001.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

[FR Doc. 01–5895 Filed 3–8–01; 8:45 am]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[UT–001–0022a, UT–001–0024a, UT–001–0025a, UT–001–0026a, UT–001–0027a, UT–001–0030a, UT–001–0031a; FRL–6888–9]

Approval and Promulgation of Air Quality Implementation Plans; State of Utah; Ogden City Carbon Monoxide Redesignation to Attainment, Designation of Areas for Air Quality Planning Purposes, and Approval of Revisions to the Oxygenated Gasoline Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On December 9, 1996, the Governor of Utah submitted a request to redesignate the Ogden City ''moderate'' carbon monoxide (CO) nonattainment area to attainment for the CO National Ambient Air Quality Standard (NAAQS). The Governor also submitted a CO maintenance plan. In addition, on July 8, 1998, the Governor submitted revisions to Utah's Rule R307–8 ''Oxygenated Gasoline Program.'' In this action, EPA is approving the Ogden City CO redesignation request, the maintenance plan, and the revisions to Rule R307–8.

DATES: This direct final rule is effective on May 8, 2001 without further notice, unless EPA receives adverse comments by April 9, 2001. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments may be mailed to: Richard R. Long, Director, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202–2466.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the following offices:

United States Environmental Protection Agency, Region VIII, Air and Radiation Program, 999 18th Street, Suite 300, Denver, Colorado 80202–2466; and,

United States Environmental Protection Agency, Air and Radiation Docket and Information Center, 401 M Street, SW, Washington, DC 20460.

Copies of the State documents relevant to this action are available for public inspection at: Utah Division of Air Quality, Department of Environmental Quality, 150 North 1950 West, P.O. Box 144820, Salt Lake City, Utah 84114–4820.

FOR FURTHER INFORMATION CONTACT: Tim Russ, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202–2466; Telephone number: (303) 312–6479.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' are used we mean the Environmental Protection Agency.

I. What is the Purpose of this Action?

In this action, we are approving a change in the legal designation of the Ogden City area from nonattainment for CO to attainment, we're approving the maintenance plan that is designed to keep the area in attainment for CO for the next 10 years, and we're also approving changes to the State's Rule R307–8 addressing the oxygenated fuels program.

On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted (Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q). Under section 107(d)(1)(C) of the Clean Air Act (CAA), we designated the Ogden City area as nonattainment for CO because the area had been designated as nonattainment before November 15, 1990. We originally designated Ogden City as nonattainment for CO on March 3, 1978 (see 43 FR 8962) under the provisions of the 1977 CAA Amendments. This designation was reaffirmed by the 1990 CAA Amendments and Ogden City was classified as a ''moderate'' CO nonattainment area with a design value of less than or equal to 12.7 parts per million (ppm). *See* 56 FR 56694, November 6, 1991. Further information regarding this classification and the accompanying requirements are described in the ''General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990.'' *See* 57 FR 13498, April 16, 1992.

Under the CAA, we can change designations if acceptable data are available and if certain other requirements are met. See CAA section 107(d)(3)(D). Section 107(d)(3)(E) of the CAA provides that the Administrator may not promulgate a redesignation of a nonattainment area to attainment unless:

(i) The Administrator determines that the area has attained the national ambient air quality standard;

(ii) the Administrator has fully approved the applicable implementation plan for the area under CAA section 110(k);

(iii) the Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable implementation plan and applicable Federal air pollutant control regulations and other permanent and enforceable reductions;

(iv) the Administrator has fully approved a maintenance plan for the area as meeting the requirements of CAA section 175A; and,

(v) the State containing such area has met all requirements applicable to the area under section 110 and part D of the CAA.

Before we can approve the redesignation request, we must decide that all applicable SIP elements have been fully approved. Approval of the