

2. Section 312.33 is amended by revising paragraph (a)(2) to read as follows:

**§ 312.33 Annual reports.**

\* \* \* \* \*

(a) \* \* \*

(2) The total number of subjects initially planned for inclusion in the study; the number entered into the study to date, characterized by age group, gender, and race; the number whose participation in the study was completed as planned; and the number who dropped out of the study for any reason.

\* \* \* \* \*

**PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG**

3. The authority citation for 21 CFR part 314 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e).

4. Section 314.50 is amended by revising the second sentence and adding two new sentences after the second sentence in paragraph (d)(5)(v) and by adding two new sentences after the first sentence in paragraph (d)(5)(vi)(a) to read as follows:

**§ 314.50 Content and format of an application.**

\* \* \* \* \*

(d) \* \* \*

(5) \* \* \*

(v) \* \* \* Evidence is also required to support the dosage and administration section of the labeling, including support for the dosage and dose interval recommended. The effectiveness data shall be presented by gender, age, and racial subgroups. Effectiveness data from other subgroups of the population of patients treated, as appropriate, such as patients with renal failure or patients with different levels of severity of disease, shall also be presented.

(vi) \* \* \*

(a) \* \* \* The safety data shall be presented by gender, age, and racial subgroups. Safety data from other subgroups of the population of patients treated, as appropriate, such as patients with renal failure or patients with different levels of severity of disease, shall also be presented. \* \* \*

\* \* \* \* \*

Dated: July 11, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95-22297 Filed 9-7-95; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF LABOR**

**Wage and Hour Division**

**29 CFR Part 552**

RIN 1215-AA82

**Application of the Fair Labor Standards Act to Domestic Service**

**AGENCY:** Wage and Hour Division, Employment Standards Administration, Labor.

**ACTION:** Proposed rule; reopening and extension of comment period.

**SUMMARY:** This document reopens and extends the period for filing written comments on a proposed revision to § 552.109 of Regulations, 29 CFR part 552, which was published in the **Federal Register** on December 30, 1993 (58 FR 69310), to clarify the minimum wage and overtime exemption under the Fair Labor Standards Act (FLSA) for certain employees of third-party employers who provide domestic companionship services. The Department is continuing to consider this particular proposal, and this action is taken in order to obtain additional comments from interested parties. A separate final rule published elsewhere in this issue amends 29 CFR part 552 to incorporate changes necessitated by amendments to Title II of the Social Security Act, which were enacted October 22, 1994, as Pub. L. 103-387 (Social Security Domestic Employment Reform Act), and makes other updating and technical revisions as proposed in the notice of December 30, 1993.

**DATES:** Comments are due on or before November 7, 1995.

**FOR FURTHER INFORMATION CONTACT:** Richard M. Brennan, Acting Director, Division of Policy and Analysis, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S-3506, 200 Constitution Avenue NW., Washington, DC 20210, (202) 219-8412. This is not a toll-free number.

**SUPPLEMENTARY INFORMATION:** The Fair Labor Standards Act of 1938 (52 Stat. 1060, as amended; 29 U.S.C. 201 *et seq.*), as amended by the Fair Labor Standards Amendments of 1974 (Pub. L. 93-259, 88 Stat. 55), extended with certain exceptions the FLSA's minimum wage, overtime pay, and recordkeeping

provisions to domestic service employees whose compensation for services would constitute wages under section 209(g) of Title II of the Social Security Act, or who are employed by one or more employers for more than 8 hours in the aggregate in any workweek. Section 13(a)(15) of the FLSA provides an exemption from the minimum wage and overtime pay requirements of the Act for "employees employed on a casual basis in domestic service employment to provide babysitting services," and for domestic service employees employed "to provide companionship services for individuals who \* \* \* are unable to care for themselves." Section 13(b)(21) provides an overtime exemption for domestic service employees who reside in the household in which they are employed. On February 20, 1975, regulations and interpretations implementing the domestic service employment provisions of the FLSA were published in the **Federal Register** (40 FR 7405) at 29 CFR part 552.

The Department published a notice of proposed rulemaking in the **Federal Register** on December 30, 1993 (58 FR 69310), inviting public comments until February 28, 1994, which, among other things, would revise § 552.109 to clarify that, in order for the exemptions in FLSA sections 13(a)(15) and 13(b)(21) to apply, employees engaged in providing companionship services and live-in domestic service employees who are employed by a third-party employer or agency must also be "jointly" employed by the family or household using their services. In addition, the Department invited public comments on certain updating and technical changes to 29 CFR part 552.

The Department proposed to revise § 552.109 to provide, consistent with rulings of the Wage-Hour Administrator, that companions and live-in domestics employed by third-party employers are eligible for the exemptions in FLSA sections 13(a)(15) and 13(b)(21) only where the individuals are also employed by the family or household using their services. This clarification was considered necessary in order to make the underlying definition of "domestic service employees" (*i.e.*, someone who performs services of a household nature "in or about a private home \* \* \* of the person *by whom he or she is employed* \* \* \*") at § 552.101 internally consistent with § 552.109, applicable to domestic service employees who provide "companionship services."

A total of 7 comments were received in response to the notice. All focused their remarks on the proposed revision

to § 552.109 concerning joint employment and third-party employers. After review of the comments received to date, the Department has concluded that it is appropriate to continue the rulemaking on the proposed revision to § 552.109. With respect to the updating and technical changes that were proposed in the December 1993 notice, they are adopted in a final rule published elsewhere in this issue. This separate document also revises Regulations, 29 CFR part 552, to incorporate changes necessitated by amendments to Title II of the Social Security Act which were enacted October 22, 1994, as Public Law 103-387 (Social Security Domestic Employment Reform Act).

Based on the comments received to date, the Department wishes to consider the implications of its proposed revision on situations where State and local governments provide companion services to the elderly or infirm, as well as situations where the companion is employed by a family member. The Department is considering revising the proposal to allow the exemption to apply to employment, either jointly with a third party agency or otherwise, by a government agency or family member, where the government agency or family member is acting on behalf of an elderly or infirm person who is unable to act on his or her own behalf. The Department is therefore reopening the comment period in order to receive additional comments relating to this proposal.

The Department is particularly interested in receiving information on the companion services provided by State and local governments, and the relationship between the government and the elderly or infirm person to whom the service is provided.

Signed at Washington, DC, on this 31st day of August 1995.

**Maria Echaveste,**

*Administrator, Wage and Hour Division.*

As a convenience to the readers of this document, the proposed revisions to § 552.109 which were published in the **Federal Register** document of December 30, 1993 (53 FR 69310), are republished as follows:

**PART 552—APPLICATION OF THE FAIR LABOR STANDARDS ACT TO DOMESTIC SERVICE**

7. In § 552.109, paragraphs (a) and (c) are proposed to be revised to read as follows:

**§ 552.109 Third party employment.**

(a) Employees who are engaged in providing companionship services, as

defined in § 552.6, and who are employed by an employer or agency other than the family or household using their services, are exempt from the Act's minimum wage and overtime pay requirements by virtue of section 13(a)(15), provided that they are also employed by the person in whose home the services are provided, *i.e.*, a joint employment relationship must exist (see 29 CFR Part 791). The assignment of such an employee to more than one household or family in the same workweek would not defeat the exemption for that workweek, provided that the services rendered during each assignment come within the definition of companionship services.

(b) \* \* \*

(c) Live-in domestic service employees who are employed by an employer or agency other than the family or household using their services are exempt from the Act's overtime requirements by virtue of section 13(b)(21), provided that they are also employed by the person in whose home the services are provided, *i.e.*, a joint employment relationship must exist. This exemption, however, will not apply where the employee works only temporarily for any one family or household, since the employee would not be "residing" on the premises of such family or household.

[FR Doc. 95-22142 Filed 9-7-95; 8:45 am]

BILLING CODE 4510-27-M

**NATIONAL ARCHIVES AND RECORDS ADMINISTRATION**

**36 CFR Part 1206**

[RIN 3095-AA43]

**National Historical Publications and Records Commission; Grant Program Procedures**

**AGENCY:** National Archives and Records Administration.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The National Archives and Records Administration (NARA) proposes to update and clarify current regulations in 36 CFR Part 1206 relating to the National Historical Publications and Records Commission (NHPRC) grant program. In particular, language has been revised to reflect an internal reorganization; to address revisions to the state historical records coordinator and advisory board program; to include mention of archival administration and documentary editing fellowships for individuals; to include prior approval requirements for changes in the grant

project; to cite Office of Management and Budget Circulars A-110, A-128 and A-133, which stipulate requirements for grant administration and audit; and to make grantees aware of the lobbying certification requirement for grants of \$100,000 or more. The rule will affect NHPRC applicants and grantees.

**DATES:** Comments must be received by November 7, 1995.

**ADDRESSES:** Comments should be sent to Director, Policy and Planning Division (PIRM-POL), National Archives and Records Administration, 8601 Adelphi Rd., College Park, MD 20740-6001.

**FOR FURTHER INFORMATION CONTACT:** Mary Ann Hadyka or Nancy Allard at 301-713-6730.

**SUPPLEMENTARY INFORMATION:**

**Background**

The purpose of the National Historical Publications and Records Commission (NHPRC) is to promote the preservation and use of historically significant documents. The Archivist of the United States awards grants recommended by the NHPRC. Publications grants are made for the preparation (compiling, editing and publishing) of printed, microform, and electronic publications. Subvention grants are made to nonprofit presses to help defray publication costs of Commission-supported editions. Records grants are made for activities relating to the preservation, arrangement and description of historical records. Educational programs sponsored by the NHPRC include an institute to provide training in documentary editing and fellowships in the fields of documentary editing and archival administration. The Catalog of Federal Domestic Assistance (CFDA) number for this program is 89.003.

**Provisions of the Proposed Rule**

In 1991, the publications and records programs of the NHPRC were merged. The proposed rule updates program descriptions and procedures to reflect this internal reorganization. The NHPRC has also been working with the state historical records coordinators and advisory boards to revise their program sections and has made changes accordingly. In addition, we have added language to reflect current guidelines that stipulate prior approval requirements for changes in a grant project once an award has been made, and to mention specifically the archival administration and documentary editing fellowships.

The proposed rule also seeks to clarify Governmentwide requirements for applicants and grantees by including language that specifies the certification