

Longview, TX, East Texas Rgnl, NDB RWY 13, Amdt 15
 Longview, TX, East Texas Rgnl, RNAV (GPS) RWY 13, Amdt 1
 Longview, TX, East Texas Rgnl, RNAV (GPS) RWY 18, Amdt 1
 Longview, TX, East Texas Rgnl, RNAV (GPS) RWY 31, Amdt 1
 Longview, TX, East Texas Rgnl, RNAV (GPS) RWY 36, Amdt 1
 Longview, TX, East Texas Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1
 Longview, TX, East Texas Rgnl, VOR/DME OR TACAN RWY 13, Amdt 2
 McAllen, TX, McAllen Miller Intl, ILS OR LOC RWY 31, Orig
 McAllen, TX, McAllen Miller Intl, LOC BC RWY 31, Amdt 9C, CANCELLED
 McAllen, TX, McAllen Miller Intl, RNAV (GPS) RWY 31, Amdt 1
 McAllen, TX, McAllen Miller Intl, Takeoff and Minimums and Obstacle DP, Amdt 1
 Everett, WA, Snohomish County (Paine Fld), ILS OR LOC/DME RWY 16R, Amdt 21

[FR Doc. E8-25511 Filed 11-7-08; 8:45 am]

BILLING CODE 4910-13-P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA 2008-0007]

RIN 0960-AG70

Representative Payment Under Titles II, VIII and XVI of the Social Security Act

AGENCY: Social Security Administration.
ACTION: Final rule.

SUMMARY: We are amending our rules governing how we investigate representative payee applicants. Under these rules, any payee who previously satisfied the payee investigation criteria, including a face-to-face interview, and currently serves as a payee generally need not appear for another face-to-face interview when subsequently applying to become a payee unless we determine within our discretion, that a new face-to-face interview is necessary. The payee applicant would still be required to satisfy the rest of the investigation process as set forth in the regulations. Reducing the number of subsequent face-to-face interviews of payee applicants will streamline our representative payee application process, allowing payee applicants to become qualified more quickly when they already serve as a payee. This rule also will expedite payment of benefits in certain representative payee situations and reduce the burden on our field office employees by eliminating the necessity of interviewing such payee applicants.

DATES: This rule will be effective on December 10, 2008.

FOR FURTHER INFORMATION CONTACT:

Jerome Albanese, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235-6401, (404) 562-1024, for information about this notice. For information on eligibility or filing for benefits, call our national toll-free number, 1-800-772-1213 or TTY 1-800-325-0778, or visit our Internet site, Social Security Online, at <http://www.socialsecurity.gov>.

SUPPLEMENTARY INFORMATION:

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at <http://www.gpoaccess.gov/fr/index.html>.

Background

We select a representative payee for certain persons eligible for Social Security benefits under title II of the Social Security Act (the Act), special veterans benefits (SVB) under title VIII of the Act, or supplemental security income under title XVI of the Act. *See* sections 205(j), 807, and 1631(a)(2) of the Act. We select a representative payee if we believe that payment through a payee rather than direct payment of benefits is in the interest of that beneficiary. Subpart U of part 404, subpart F of part 408, and subpart F of part 416 of our regulations explain the procedures we follow when determining whether to make representative payment and in selecting a representative payee under the title II, VIII and XVI programs.

Our current rules at 20 CFR 404.2024 and 416.624 require that, before selecting an individual or organization to act as a person's representative payee, we will investigate the payee applicant to determine the applicant's suitability. Our rule at § 408.624 adopts these investigatory requirements for SVBs by cross-reference to § 404.2024. *See* sections 205(j)(2), 807(b), and 1631(a)(2)(B) of the Act.

The Act states that to the extent practicable, an investigation shall include a face-to-face interview with a payee applicant. *See* sections 205(j)(2)(A)(i), 807(b)(1)(A), and 1631(a)(2)(B)(i)(I). Based on this authority, our current rules at §§ 404.2024 and 416.624 indicate that we generally conduct a face-to-face interview with a payee applicant each time they file to become a payee, regardless of whether the payee has previously satisfied the investigation

criteria and participated in a face-to-face interview.

The requirement for holding a face-to-face interview may be waived only if conducting the interview is impracticable and would cause undue hardship for the payee applicant such as when a payee applicant would have to travel a great distance to the field office. Our current rules also indicate that we may decide it is impracticable to require subsequent face-to-face interviews for organizational payees that are known by our field office as suitable payees. We base this decision on the organization's past performance, recent contacts, and the organization's knowledge of and compliance with our reporting requirements.

Explanation of Changes

With these final rules, we are eliminating the requirement that we conduct a face-to-face interview before selecting an individual or organization to be a representative payee if we have already conducted a face-to-face interview with that payee and the payee is qualified and currently acting as a payee. However, we retain discretionary authority to require a subsequent face-to-face interview of any payee applicant. We are revising our rules in §§ 404.2024(b) and 416.624(b) to accomplish these changes.

We also have added a new paragraph (c), "Impracticable," to §§ 404.2024 and 416.624. This new paragraph contains the first three sentences of current §§ 404.2024(b) and 416.624(b), with editorial changes. We are not making substantive changes to this text.

Public Comment

In the notice of proposed rulemaking we published in the **Federal Register** at 73 FR 12923 (March 11, 2008), we provided the public a 60-day period within which to comment on the proposed changes. That comment period ended on May 12, 2008. We received one comment, from an individual who opposed the proposed changes.

Comment: The commenter noted that because the representative payment program removes the beneficiary's right to manage his own benefit payments, we must act with extreme care when determining the need for a payee and in selecting the person or organization that would best serve as a payee. The commenter believed that in order to protect beneficiary rights, we should require all payee applicants to undergo a face-to-face interview every time they apply to be a payee. Accordingly, the commenter asked that we withdraw our proposal to eliminate such a

requirement. In the alternative, the commenter suggested that if we adopt these changes, we should consider reviewing the payee's activities with regard to other beneficiaries before waiving subsequent face-to-face interviews.

Response: Although we share the commenter's concern that payees must manage benefits properly, we do not accept the commenter's suggestion to withdraw this rule. Under our current rules, there are nine criteria that must be met before selecting an individual or organization to act as a representative payee. See §§ 404.2024(a) and 416.624(a). Eight of these criteria remain unchanged. We are changing only our requirement regarding subsequent face-to-face interviews for payees who previously satisfied all of our criteria, including a face-to-face interview, and are qualified and currently acting as payees.

Our rules regarding recovery of misused benefits and potential civil monetary penalties remain unchanged and will continue to protect beneficiaries from payee misuse of benefits. As an added protection, we also retain the discretion to perform a subsequent face-to-face interview if we believe one is necessary. Our final rules specifically note that we base the decision concerning the necessity of a subsequent face-to-face interview on the payee's past performance and the payee's knowledge of and compliance with our reporting requirements. Because the final rules provide that we look at the payee's past performance, they address the commenter's concern that we review the payee's activities with regard to other beneficiaries prior to waiving a subsequent face-to-face interview. Additionally, our existing rules at §§ 404.2024(a)(5) and 416.624(a)(5) require that we determine whether the payee applicant has previously served as a representative payee and whether any previous appointment as a payee was terminated for misuse. Thus, we made no changes from the rules we proposed.

Regulatory Procedures

Executive Order 12866, as Amended

The Office of Management and Budget (OMB) determined that the final rules meet the criteria for a significant regulatory action under Executive Order 12866, as amended. Thus, OMB reviewed these final rules.

Regulatory Flexibility Act

We certify that these final rules will not have a significant economic impact on a substantial number of small entities

as they affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These final rules impose no reporting or recordkeeping requirements subject to OMB clearance.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income; 96.020, Special Benefits for Certain World War II Veterans.)

List of Subjects

20 CFR Part 404

Administrative practice and procedure; Blind; Disability benefits; Old-Age, Survivors, and Disability Insurance; Reporting and recordkeeping requirements; Social security.

20 CFR Part 416

Administrative practice and procedure; Aged; Blind, Disability benefits; Public Assistance programs; Reporting and recordkeeping requirements; Supplemental Security Income (SSI).

Dated: August 18, 2008.

Michael J. Astrue,
Commissioner of Social Security.

■ For the reasons set out in the preamble, we amend subpart U of part 404 and subpart F of part 416 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950-)

Subpart U—[Amended]

■ 1. The authority citation for subpart U continues to read as follows:

Authority: Secs. 205(a), (j), and (k), and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), (j), and (k), and 902(a)(5)).

■ 2. Amend § 404.2024 by revising paragraphs (a)(1) and (b) and by adding new paragraph (c) as follows:

§ 404.2024 How do we investigate a representative payee applicant?

* * * * *

(a) * * *

(1) Conduct a face-to-face interview with the payee applicant unless it is impracticable as explained in paragraph (c) of this section.

* * * * *

(b) *Subsequent face-to-face interviews.* After holding a face-to-face interview

with a payee applicant, subsequent face-to-face interviews are not required if that applicant continues to be qualified and currently is acting as a payee, unless we determine, within our discretion, that a new face-to-face interview is necessary. We base this decision on the payee's past performance and knowledge of and compliance with our reporting requirements.

(c) *Impracticable.* We may consider a face-to-face interview impracticable if it would cause the payee applicant undue hardship. For example, the payee applicant would have to travel a great distance to the field office. In this situation, we may conduct the investigation to determine the payee applicant's suitability to serve as a representative payee without a face-to-face interview.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart F—[Amended]

■ 1. The authority citation for subpart F continues to read as follows:

Authority: Secs. 702(a)(5), 1631 (a)(2) and (d)(1) of the Social Security Act (42 U.S.C. 902(a)(5) and 1383 (a)(2) and (d)(1)).

■ 2. Amend § 416.624 by revising paragraphs (a)(1) and (b) and by adding new paragraph (c) as follows:

§ 416.624 How do we investigate a representative payee applicant?

* * * * *

(a) * * *

(1) Conduct a face-to-face interview with the payee applicant unless it is impracticable as explained in paragraph (c) of this section.

* * * * *

(b) *Subsequent face-to-face interviews.* After holding a face-to-face interview with a payee applicant, subsequent face-to-face interviews are not required if that applicant continues to be qualified and currently is acting as a payee, unless we determine, within our discretion, that a new face-to-face interview is necessary. We base this decision on the payee's past performance and knowledge of and compliance with our reporting requirements.

(c) *Impracticable.* We may consider a face-to-face interview impracticable if it would cause the payee applicant undue hardship. For example, the payee applicant would have to travel a great distance to the field office. In this situation, we may conduct the investigation to determine the payee applicant's suitability to serve as a

representative payee without a face-to-face interview.

[FR Doc. E8-26680 Filed 11-7-08; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA-2004-N-0511] (formerly Docket No. 2004N-0556)

RIN 0910-AF21

Obstetrical and Gynecological Devices; Designation of Special Controls for Male Condoms Made of Natural Rubber Latex

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the classification regulation for condoms to designate a special control for male condoms made of natural rubber latex (latex). The special control for the device is the guidance document entitled "Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300." The FDA will publish a notice in the **Federal Register** announcing the availability of the special control guidance document no later than the effective date of this final rule.

DATES: *Effective Date:* This rule is effective January 9, 2009.

Compliance Dates: Premarket notification submissions (510(k)s) for latex condoms filed on or after the effective date of this rule are expected to comply with the requirement of special controls at the time that the 510(k) is submitted. Latex condoms cleared for marketing on or after the effective date of the rule but submitted in 510(k)s filed before the effective date of the rule are expected to comply with the requirement of special controls on or before March 10, 2009. Latex condoms legally marketed before the effective date of this rule are expected to comply with the requirement of special controls December 10, 2009. Specific information on how the rule will be implemented can be found in section II.B of this document.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200

Corporate Blvd., Rockville, MD 20850, 301-594-1180.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
 - A. Statutory Framework
 - B. Regulatory History of Latex Condoms
 - C. Overview of Proposed Rule
 - D. Additional Scientific Information Developed After the Completion of the Proposed Rule and Draft Special Control Guidance
 1. FDA Update of Epidemiology
 2. Latex Condom Label Comprehension Study
- II. Summary of the Final Rule
 - A. Overview of the Final Rule
 - B. Implementation Strategy
 - C. Issues Requiring Special Controls
 1. Unintended Pregnancy
 2. Transmission of Sexually Transmitted Infections (STIs)
 3. Incorrect or Inconsistent Use
- III. Comments and FDA's Responses
 - A. Identification Section of the Classification Regulation
 - B. Establishment of a Guidance Document as a Special Control
 - C. FDA's Review of Scientific Information
 1. General Comments
 2. Slippage and Breakage
 3. Risk Reduction
 4. Evaluation of Latex Condom Effectiveness
 - D. Labeling Recommendations
 1. General
 2. Comprehension
 3. Pregnancy
 4. STIs
 5. Correct and Consistent Use
 6. Risk Reduction
 7. Directions for Use and Precautions
 8. Additional Information
 - E. Comments in Response to FDA's Specific Requests
 1. Human Papillomavirus (HPV)
 2. Nonlatex Condoms Without Nonoxynol-9
 - F. Implementation
- IV. Environmental Impact
- V. Analysis of Impacts
 - A. Background
 - B. Affected Entities and Scope of Effect
 - C. Costs of Implementation
 - D. Regulatory Flexibility Analysis
- VI. Federalism
- VII. Paperwork Reduction Act of 1995
- VIII. References

I. Background

In the **Federal Register** of November 14, 2005 (70 FR 69102), FDA proposed to amend existing classification regulations to designate a labeling guidance document as the special

control for condoms made of natural rubber latex (latex condoms), classified under 21 CFR 884.5300, and latex condoms with spermicidal lubricant containing nonoxynol-9 (N-9), classified under § 884.5310 (21 CFR 884.5310). As proposed, the final rule amends § 884.5300 (21 CFR 884.5300) and designates a guidance document containing labeling recommendations as the special control for latex condoms. However, FDA continues to review the comments it received in response to its general and specific requests for comment on latex condoms with spermicidal lubricant and to evaluate the controls appropriate for condoms with spermicidal lubricant (§ 884.5310). Therefore, FDA is not issuing a final rule on that device at this time.¹

In the following sections of this preamble, FDA addresses the statutory framework, regulatory history, and scientific information related to latex condoms; summarizes the final rule; and responds to the comments on FDA's designation of special controls for the latex condom.

A. Statutory Framework

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended, including the Medical Device Amendments of 1976 (the 1976

¹ On December 19, 2007, FDA published a final rule, codified at 21 CFR 201.66(c)(5)(ii)(H) and 21 CFR 201.325, that requires that labeling of OTC vaginal contraceptive/spermicidal drug products containing N-9 bear the following warnings:

- For vaginal use only
- Not for rectal (anal) use
- Sexually transmitted diseases (STDs) alert: This product does not protect against HIV/AIDS or other STDs and may increase the risk of getting HIV from an infected partner
- Do not use if you or your sex partner has HIV/AIDS. If you do not know if you or your sex partner is infected, choose another form of birth control.
- When using this product you may get vaginal irritation (burning, itching, or a rash)
- Stop use and ask a doctor if you or your partner get burning, itching, a rash or other irritation of the vagina or penis

Other information in the new labeling includes:

- When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate the risk of catching or spreading HIV, the virus that causes AIDS.
- Studies have raised safety concerns that products containing the spermicide nonoxynol 9 can irritate the vagina and rectum. Sometimes this irritation has no symptoms. This irritation may increase the risk of getting HIV/AIDS from an infected partner.

• You can use nonoxynol 9 for birth control with or without a diaphragm or condom if you have sex with only one partner who is not infected with HIV and who has no other sexual partners or HIV risk factors

• Use a latex condom without nonoxynol 9 if you or your sex partner has HIV/AIDS, multiple sex partners, or other HIV risk factors

• Ask a health professional if you have questions about your best birth control and STD prevention methods.