Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulations No. 4]

RIN 0960–AE35

Reduction of Disability Benefits—Workers' Compensation and Public Disability Benefits and Payments

AGENCY: Social Security Administration (SSA).

ACTION: Proposed rule.

SUMMARY: We propose to revise our rules on reduction of Social Security benefits based on disability on account of receipt of workers' compensation and/or public disability benefits and payments provided under Federal (other than Social Security), State, or local laws or plans to clarify our existing policies. We also propose to adopt a uniform method for proration of workers' compensation and public disability benefit/payment settlements. In addition, we propose to incorporate into our rules certain policy interpretations established previously in relevant Social Security Rulings (SSRs). Finally, we propose to update provisions that have not been changed since 1984.

DATES: To be sure that your comments are considered, we must receive them no later than November 3, 1997.

ADDRESSES: Comments should be submitted in writing to the Commissioner of Social Security, P.O. Box 1585, Baltimore, MD 21235, sent by telefax to (410) 966–2830, sent by E-mail to ''regulations@ssa.gov'', or delivered to the Division of Regulations and Rulings, Social Security Administration, 3–B–1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235–0001, between 8:00 a.m. and 4:30 p.m. on regular business days. Comments may be inspected during these same hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Daniel T. Bridgewater, Legal Assistant, Division of Regulations and Rulings, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–3298 for information about these rules.

SUPPLEMENTARY INFORMATION:

Background

Certain disabled workers may be eligible for cash benefits under both workers' compensation and/or other public disability benefit programs and the Social Security disability insurance (SSDI) program. Section 224 of the Social Security Act (the Act) provides for a reduction in SSDI benefits so that total benefits under both workers' compensation and/or other public disability benefit programs and SSDI do not exceed the higher of 80 percent of a worker's predisability earnings (''average current earnings'') or the total family benefit (i.e., the sum of the individual's Social Security disability benefits and the Social Security benefits payable to others based upon his work record) under Social Security before reduction.

Present Policy

The policy interpreted in SSRs over the years has focused mainly on certain aspects of the law. First, some State workers' compensation laws prescribe specific benefit amounts for certain permanent impairments (e.g., loss of a bodily member) without regard to actual loss of wages. Some beneficiaries questioned whether Congress intended to exclude such benefits based on permanent impairments from the SSDI benefit reduction. This issue was resolved in the courts, and SSA developed two SSRs to reflect its policy that permanent impairment benefits, compensable under State workers' compensation laws, are subject to offset against SSDI benefits. (SSR 74–21c, based on *Grant* v. *Weinberger,* 482 F.2d 1290 (6th Cir. 1973), and SSR 92–6c, based on *Davidson* v. *Sullivan,* 942 F.2d 90 (1st Cir. 1991)). More recent cases, *Krysztoforski* v. *Chater,* 55 F.3d 857 (3rd Cir. 1995) and *Hodge* v. *Shalala,* 27 F.3d 430 (9th Cir. 1994), also uphold SSA's policy in this regard. We now propose to amend our regulatory language to reflect this policy interpretation.

Second, some have questioned our policy that non-covered earnings (i.e., those earnings from employment not covered under the Act) cannot be used in determining the ''average current earnings'' for an individual. This policy, which is described in SSR 92–2a, is based on section 224(a) of the Act, which provides that ''average current earnings'' are to be computed by reference to the average monthly wage under section 215(b) of the Act and to wage and self-employment income totals under sections 209(a)(1) and 211(b)(1) of the Act. These statutory sections are concerned strictly with wages and self-employment income covered under the Act, and, thus, we cannot count non-covered earnings.

Judicial precedent strongly supports the Social Security Administration's (SSA) position: *Prather* v. *Shalala,* 844 F. Supp. 239 (D. Md. 1993), *aff'd w/o opinion,* 14 F.3d 595 (4th Cir. 1994); *Smith* v. *Sullivan,* 982 F.2d 308 (8th Cir. 1992); *Sousa* v. *Shalala,* No. C–92–2796 MHP (N.D. Cal. Jan. 19, 1995); *Everette* v. *Chater,* No. 92–C–714 (E.D. Wis. Aug. 8, 1995). Accordingly, we propose to clarify the regulatory language to express this policy in a more direct manner.

Proposed Policy—Proration of Lump-Sum Awards

In many cases, an individual may receive some or all of his or her workers' compensation in a lump-sum. Because a lump-sum award is a substitute for periodic payments, the Act requires that we look to State law to see what rate would have been paid had the workers' compensation payment been made on a periodic basis, and that we prorate and offset at the rate that most closely approximates State law.

State workers' compensation laws clearly define how to compute the periodic rate. States base the weekly rate on a specified percentage of the worker's average weekly wage subject to a maximum amount set by law. Forty-two States use sixty-six and two-thirds percent.

SSA has been using three methods to establish the rate of offset. In order of priority, they are as follows:

1. The rate specified in the award. (If the award specifies a rate based on life expectancy, we use that rate and list the case for future reference.)

2. The periodic rate paid prior to the lump-sum award (if no rate was specified in the award).

3. The State's workers' compensation maximum weekly rate in effect at the time of the injury (if no rate was

specified in the award and if no periodic payments were made).

For years, lump-sum awards were rare, and they were prorated using method 1 or 2. Method 3 was added later.

Our experience in determining rates has been that, in almost every case, because of the worker's actual earnings, the specified percentage of the average weekly wage would have exceeded the State's maximum rate. Thus, the worker would have received the State's maximum periodic rate. Likewise, the prior periodic rate would have been paid at the maximum rate.

Although we believed that this policy would closely approximate the monthly rate that would have been paid in the absence of a lump-sum settlement, we have witnessed an ever-increasing number of cases nationwide where attorneys are requesting insurers to specify an artificially low rate in the lump-sum award. For example, some awards purport to set a proration rate based on the worker's life expectancy. This rate, often lower than the State's minimum rate, results in little or no offset under our present method of proration.

We do not believe that the use of a life expectancy rate in the lump sum award is a bona fide representation of the periodic rate that would have otherwise been paid. We do not believe that disabled workers would, in fact, accept such low rates if the lump-sum award were paid periodically. Also, we do not believe that these low rates are specified when SSA disability benefits and offset are not an issue.

Life expectancy can be based on subjective factors, such as health, life style, age, job, etc. Given the fact that these workers are disabled, it does not appear to be reasonable to utilize life expectancies to age 75 or older as these awards specify.

We conducted a survey in States where this practice started. One of the questions we asked of the States was whether a low rate based on life expectancy was a bona fide representation of the lump-sum award and in accordance with State law. Six of the eight States said, ''No.'' (One State said the question did not apply and one did not return the survey.)

It is clear that while State law may not provide life expectancy as the basis for a lump-sum award or as the basis for periodic benefits that the lump-sum represents, the actual awards do contain such language. Once a lump-sum award has been agreed upon, it is of no consequence to the insurer how the award is portrayed (i.e., whether the proration rate of the lump-sum award is based on the worker's life expectancy or the State's maximum weekly rate).

When our order of priority for setting the rate of offset was established, lump-sum awards were quite straightforward, even rare. Currently, lump-sum awards are being structured individually in order to best circumvent the offset required by section 224 of the Act. Attorneys have even called SSA personnel to seek guidance in structuring lump-sums to avoid offset.

In short, our policy on the proration of lump-sum awards has become a tool by which people avoid the offsets intended by Congress, rather than a means of approximating, as nearly as practicable, the offset that would have occurred had benefits been paid periodically. It thus can be viewed as no longer satisfying the requirements of section 224(b) of the Act.

In order to prorate and offset a lump-sum award using a rate that is more representative of the periodic rate that would have otherwise been paid under State law and in order to ensure a more uniform policy for all lump-sum cases nationwide, we propose a change in the order of priority for determining the weekly rate used. Specifically, we propose that lump-sum awards be prorated based on:

1. The rate specified in the award; but only if that rate is based on the percentage of the worker's average weekly wage required by State law;

2. The periodic rate paid prior to the lump-sum award (if method 1 does not apply); or

3. The State's maximum weekly rate in effect at the time of the injury (if methods 1 and 2 do not apply).

We believe this proposed change is needed to better implement section 224 of the Act more effectively.

Proposed Policy—Exclusion of Legal and Medical Expenses

Our present policy is that when workers incur legal, medical, and related expenses in connection with the claim for workers' compensation payments or related injury, those expenses are excluded from the lump-sum award for purposes of the offset computation to the extent consonant with applicable law. Any deductions from the workers' compensation payment such as tax withholdings, life insurance, medical premiums, etc., are included in the amount used in the offset computations, as are amounts garnished or attached to satisfy legal obligations.

There are three methods which we use in prorating a lump-sum award with excludable expenses:

Method A—Delays imposition of offset because it allows SSA to take the excludable expenses from the beginning of the proration. This is advantageous to the worker who is approaching age 62 or 65 years of age or when a closed period of disability is involved.

Method B—Divides the lump-sum award, minus the expenses by the total lump-sum award. This percentage is then multiplied by the weekly rate, resulting in a reduced weekly rate. This method reduces the weekly workers' compensation rate so the offset amount is lowered during the entire proration period.

Method C—Reduces the lump-sum award by the amount of the excludable expenses prior to the proration. This method removes offset at the earliest possible time and could even end the proration prior to the first possible month of offset.

Until 1971, only Method C was used. Since then, we have used the method most advantageous to the claimant, unless the lump-sum award specifies the manner in which expenses are to be deducted.

We propose to return to our pre-1971 policy for prorating a lump-sum award with excludable expenses. Using only Method C would provide uniformity and consistency for all claimants. Since the Act and the regulations do not require a specific method of proration, we believe Methods A and B can be discontinued.

Lastly, the meaning of the term ''related'' expenses has caused unnecessary confusion. We have received several questions as to whether items such as new homes, patios, ramps, costs of vans and vacations, moving expenses to a milder climate, etc., may be ''related'' expenses. Because we are aware of no expenses, other than medical or legal expenses, that should be excluded from offset, we propose to remove the category of ''related'' expenses and offset only medical and legal expenses.

Miscellaneous Proposed Changes

We propose to change the language in section 404.408(a)(1) regarding the application of the offset to certain individuals who first became entitled to SSDI after 1965 but before September 1981 based on a period of disability that began after June 1, 1965, and before March 1981. We wish to delete the word, ''first,'' as it is not required by the law. Also, we wish to delete the dates ''September 1981'' and ''March 1981'' to remove an anomaly that affects claims with a month of entitlement of September 1981 or later with disability onsets prior to March 1981.

Example: A claim is filed September 1982 establishing a disability onset date of January 10, 1980. The month of entitlement is determined to be September 1981. This example would not be covered by the current regulatory language.

We also propose to change the language in section 404.408(a)(1)(i) and elsewhere to refer to ''benefits or payments'' under a workers' compensation law or plan, rather than simply ''benefits,'' as many attorneys have claimed that certain workers' compensation is not a ''benefit'' but is in fact a ''payment.''

We propose to change the language in section 404.408(a)(2)(i) regarding individuals entitled to SSDI who also are concurrently entitled to certain other payments based on disability. We believe ''concurrently'' is redundant.

In addition, we propose to make revisions throughout § 404.408 to add the language ''workers' compensation,'' where appropriate, to current references to ''public disability benefits'' because ''workers' compensation'' is the designation given for the majority of public disability benefits other than SSDI or Supplemental Security Income benefits. Using this language makes explicit that section 404.408 applies to ''workers' compensation'' laws.

Finally, in § 404.408 (h), (i), (j), (k), and (*l*), we propose to remove outdated, unnecessary computation examples, leaving one basic example in paragraph (h) of this section. We believe that the removal of outdated, unnecessary examples will clarify this rule.

Electronic Version

The electronic file of this document is available on the Federal Bulletin Board (FBB) at 9:00 a.m. on the date of publication in the **Federal Register**. To download the file, modem dial (202) 512–1387. The FBB instructions will explain how to download the file and the fee. This file is in WordPerfect and will remain on the FBB during the comment period.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they are not subject to OMB review.

Regulatory Flexibility Act

We certify that these proposed rules will not have a significant economic impact on a substantial number of small entities since these rules affect only individuals. Therefore, a regulatory flexibility analysis as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

These proposed rules impose no additional reporting or recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program No. 96.001 Social Security—Disability Insurance)

List of Subjects in 20 CFR Part 404

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

Dated: August 26, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

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

For the reasons set out in the preamble, subpart E of part 404 of chapter III of title 20 of the Code of Federal Regulations is amended as follows:

1. The authority citation for subpart E of part 404 continues to read as follows:

Authority: Secs. 202, 203, 204 (a) and (e), 205 (a) and (c), 222(b), 223(e), 224, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 403, 404 (a) and (e), 405 (a) and (c), 422(b), 423(e), 424a, 425, and 902(a)(5)).

2. Section 404.408 is amended by removing Example 2 from paragraph (h)(2) and by removing the examples from paragraphs (i), (j), (k), and (l)(3) and by revising the section heading and the headings and texts of the following paragraphs: (a)(1) introductory text, (a)(1)(i), (a)(1)(ii), (a)(2)(i), (b)(1), (b)(2)(ii), (c)(1) introductory text, (c)(1)(i), (c)(3), (c)(5), (d)—introductory text, (d)(1), (d)(2), (e), (f), (g), (h)(2)—Example 1, (j), (k), (l)(1), and (l)(2)(i). They read as follows:

§ 404.408 Reduction of benefits based on disability on account of receipt of certain other disability benefits or payments provided under Federal, State, or local laws or plans.

(a) * * *

(1) The individual became entitled to disability insurance benefits after 1965 based on a period of disability that began after June 1, 1965 (but see paragraph (a)(2) of this section), and

(i) The individual entitled to the disability insurance benefit is also entitled to periodic benefits or payments under a workers' compensation law or plan of the United States or a State for that month for an injury or illness, and

(ii) The Commissioner has, in a month before that month, received a notice of the entitlement, and

* * * * *

(2) * * *

(i) The individual entitled to the disability insurance benefit is also, for that month, entitled to a periodic benefit (including workers' compensation or any other payments) on account of a total or partial disability (whether or not permanent) under a law or plan of the United States, a State, a political subdivision, or an instrumentality of two or more of these entities, and

* * * * *

(b) *When reduction not made.* (1) The reduction of a benefit otherwise required by paragraph (a)(1) of this section is not made if the workers' compensation law or plan under which the periodic benefit or payment is payable provides for the reduction of such periodic benefit or payment when anyone is entitled to a benefit under title II of the Act on the basis of the earnings record of an individual entitled to a disability insurance benefit under section 223 of the Act.

(2) * * *

(ii) The benefit or payment is a Veterans' Administration benefit, a public disability benefit (except workers' compensation) payable to an employee based on employment covered under Social Security, a benefit based on need, or a wholly private pension or private insurance benefit.

(c) *Amount of reduction*—(1) *General.* The total of benefits for a month under sections 223 and 202 of the Act to which paragraph (a) of this section applies is reduced monthly (but not below zero) by the amount by which the sum of the monthly disability insurance benefits payable on the disabled individual's earnings record and benefits or payments under a workers' compensation law or plan payable for that month exceeds the higher of:

(i) Eighty percent of the individual's *average current earnings*, as defined in paragraph (c)(3) of this section; or

* * * * *

(3) *Average current earnings defined.*

(i) Beginning January 1, 1979, for purposes of this section, an individual's average current earnings is the largest amount computed under either paragraph (c)(3)(i)(A), (B), or (C) of this section (after reducing the amount to the next lower multiple of $1 when the amount is not a multiple of $1):

(A) The average monthly wage (determined under section 215(b) of the Act as in effect prior to January 1979) used for purposes of computing the individual's disability insurance benefit under section 223 of the Act;

(B) One-sixtieth of the total of the individual's wages and earnings from self-employment covered under the Act, without the limitations under sections 209(a) and 211(b)(1) of the Act (see paragraph (c)(3)(ii) of this section), for the 5 consecutive calendar years after 1950 for which the wages and earnings from self-employment covered under the Act (see subpart K of this part) were highest; or

(C) One-twelfth of the total of the individual's wages and earnings from self-employment covered under the Act, without the limitations under sections 209(a) and 211(b)(1) of the Act (see paragraph (c)(3)(ii) of this section), for the calendar year in which the individual had the highest wages and earnings from self-employment during the period consisting of the calendar year in which the individual became disabled and the 5 years immediately preceding that year.

(ii) *Method of determining calendar year earnings in excess of the limitations under sections 209(a) and 211(b)(1) of the Act.* For the purposes of paragraph (c)(3)(i) of this section, the extent by which the wages or earnings from self-employment of an individual exceed the maximum amount of earnings creditable under sections 209(a) and 211(b)(1) of the Act in any calendar year after 1950 and before 1978 will ordinarily be estimated on the basis of the earnings information available in the records of the Social Security Administration. (See subpart I of this part.) If an individual provides satisfactory evidence of the actual earnings in any year, the extent, if any, by which the earnings exceed the limitations under sections 209(a) and 211(b)(1) of the Act shall be determined by the use of such evidence instead of by the use of estimates.

* * * * *

(5) *Computing disability insurance benefits.* When reduction is required, the total monthly Social Security disability insurance benefits payable after reduction can be more easily computed by subtracting the monthly amount of the other workers' compensation/public disability benefits or payments from the higher of paragraph (c)(1)(i) or (ii) of this section. This is the method employed in the example used in this section.

(d) *Items not counted for reduction.* Amounts paid or incurred and/or a reasonable estimate of amounts to be incurred, by the individual for medical and/or legal expenses in connection with the claim for workers' compensation/public disability benefits or payments (see § 404.408 (a) and (b)) or the injury or occupational disease on which the workers' compensation/public disability award or settlement agreement is based, are excluded in computing the reduction under paragraph (a) of this section to the extent they are consonant with the applicable Federal, State, or local law or plan. The reduction must reflect either the actual amount of expenses already paid or incurred and/or a reasonable estimate of amounts to be incurred, given the circumstances in the individual's case, of future medical and/or legal expenses. The total of such expenses will be subtracted from the total of a settlement agreement prior to the proration of the reduction. Any expenses not established by evidence required by the Commissioner or not reflecting a reasonable estimate of the individual's actual future expenses will not be excluded. These medical and/or legal expenses may be evidenced by the workers' compensation/public disability award, compromise agreement, a court order, or by other evidence as the Commissioner may require. This other evidence may consist of:

(1) A detailed statement by the individual's physician or the employer's insurance carrier; or

(2) Bills, receipts, or canceled checks; or

* * * * *

(e) *Certification by individual concerning eligibility for workers' compensation/public disability benefits or payments.* Where it appears that an individual may be eligible for a workers' compensation/public disability benefit or payment which would give rise to a reduction under paragraph (a) of this section, the individual may be required, as a condition of certification for payment of any benefit under section 223 of the Act to any individual for any month, and of any benefit under section 202 of the Act for any month based on such individual's earnings record, to furnish evidence as requested by the Commissioner and to certify as to:

(1) Whether he or she has filed or intends to file any claim for a workers' compensation/public disability benefit or payment; and

(2) If he or she has so filed, whether there has been a decision on the claim. The Commissioner may rely, in the absence of evidence to the contrary, upon a certification that he or she has not filed and does not intend to file such a claim, or that he or she has filed and no decision has been made, in certifying any benefit for payment pursuant to section 205(i) of the Act.

(f) *Verification of eligibility or entitlement to a workers' compensation/public disability benefit or payment under paragraph (a).* Section 224 of the Act requires the head of any Federal agency to furnish the Commissioner information from the Federal agency's records that is needed to determine the reduction amount, if any, or verify other information to carry out the provisions of this section. The Commissioner is authorized to enter into agreements with States, political subdivisions, and other organizations that administer a law or plan of workers' compensation/public disability benefits in order to obtain information that may be required to carry out the provisions of this section.

(g) *Workers' compensation/public disability benefit or payment payable on other than a monthly basis.* (1) Where workers' compensation/public disability benefits or payments are paid periodically but not monthly, or are paid in a lump-sum as a commutation of or a substitute for periodic benefits or payments, the reduction under this section is made at the time or times and in the amounts that the Commissioner determines will approximate, as nearly as practicable the reduction required under paragraph (a) of this section.

(2) The rate at which to prorate the benefits or payments is the rate in the award if that rate is based on the percentage of the worker's average weekly wage required by Federal or State law. Otherwise, the rate to be used is the prior periodic rate or the State's maximum weekly rate in effect at the time of the injury.

(3) All lump-sum awards, whether for total or partial disability, for temporary or permanent disability, or for scheduled or unscheduled disabilities, including loss of body function, will be offset against Social Security disability insurance benefits as provided in paragraph (a) of this section.

(h) * * *

(2) * * *

Example: Effective September 1995, Harold is entitled to a monthly disability primary insurance amount of $507.90 and a monthly public disability benefit of $410.00 from the State. Eighty percent of Harold's average current earnings is $800.00. Because this amount ($800.00) is higher than Harold's disability insurance benefit ($507.90), we subtract Harold's monthly public disability benefit ($410.00) from eighty percent of his average current earnings ($800.00). This leaves Harold a reduced monthly disability benefit of $390.00.

(j) *Effect of social security disability insurance benefit or payment increases.* Any increase in benefits due to a recomputation or a statutory increase in benefit rates is not subject to the reduction for workers' compensation/public disability benefits or payments

under paragraph (a) of this section and does not change the amount to be deducted from the family benefit or payment. The increase is simply added to what amount, if any, is payable. If a new beneficiary becomes entitled to monthly benefits on the same earnings record after the increase, the amount of the reduction is redistributed among the new beneficiaries entitled under section 202 of the Act and deducted from their current benefit rate.

(k) *Effect of changes in the amount of the workers' compensation/public disability benefit or payment.* Any change in the amount of the workers' compensation/public disability benefit or payment received will result in a recalculation of the reduction under paragraph (a) of this section and, potentially, an adjustment in the amount of such reduction. For those individuals described in paragraph (a)(1) of this section who do not meet the conditions specified in paragraph (a)(2) of this section, any increased reduction will be imposed effective with the month after the month the Commissioner received notice of the increase in the workers' compensation benefit or payment (it should be noted that only workers' compensation can cause this reduction). Adjustments due to a decrease in the amount of the workers' compensation/public disability benefit or payment will be effective with the actual date the decreased amount was effective. For individuals described in paragraph (a)(2) of this section, any increase or decrease in the reduction will be imposed effective with the actual date of entitlement to the new amount of the workers' compensation/public disability benefit or payment.

(l) *Redetermination of benefits*—(1) *General.* In the second calendar year after the year in which reduction under this section in the total of an individual's benefits under section 223 of the Act and any benefits under section 202 of the Act based on his or her wages and self-employment income was first required (in a continuous period of months), and in each third year thereafter, the amount of those benefits which are still subject to reduction under this section are redetermined. The redetermination will be made unless it results in any decrease in the total amount of benefits payable under title II of the Act on the basis of the workers' wages and self-employment income. The redetermined benefit is effective with the January following the year in which the redetermination is made.

(2) * * *

(i) The ratio of the average of the total wages (as defined in § 404.1048(c)) of all persons for whom wages were reported to the Secretary of the Treasury or his delegate for the calendar year before the year in which the redetermination is made, to the average of the total wages of all persons reported to the Secretary of the Treasury or his delegate for calendar year 1977 or, if later, the calendar year before the year in which the reduction was first computed (but not counting any reduction made in benefits for a previous period of disability); and

* * * * *

[FR Doc. 97–23506 Filed 9–3–97; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 97N–0335]

Obstetric and Gynecologic Devices: Reclassification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify instrumentation intended for use in in vitro fertilization (IVF) and related assisted reproduction procedures from class III to class II. FDA is also proposing to reclassify assisted reproduction microscopes and microscope accessories from class III to class I and to exempt this device from the requirement of premarket notification. This reclassification is being proposed on the Secretary of Health and Human Services' own initiative, based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA).

DATES: Written comments by December 3, 1997. FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elisa D. Harvey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory Authorities

The act (21 U.S.C. 201 *et seq.*), as amended by the 1976 amendments (Pub. L. 94–295) and the SMDA (Pub. L. 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are: Class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

Section 513(f)(2) of the act provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the agency to reclassify the device into class I or class II. FDA's regulations in § 860.134 (21