

List of Subjects in 14 CFR Part 1206

Freedom of information.

Dated: March 23, 2000.

Daniel S. Goldin,
Administrator.

Accordingly as set forth above, NASA amends 14 CFR chapter V as follows:

PART 1206—AVAILABILITY OF AGENCY RECORDS TO MEMBERS OF THE PUBLIC

1. The authority citation for part 1206 continues to read as follows:

Authority: 5 U.S.C. 552, 552a; 42 U.S.C. 2473.

§ 1206.610 [Amended]

2. In § 1206.610, remove paragraph (e)(4).

[FR Doc. 00-8769 Filed 4-11-00; 8:45 am]

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RAILROAD RETIREMENT BOARD**20 CFR Parts 325, 330, 335, and 336**

RIN 3220-AB39

Registration for Railroad Unemployment Benefits; Sickness Benefits; Determination of Daily Benefit Rates; Duration of Normal and Extended Benefits

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (Board) amends its regulations to incorporate amendments made to the Railroad Unemployment Insurance Act, which shortened the waiting period for receipt of benefits under the RUIA, changed the method of computing the daily benefit rate, and eliminated certain extended benefits.

EFFECTIVE DATE: This rule will be effective May 12, 2000.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Marguerite P. Dadabo, Senior Attorney, (312) 751-4945, TDD (312) 751-4701.

SUPPLEMENTARY INFORMATION: Public Law 104-251 (110 Stat. 3161), commonly known as the Railroad Unemployment Insurance Act Amendments of 1996, amended the Railroad Unemployment Insurance Act (RUIA) to shorten the waiting period for receipt of unemployment and sickness benefits payable under that statute, to change the method of computing the daily benefit rate, and to eliminate certain extended payments of benefits,

and the Board amends its regulations under the RUIA to conform to those amendments.

Section 325.1 is amended to reflect the change in the waiting period for unemployment benefits from 14 days to seven days. As amended, § 325.1 would provide that unemployment benefits are payable to any qualified employee for each day of unemployment in excess of seven in his or her first two-week registration period, and then for up to ten days of unemployment in any subsequent registration period within the same period of continuing unemployment. However, if the unemployment is the result of a strike, no benefits are payable for the first day 14 days of unemployment. For purposes of applying the seven-day waiting period, a period of continuing unemployment would end when an employee exhausts his or her unemployment benefits for a benefit year. Section 325.1 would also be amended to incorporate a definition of "period of continuing unemployment", a concept added by the 1996 amendments. The concept of a period of continuing unemployment was added to the RUIA so as to permit the continued payment of benefits from one benefit year to the next without a new waiting period if the period of unemployment runs from one year to the next. Finally, § 325.1 is amended to provide that if an employee's earnings in a registration period exceed the monthly compensation base for the applicable base year, then no unemployment benefits are payable in that registration period. For example, for benefit year 2000 the base year is calendar year 1999 in which the monthly compensation base was \$970. No benefits are payable for any days of unemployment in the benefit year beginning July 1, 2000, for any registration period in which the employee earns more than \$970. An employee who declines suitable work during a registration period is treated as having earned the amount of earnings he would have received had he not declined employment.

Section 330.2 is amended to provide that the maximum daily benefit rate under the RUIA is the monthly compensation base, as computed under 20 CFR part 302, multiplied by 5%, rounded down to the nearest \$1. This change is the result of a change in the RUIA enacted under the 1996 amendments. The Board will publish the maximum daily benefit rate for the upcoming benefit year by June 1 of each year.

Section 335.6 is revised to reflect the same changes with respect to the waiting period for sickness benefits that

the amendments to § 325.1 make with respect to unemployment benefits.

Finally, § 336.13 is revised, and § 336.14 is amended to reflect a change in the payment of extended benefits made by the 1996 amendments. Under the RUIA, as amended, an employee with ten or more years of service will receive a maximum of 65 days of extended unemployment or sickness benefits after the employee has exhausted his or her normal 130 days of unemployment or sickness.

The Board published this rule as a proposed rule on December 3, 1999 (64 FR 67811), and invited comments by February 1, 2000. No comments were received.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action under Executive Order 12866; therefore no regulatory impact analysis is required. There are no information collections associated with these rules.

List of Subjects in 20 CFR Parts 325, 330, 335, and 336

Railroad employees, Railroad unemployment and sickness benefits.

For the reasons set out in the preamble, the Railroad Retirement Board amends chapter II, title 20 of the Code of Federal Regulations as follows:

PART 325—REGISTRATION FOR RAILROAD UNEMPLOYMENT BENEFITS

1. The authority citation for part 325 continues to read as follows:

Authority: 45 U.S.C. 362(i) and 362(1).

2. Paragraphs (a) through (d) of § 325.1 are revised, paragraph (e) is redesignated as paragraph (h), and new paragraphs (e) through (g) are added as follows:

§ 325.1 General.

(a) *Day of unemployment.* A "day of unemployment" is a calendar day on which an employee, although ready and willing to work, is unemployed, and on which no remuneration is payable and for which the employee has registered, as required by this part. The amount of compensable days of unemployment shall be computed in accordance with this section.

(b) *Registration period.* Except for registration periods in extended unemployment benefit periods, a "registration period" means a period of 14 consecutive days beginning with the first day for which an employee registers following:

(1) His or her last day of work, or

(2) The last day of the employee's last preceding registration period, and with respect to which the employee properly files a claim for benefits on such form and in such manner as the Board prescribes.

(c) *General waiting period.* Benefits are payable to any qualified employee for each day of unemployment in excess of seven during his or her first registration period in a period of continuing unemployment if such period of continuing unemployment is his or her initial period of continuing unemployment beginning in the benefit year, and then for each day of unemployment in excess of four during any subsequent registration period within the same period of continuing unemployment. A strike waiting period, described in paragraph (d) of this section, will satisfy a general waiting period with respect to a benefit year.

(d) *Strike waiting period.* If a qualified employee has a period of continuing unemployment that includes days of unemployment due to a stoppage of work because of a strike in the establishment, premises, or enterprise at which he or she was last employed, no benefits are payable for his or her first 14 days of unemployment due to such stoppage of work. For subsequent days of unemployment due to the same stoppage of work, benefits are payable for days of unemployment in excess of four in each subsequent registration period within the period of continuing unemployment. If such period of continuing unemployment ends because the employee has exhausted his or her benefits as provided for under part 336 of this chapter, but the stoppage of work continues, benefits are payable for days of unemployment in excess of seven in the employee's first registration period in a new period of continuing unemployment based upon the same stoppage of work and for days of unemployment in excess of four in subsequent registration periods in the same period of continuing unemployment.

(e) *Period of continuing unemployment.* A "period of continuing unemployment" means a single registration period that includes more than four days of unemployment or a series of consecutive periods each of which includes more than four days of unemployment, or a series of successive registration periods, each of which includes more than four days of unemployment, if each succeeding registration period begins within 15 days after the last day of the immediately preceding registration period. An employee's period of continuing unemployment ends on the

last day of a benefit year in which he or she exhausts rights to unemployment benefits as provided for in part 336 of this chapter.

(f) *Computation of compensable days.*

(1) *Example 1.* An employee has an initial period of continuing unemployment from June 14 through July 25 and is unemployed on all days in that period. The employee's first registration period covers June 14 to June 27, and his subsequent registration periods cover June 28 to July 11 and July 12 to July 25. Under paragraph (c) of this section, a one-week waiting period applies to his first registration period and the employee is therefore paid benefits for days of unemployment in excess of seven in that period. The employee is then paid benefits for days of unemployment in excess of four in each of the two ensuing registration periods. [Note: if this employee's period of continuing unemployment had been the result of a strike in the establishment, premises, or enterprise at which the employee was last employed, then under paragraph (d) of this section, no benefits would be payable for the period June 14 to June 27, and benefits would then be payable for days of unemployment in excess of four in each of the ensuing registration periods.]

(2) *Example 2.* Same facts as in example 1, but the employee is unemployed again beginning August 18. Since August 18 is more than 15 days after July 25, the end of his last registration period, the employee begins a new period of continuing unemployment. The employee's first registration period in the new period of continuing unemployment covers August 18 to August 31. The employee is paid benefits for days of unemployment in excess of seven in that registration period because that period is the employee's first registration period in a new period of continuing unemployment commencing in the benefit year beginning July 1, and he or she did not previously have a waiting period in any registration period earlier in that benefit year. The employee's next registration period covers September 1 to September 14, and the employee returned to work on September 12. In that registration period, the employee has 11 days of unemployment and is therefore paid benefits for days of unemployment in excess of four.

(3) *Example 3.* Same facts as in examples 1 and 2, but the employee then has a new period of continuing unemployment beginning November 1 in the same benefit year. November 1 to November 14 is the employee's first registration period in that period of

continuing unemployment. The employee is paid benefits for days of unemployment in excess of four in that registration period and for days of unemployment in excess of four in any subsequent registration period in the same benefit year because earlier in the benefit year the employee had a registration period, August 18 to August 31, in which he or she satisfied the waiting period.

(g) *Remuneration exceeds base year compensation.* (1) No benefits are payable to any otherwise eligible employee for any day of unemployment in a registration period where the total amount of remuneration, as defined in part 322 of this chapter, payable to the employee during a registration period exceeds the amount of the base year monthly compensation base. For this purpose an employee is considered to have received the amount he would have earned except for the fact that he declined suitable work available to him or her during the registration period.

(2) Days of unemployment which are not compensable by virtue of paragraph (g)(1) of this section shall nevertheless be counted as days of unemployment for purposes of determining whether the general waiting period, as described in paragraph (c) of this section, has been satisfied, and for purposes of determining a period of continuing unemployment.

PART 330—DETERMINATION OF DAILY BENEFIT RATES

3. The authority citation for part 330 continues to read as follows:

Authority: 45 U.S.C. 362(l).

4. Section 330.1 is revised to read as follows:

§ 330.1 Introduction.

The Railroad Unemployment Insurance Act provides for the payment of benefits, at a specified daily benefit rate, to any qualified employee for his or her days of unemployment or days of sickness, subject to a maximum amount per day. The "daily benefit rate" for an employee is the amount of benefits that he or she may receive for each compensable day of unemployment or sickness in any registration period in a period of continuing unemployment or sickness.

5. Paragraphs (b), (c), and (d) of § 330.2 are revised to read as follows:

§ 330.2 Computation of daily benefit rate.

* * * * *

(b) *Maximum daily benefit rate.* The maximum daily benefit rate is the

product of the monthly compensation base, as computed under part 302 of this chapter, for the base year immediately preceding the beginning of the benefit year, multiplied by five percent. If the maximum daily benefit rate so computed is not a multiple of \$1.00, the Board will round it down to the nearest multiple of \$1.00.

(c) *When increase effective.* Whenever the annual application of the formula in paragraph (b) of this section triggers an increase in the maximum daily benefit rate, such increase will apply to days of unemployment or days of sickness in registration periods beginning after June 30 of the calendar year immediately following the base year referred to in paragraph (b) of this section.

(d) *Notice.* Whenever the annual application of the formula in paragraph (b) of this section triggers an increase in the maximum daily benefit rate, or if the annual application of the formula does not trigger an increase, the Board will publish a notice in the **Federal Register** explaining how it computed the maximum daily benefit rate for the year. The Board will also notify each employer of the maximum amount of the daily benefit rate. The Board will make the computation as soon as it has computed the amount of the monthly compensation base under part 302 of this chapter and will publish notice as soon as possible thereafter, but in no event later than June 1 of each year. Information as to the current amount of the maximum daily benefit rate will also be available in any Board district or regional office.

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PART 335—SICKNESS BENEFITS

6. The authority citation for part 335 continues to read as follows:

Authority: 45 U.S.C 362(i) and 362(l).

7. Section 335.6 is revised to read as follows:

§ 335.6 Payment of sickness benefits.

(a) *General rule.* Except as provided in this section, benefits are payable to any qualified employee for each day of sickness after the fourth consecutive day of sickness in a period of continuing sickness, as defined in § 335.1(c), but excluding four days of sickness in any registration period in such period of continuing sickness.

(b) *Waiting period.* Benefits are payable to any qualified employee for each day of sickness in excess of seven during his or her first registration period in a period of continuing sickness if such period of continuing sickness is his or her initial period of continuing sickness beginning in the benefit year.

For this purpose, the first registration period in a period of continuing sickness is the registration period that first begins with four consecutive days of sickness and includes more than four days of sickness. For the purpose of computing benefits under this section, a period of continuing sickness ends on the last day of a benefit year in which the employee exhausts rights to sickness benefits as provided for under part 336 of this chapter.

(c) *Computation of compensable days.*

(1) *Example 1.* An employee has an initial period of continuing sickness from June 14 through July 25, and all days in that period are days of sickness. The employee's first registration period covers June 14 to June 27, and his or her subsequent registration period covers June 28 to July 11, and July 12 to July 25. In the one-week waiting period the employee is paid benefits for days of sickness in excess of seven. In each of the two ensuing registration periods the employee is paid benefits for days of sickness in excess of four.

(2) *Example 2.* Same facts as in Example 1, but the employee later has a new period of continuing sickness based upon a different illness or impairment beginning September 17. The employee's first registration period in his or her new period of continuing sickness covers September 17 to September 30. The employee is paid benefits for days of sickness in excess of seven in that 14-day period because that period is his or her first registration period in a new period of continuing sickness commencing in the benefit year beginning July 1, and he or she did not previously have a waiting period in any registration period earlier in the benefit year.

(3) *Example 3.* Same facts as in examples 1 and 2, but the employee then has a new period of continuing sickness beginning January 1 in the same benefit year. January 1 to January 14 is the employee's first registration period in that period of continuing sickness. The employee is paid benefits for days of sickness in excess of four in that registration period because earlier in the benefit year he or she had a registration period, September 17 to September 30, in which he or she satisfied the initial seven-day waiting period.

(d) *Amount payable.* The gross amount of sickness benefits for any registration period in a period of continuing sickness shall be computed by multiplying the number of compensable days of sickness in such registration period by the employee's daily benefit rate, as computed under part 330 of this chapter.

PART 336—DURATION OF NORMAL AND EXTENDED BENEFITS

8. The authority citation for part 336 continues to read as follows:

Authority: 45 U.S.C. 362(l).

9. Section 336.13 is revised to read as follows:

§ 336.13 Years of service requirement.

(a) *Eligibility.* For the purposes of this part, an employee is not eligible for extended unemployment or sickness benefits if he or she does not have at least 10 years of railroad service. An employee who has 120 service months, as defined in part 210 of this chapter, whether or not consecutive, is considered to have 10 years of railroad service.

(b) *Initial determination.* The Board will determine whether an employee has 10 years of railroad service on the basis of reports filed by employers pursuant to part 209 of this chapter. The number of years of service shown in the Board's records will be accepted as correct for the purposes of this part, unless the employee claims credit for more service than that shown in the Board's records and such additional service is verified, subject to part 211 of this chapter.

(c) *Effective date.* An employee acquires ten years of railroad service as of the first day with respect to which creditable compensation is attributable in his 120th month of service.

10. In § 336.14, paragraphs (a), (c), and (d) are revised to read as follows:

§ 336.14 Extended benefit period.

(a) *Defined.* An extended benefit period consists of seven consecutive 14-day registration periods.

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(c) *Ending date.* An employee's extended benefit period ends on the 97th day after it began. If an employee attains age 65 during an extended sickness benefit period, such extended benefit period will terminate on the day next preceding the date on which the employee attains age 65, except that it may continue for the purpose of paying benefits for his or her days of unemployment, if any, during such extended period. If an extended sickness benefit period terminates because the employee has attained age 65, and if at that point the employee has rights to normal sickness benefits, the employee will be paid normal sickness benefits if he or she is otherwise entitled to payment thereof.

(d) *Maximum number of compensable days.* Extended benefits may be paid for a maximum of 65 days of

unemployment (or 65 days of sickness, as the case may be) within an employee's extended benefit period.

Dated: March 24, 2000.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 00-9025 Filed 4-11-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 92N-0445]

Gastroenterology-Urology Devices; Effective Date of Requirement for Premarket Approval of the Penile Inflatable Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the penile inflatable implant, a generic type of medical device intended for the treatment of erectile dysfunction. This regulation reflects FDA's exercise of its discretion to require PMA's or PDP's for preamendments devices and is consistent with FDA's stated priorities and Congress' requirement that class III devices are to be regulated by FDA's premarket review. 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 amendments), the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997.

DATES: This rule is effective April 12, 2000.

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of November 23, 1983 (48 FR 53023), FDA published a final rule classifying into class III (premarket approval) the penile inflatable implant, a medical device.

Section 876.3350 (21 CFR 876.3350) of FDA's regulations setting forth the classification of the penile inflatable implant applies to: (1) Any penile inflatable implant that was in commercial distribution before May 28, 1976, and (2) any device that FDA has found to be substantially equivalent to a penile inflatable implant in commercial distribution before May 28, 1976.

In the **Federal Register** of April 28, 1993 (58 FR 25902), FDA published a proposed rule, under section 515(b) of the act (21 U.S.C. 360e(b)), to require the filing of PMA's or PDP's for the classified penile inflatable implant and all substantially equivalent devices (hereinafter referred to as the April 1993 proposed rule). In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble, the agency's proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and (2) the benefits to the public from use of the device.

The preamble also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. Under section 515(b)(2)(B) of the act, it also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the penile inflatable implant was required to be submitted by May 13, 1993. The comment period initially closed on June 28, 1993. In the **Federal Register** of July 1, 1993 (58 FR 35416), FDA extended the comment period for 60 days to August 27, 1993, to ensure that there was adequate time for preparation and submission of comments on the proposed rule.

The agency received 32 comments in response to the April 1993 proposed rule. These comments were from physicians and other health care providers, professional organizations, physician groups, manufacturers, and consumers and other individuals. Most of the comments supported the proposed rule.

This regulation is final upon publication and requires PMA's or notices of completion of a PDP for all penile inflatable implants classified under § 876.3350 and all devices that are substantially equivalent to them. PMA's or notices of completion of a PDP for these devices must be filed with FDA within 90 days of the effective date of this regulation. (See section

501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)).) This regulation does not include the penile rigidity implant (21 CFR 876.3630).

II. Summary and Analysis of Comments and FDA's Response

A. General Comments

(Comment 1) FDA received 23 comments from individual physicians and 2 comments from professional medical organizations. Although the majority of these comments did not object to the proposed call for PMA's or PDP's, they voiced the following common concerns: (1) Erectile dysfunction is a serious medical problem affecting tens of millions of American men and their partners, (2) removal of this device from the U.S. market would be detrimental to public health, and (3) citing the 25 years of use of the device, sufficient historical data exist to evaluate the safety and effectiveness of the penile inflatable implant. This last concern was also noted in two comments from penile inflatable implant manufacturers, which stated that the decades of medical literature regarding the risks and benefits of this device provide sufficient evidence of its safety and effectiveness. Several comments remarked that FDA has overstated the risks of the inflatable penile implant.

FDA agrees that erectile dysfunction is a significant medical problem that negatively affects the lives of more than 10 million men in the United States. Furthermore, since penile inflatable implants represent an important option in the treatment of erectile dysfunction, FDA agrees with these comments that removal of the penile inflatable implant from the market would negatively impact public health. As a result of this concern, FDA has taken the following steps to promote the continued availability of the penile inflatable implant during the call for PMA's or PDP's: (1) FDA issued the guidance document entitled "Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants" in March 1993 (the 1993 guidance document) to provide industry with detailed recommendations on the content of PMA's; (2) FDA has communicated closely with each penile inflatable implant manufacturer to address the concerns identified in the proposed rule using least burdensome methods, as well as provided recommendations on the design of preclinical and clinical studies; and (3) FDA intentionally postponed the call for PMA's or PDP's to allow manufacturers to collect