

	Fiscal year						Total, 1999–2004
	1999	2000	2001	2002	2003	2204	
Medicaid State Share	30	45	55	55	70	75	330

Although the costs are significant, we consider these changes as necessary improvements to existing work incentives. The costs of these regulations would be paid for through programmatic and regulatory changes.

Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because they primarily affect individuals who are applying for or receiving title II or applying for title XVI benefits because of disability, and States which administer the Medicaid program.

(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)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Death benefits, 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: February 10, 1999.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons stated in the preamble, the Social Security Administration proposes to amend parts 404 and 416 of chapter III of title 20 of the Code of Federal Regulations as follows:

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

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

Authority: Secs. 202, 205(a), (b), and (d)—(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)—(h), 416(i), 421(a) and (i), 422(c), 423, 425, and

902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Section 404.1574 is amended by revising paragraph (b)(2)(vi) and (b)(2)(vii), adding a new paragraph (b)(2)(viii), revising paragraphs (b)(4)(vi) and (b)(4)(vii) and adding a new paragraph (b)(4)(viii) to read as follows:

§ 404.1574 Evaluation guides if you are an employee.

* * * * *

(b) * * *

(2) * * *

(vi) Your earnings averaged more than \$300 a month in calendar years after 1979 and before 1990;

(vii) Your earnings averaged more than \$500 a month after calendar year 1989 and before (insert first day of the month beginning after 30 days following date of publication of the final rules in the **Federal Register**); or

(viii) Your earnings averaged more than \$700 a month after (insert date that is one day earlier than date shown at the end of paragraph (b)(2)(vii) of this section).

* * * * *

(4) * * *

(vi) Your average earnings are not greater than \$300 a month in calendar years after 1979 and before 1990;

(vii) Your average earnings are not greater than \$500 a month after calendar year 1989 and before (insert first day of the month beginning after 30 days following date of publication of the final rules in the **Federal Register**); or

(viii) Your average earnings are not greater than \$700 a month after (insert date that is one day earlier than date shown at the end of paragraph (b)(4)(vii) of this section).

* * * * *

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

1. The authority citation for Subpart I of Part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631(a), (c) and (d)(1), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c) and (d)(1), and 1383b); secs. 4(c) and 5, 6(c)—(e), 14(a) and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

2. Section 416.974 is amended by revising paragraph (b)(2)(vi) and

(b)(2)(vii), adding a new paragraph (b)(2)(viii), revising paragraphs (b)(4)(vi) and (b)(4)(vii) and adding a new paragraph (b)(4)(viii) to read as follows:

§ 416.974 Evaluation guides if you are an employee.

* * * * *

(b) * * *

(2) * * *

(vi) Your earnings averaged more than \$300 a month in calendar years after 1979 and before 1990;

(vii) Your earnings averaged more than \$500 a month after calendar year 1989 and before (insert first day of the month beginning after 30 days following date of publication of the final rules in the **Federal Register**); or

(viii) Your earnings averaged more than \$700 a month after (insert date that is one day earlier than date shown at the end of paragraph (b)(2)(vii) of this section).

* * * * *

(4) * * *

(vi) Your average earnings are not greater than \$300 a month in calendar years after 1979 and before 1990;

(vii) Your average earnings are not greater than \$500 a month after calendar year 1989 and before (insert first day of the month beginning after 30 days following date of publication of the final rules in the **Federal Register**); or

(viii) Your average earnings are not greater than \$700 a month after (insert date that is one day earlier than date shown at the end of paragraph (b)(4)(vii) of this section).

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[FR Doc. 99–3677 Filed 2–12–99; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98D–0785]

Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of guidance; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending until April 14, 1999, the comment period for the draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologics." FDA published a notice of availability of the draft guidance in the **Federal Register** of October 14, 1998 (63 FR 55067). FDA is taking this action in response to requests for an extension.

DATES: Written comments on the draft guidance may be submitted by April 14, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, FAX 888-CBERFAX or 301-827-3844. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert K. Leedham, Jr., Center for Drug Evaluation and Research (HFD-160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3500, or George Q. Mills, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-5097.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a notice announcing the availability of a draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologics." The draft guidance is intended to assist developers of drug and biological products used for medical imaging, as well as radiopharmaceutical drugs used in disease diagnosis, in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The draft guidance also provides information on how the agency would interpret and apply provisions in proposed regulations, published in the **Federal Register** of May 22, 1998 (63 FR

28301), for in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The draft guidance applies to medical imaging drugs that are used for diagnosis and monitoring and that are administered in vivo. The draft guidance is not intended to apply to possible therapeutic uses of these drugs or to in vitro diagnostic products. Interested persons were given until December 14, 1998, to submit written comments on the draft guidance.

In a notice published in the **Federal Register** of January 5, 1999 (64 FR 457), FDA reopened the comment period on the draft guidance until February 12, 1999.

At a January 25, 1999, public meeting on the draft guidance requested by the Council on Radionuclides and Radiopharmaceuticals (CORAR), a representative of Bracco Diagnostics Inc. (Bracco) requested that FDA extend the comment period on the draft guidance to allow manufacturers of contrast media to attempt to reach consensus and submit comments on the draft guidance. On January 27, 1999, FDA received letters from Bracco and from CORAR's legal counsel requesting that the agency extend the comment period.

In response to these requests, FDA has decided to extend the comment period on the draft guidance until April 14, 1999, to allow the public more time to review and comment on its contents. FDA also intends to hold another public meeting to discuss the draft guidance prior to the close of the comment period.

Interested persons may, on or before April 14, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 9, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99-3634 Filed 2-12-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 25

[A.G. Order No. 2206-99]

RIN 1105-AA56

Regulations Under the Pam Lychner Sexual Offender Tracking and Identification Act of 1996, as Amended

AGENCY: Office of the Attorney General, Department of Justice.

ACTION: Proposed rule.

SUMMARY: The United States Department of Justice is publishing proposed regulations to implement the Pam Lychner Sexual Offender Tracking and Identification Act of 1996, as amended. The proposed regulations describe the operation of the National Sex Offender Registry and set forth notification requirements to be followed by registered sex offenders who move to another state.

DATES: Submit comments on or before April 19, 1999.

ADDRESSES: Send comments to the Unit Chief, Office of Crimes Against Children, Federal Bureau of Investigation, 935 Pennsylvania Avenue, N.W., Room 4127, Washington, DC 20535.

FOR FURTHER INFORMATION CONTACT: Venetia Sims, Criminal Justice Information Systems Division, Federal Bureau of Investigation, 1000 Custer Hollow Road, Clarksburg, West Virginia, 26306.

SUPPLEMENTARY INFORMATION: The proposed regulations address two topics: (1) The operation of the National Sex Offender Registry ("NSOR") established by the Federal Bureau of Investigation ("FBI") in accordance with Pam Lychner Sexual Offender Tracking and Identification Act of 1996, Pub. L. 104-236, 110 Stat. 3093, as amended (the "Pam Lychner Act" or the "Act"); and (2) the action required of registered sex offenders who move to another state. With respect to the NSOR, the regulations describe how the interim and permanent registries will operate and what action can be taken by states to notify the FBI and update the NSOR if a convicted sex offender fails to comply with his or her state registration obligations. With respect to offenders who move interstate, the regulations notify such offenders that they should contact the local FBI office in their new state of residence so that the FBI can take the steps necessary to ensure that the new state of residence has also been