Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth

* * * * *

ASO GA E5 Toccoa, GA [Revised]

Toccoa RG Letourneau Field Airport, GA (Lat. 34°35′37″N, long. 83°17′45″W Foothills VOR

(Lat. 34°41′45″N, long. 83°17′52″W Habersham County Airport (Lat. 34°30′01″N, long. 83°33′20″W

That airspace extending upward from 700 feet or more above the surface of the earth within a 10-mile radius of Toccoa RG Letourneau Field Airport and within 3.4-miles each side of the 023 degree radial from the Foothills VOR, extending 7 miles northeast of the VOR and within an 8.2-mile

* * * * *

Issued in College Park, Georgia, on February 4, 1999.

radius of Habersham County Airport.

Nancy B. Shelton,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 99–3686 Filed 2–12–99; 8:45 am] BILLING CODE 4910–13–M

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Regulations No. 4 and 16]

RIN 0960-AE98

Old-Age, Survivors, and Disability Insurance and Supplemental Security Income for the Aged, Blind, and Disabled; Substantial Gainful Activity Amounts

AGENCY: Social Security Administration. **ACTION:** Notice of proposed rulemaking.

SUMMARY: These proposed rules would raise from \$500 to \$700 the average monthly earnings guidelines used to determine whether work done by persons with impairments other than blindness is substantial gainful activity (SGA) for purposes of Social Security disability benefits provided under title II of the Social Security Act (the Act) and Supplemental Security Income (SSI) benefits based on disability under title XVI of the Act. (Eligibility for

benefits under titles II and XVI also confers eligibility for related Medicare and Medicaid benefits under titles XVIII and XIX of the Act.) We propose to revise this level as part of efforts to encourage individuals with disabilities to attempt to work, and to provide an updated indicator of when earnings demonstrate the ability to engage in SGA. The proposed increase reflects our assessment of the amount which roughly corresponds to wage growth since the last increase in 1990.

DATES: In order to be considered, we must receive your comments on the specific proposal to increase the amount

must receive your comments on the specific proposal to increase the amount of the earnings guidelines, by March 18, 1999.

Note: Under the heading "Additional Items," we ask for more general suggestions concerning work incentive provisions and how best to review and revise guidelines in the future. We will accept these suggestions until April 19, 1999.

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 Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise, 6401 Security Boulevard, Baltimore, MD 21235, 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: Jack Baumel, Office of Disability, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235, (410) 965–9834 or TTY (410) 966–6210. SUPPLEMENTARY INFORMATION:

Background

Under 20 CFR 404.1572 and 416.972, the term "substantial gainful activity" means work activity that involves significant physical or mental effort and that is done for pay or profit. Work activity is gainful if it is the kind of work usually performed for pay or profit, whether or not a profit is realized. Sections 223(d)(4)(A) and 1614(a)(3)(E) of the Act require the Commissioner to prescribe by regulations the criteria for determining when earnings demonstrate an individual's ability to engage in SGA.

These proposed rules would increase the amount in the monthly earnings guidelines used in determining whether an individual's work activities demonstrate that he or she is able to perform SGA. Under the current guidelines in §§ 404.1574 and 416.974,

if a person claiming title II or title XVI benefits or receiving title II benefits based on disability had earnings from work activities as an employee (including as an employee of a sheltered workshop or comparable facility) that averaged more than \$500 a month, we would ordinarily consider that the person had engaged in SGA. Under the proposed rules, the \$500 amount would be raised to \$700 per month.

The amount of average monthly earnings that ordinarily demonstrates SGA has not been increased since January 1, 1990. We are revising this level now after reassessing the current guidelines as part of our effort to improve incentives to encourage individuals with disabilities to attempt to work. We believe that the increase in the amount of earnings that constitutes SGA would provide an updated indicator of when earnings demonstrate the ability to engage in SGA and would be a significant improvement to the existing work incentive provisions.

Proposed Regulations

We propose to revise §§ 404.1574(b) (2) and (4), and 416.974(b) (2) and (4) to increase from \$500 to \$700 the earnings guidelines that we use to determine whether a non-blind employee is engaging in SGA. (This standard would also be applied to the self-employed in certain circumstances by cross-references now present in §§ 404.1575 and 416.975.) We have not raised the SGA earnings amount for approximately nine years. We are proposing to raise the SGA level now to \$700, which roughly corresponds to wage growth since the last increase in 1990.

Additional Items

While these proposed rules would make specific increases to the amount of earnings that will ordinarily show that a person has engaged in SGA, we will, at a future point, consider making other changes in this area as well. Therefore, we invite the public to provide us with general suggestions for changes which might be desirable in related provisions (e.g., the trial work period services amount, and the earnings level that ordinarily demonstrates that an individual has not engaged in SGA). We also request suggestions reviewing and revising SGA guidelines in the future. Please note that, in order to be considered, we must receive comments on the specific provisions in these proposed rules by March 18, 1999. However, we will accept general suggestions on the "additional items" mentioned in this paragraph if they are received by April 19, 1999.

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

Justification for 30-day Comment Period

Executive Order 12866 states that, in most cases, an agency should provide a 60-day period for comments on its proposed rules. We ordinarily provide a 60-day period. However, for these proposed rules we are providing a 30day comment period. As these proposed rules would increase the scope of disability eligibility for Old-age, Survivors and Disability Insurance and SSI benefits, as well as for related Medicare and Medicaid benefits, we believe it is in the public interest to proceed quickly to advance this change. In this way, this important change could have an impact at the earliest date practicable. However, it remains important to us to consider public comments on the proposal. Therefore, we are establishing a 30-day comment period.

Paperwork Reduction Act

These regulations impose no new reporting/record-keeping requirements necessitating clearance by OMB.

Executive Order 12866

Regulatory Impact Analysis

Introduction—Based on the costs associated with these proposed rules, the Social Security Administration has determined that they require an

assessment of costs and benefits to society per Executive Order 12866 because they meet the definition of a "significant regulatory action." These proposed rules also meet the definition of a "major rule" under 5 U.S.C. 801ff., and this assessment also fulfills the requirements of those provisions as well. In addition, SSA has determined, as required under the aforementioned statute, that these regulations do not create any unfunded mandates for State or local entities pursuant to sections 202-205 of the Unfunded Mandates Act of 1995. The Office of Management and Budget has reviewed this proposed rule.

Executive Order 12866 includes in its definition of a "significant regulatory action" one which generates a major increase in costs for the Federal government. Accordingly, a discussion follows of the effect of the regulations and general information on estimated costs and benefits to society.

Nature of the Program—Benefits to disabled and blind individuals are provided under title II and title XVI of the Act. Disability is defined under both programs as, "* * * inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment * * *." Related medical benefits to disabled and blind individuals are provided under title XVIII and title XIX of the Act.

We use earnings guidelines to evaluate a person's work activity to determine whether the work activity is SGA and therefore whether that person may be considered disabled under the law. While this is only one of the tests used to determine disability, it is a critical threshold in disability evaluation. We evaluate the work activity of persons claiming or receiving disability benefits under title II of the Act and that of persons claiming benefits because of a disability under

title XVI of the Act. These proposed regulations would increase the amounts of those earnings guidelines. We have not raised the SGA earnings amount for approximately nine years. We are proposing to raise it now to approximate wage growth during that time.

Intended Effect—We expect that the increase in the amount of earnings that constitute SGA would provide a greater incentive for many beneficiaries to attempt to work or, if already working, to continue to work or increase their work effort. Hundreds of thousands of beneficiaries already work and could be advantaged by the proposed revisions. For these individuals, as well as those not now working, the proposed revisions could enhance their potential to participate in the workforce, and, as a consequence, improve their economic well-being by increasing their income through earnings.

In addition, the increase would permit some individuals with disabilities who have earnings in excess of the current regulatory limit (\$500) but less than the amount in these proposed rules (\$700), to receive benefits. We estimate that by 2004, an additional 27,000 individuals who would not otherwise be receiving benefits will do so as a result of these changes. This estimate is based on analyses of the earnings distributions of a representative sample of disabled individuals.

The following chart provides the estimated increases in Old-age, Survivors and Disability Insurance payments, Federal SSI payments, Medicare benefits, and Federal share of Medicaid benefits due to the proposed increase in the SGA amount to \$700 in 1999, for fiscal years 1999–2004. (Amounts are in millions.)

	Fiscal year						Total, 1999– 2004
	1999	2000	2001	2002	2003	2004	2004
OASDI SSI Medicare Medicaid	10 15 10 40	30 20 20 60	55 25 30 70	75 25 50 75	100 30 60 90	120 30 80 100	390 145 250 435
Subtotal, all programs	75	130	180	225	280	330	1220

Notes:

¹ Totals may not equal sum of rounded components.

³ Estimates for Medicare and Medicaid provided by the Office of the Actuary in the Health Care Financing Administration (HCFA).

In addition, since States share in the costs of financing Medicaid, States will

have some costs associated with the proposed increase in the SGA as well.

These costs are estimated by HCFA to be (in millions):

² Above estimates based on the assumptions underlying the President's FY 2000 Budget, including the SSA Actuary's normal assumption of an SGA amount increasing with average wages.

	Fiscal year						Total,
	1999	2000	2001	2002	2003	2204	1999–2004
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).

[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,

ACTION: Availability of guidance; extension of comment period.