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SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

RIN 0960–AE74

Federal Old-Age, Survivors, and Disability Insurance Benefits; Supplemental Security Income for the Aged, Blind, and Disabled; Organization and Procedures; Application of Circuit Court Law

AGENCY: Social Security Administration (SSA).

ACTION: Final rules.

SUMMARY: These final regulations revise the current regulations governing how we apply holdings of the United States Courts of Appeals (circuit courts) that we determine conflict with our interpretation of the Social Security Act or regulations in adjudicating claims under title II and title XVI of the Social Security Act (the Act). The regulations explain the new goal we have adopted to ensure that Acquiescence Rulings (ARs) are developed and issued promptly and the new procedures we are implementing to identify claims pending in the administrative review process that might be affected by ARs.

EFFECTIVE DATES: These amendments are effective June 5, 1998.

FOR FURTHER INFORMATION CONTACT: Gary Sargent, Litigation Staff, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1695 for information about these rules. For information on eligibility or claiming benefits, call our national toll free number, 1–800–772–1213.

SUPPLEMENTARY INFORMATION: On January 11, 1990, (55 FR 1012) we published final regulations, set out at 20 CFR 404.985 and 416.1485, to implement a revised policy explaining how we apply circuit court holdings that we determine conflict with our interpretation of the Act or regulations to subsequent claims within that circuit involving the same issue. Under those regulations, we prepare ARs which explain the circuit court holdings and provide instructions to adjudicators, at all levels of the administrative review process, on how to apply the circuit court's holding to subsequent claims within the circuit involving the same issue. Those regulations reflected the agency's decision in 1985 to abandon its prior policy of applying circuit court holdings that we determined conflicted with our interpretation of the Act or regulations only to the named party or parties to the decision, rather than to other cases pending in the administrative review process involving the same issue or issues.

On July 2, 1996, we issued Social Security Ruling (SSR) 96–1p (61 FR 34470) clarifying and reaffirming the rules established in the 1990 regulations. Since that time, we have reviewed our rules and our implementing procedures to determine what changes could be instituted to further improve the acquiescence process. Based upon that review, on September 18, 1997, we published at 62 FR 48963, proposed revisions to the acquiescence regulations, which we are now publishing as final rules.

The proposed rules provided the addition of new paragraphs 404.985(b)(1) and 416.1485(b)(1) to establish a general goal for issuing ARs no later than 120 days from the date of our receipt of a precedential circuit court decision. The proposed rules also provided, by the addition of new paragraphs 404.985(b)(3) and 416.1485(b)(3), for new procedures to identify claims pending within SSA which may be affected by an AR that may subsequently be issued. These same sections also provided that, once an AR is issued, we will send notices to those individuals whose claims have been identified as potentially being affected by the AR informing them of their right to request a readjudication, as described in paragraphs 404.985(b)(2) and 416.1485(b)(2) of the rules.

The Final Rules

The Role of Litigation in the Policymaking Process

Our review indicated that it is important to reaffirm the principle that our goal in administering our programs is to have uniform, national program standards. Our procedures, which provide for acquiescence within the circuit when a circuit court issues a precedential decision containing a holding that we determine conflicts with our interpretation of the Act or regulations, result in differing rules in different sections of the country. This situation is not desirable and ordinarily should not, if possible, continue indefinitely.

Therefore, we wish to make it clear that generally ARs are temporary measures. When we receive a precedential circuit court decision containing a holding that we determine conflicts with our interpretation of the Act or regulations, we consider whether the rules at issue should be changed on a nationwide basis to conform to the court's holding. If we continue to believe that our interpretation of the statute or regulations at issue is correct and we seek further judicial review of the circuit court's decision, we will stay further development of the AR until the judicial review process runs its course. If our assessment shows that we should change our rules and adopt a circuit court's holding nationwide, we will, at the time we publish the AR, have determined the steps necessary to do so. This may require changing our regulations or rulings; it may also require seeking a clarifying legislative change to the Act. We would then proceed to issue an AR because changing our nationwide rules through legislation or rulemaking may require a significant period of time.

Similarly, if our assessment shows that our rules represent a reasonable interpretation of the Act or regulations, but we are unable to resolve the matter by seeking further judicial review, we will issue an AR and at the time we publish the AR have determined the appropriate steps to attempt to address the issue which was the subject of the circuit court's holding. This may mean issuing clarifying regulations or seeking legislation. There are certain instances when an issue cannot be resolved, such as a constitutional issue which the Supreme Court chooses not to review or legislation is required but not enacted and, therefore, an AR may remain in effect.

Although our goal to have uniform national standards is implicit in the current regulations, we are including in this preamble an explicit statement of our commitment to maintaining a uniform nationwide system of rules. In addition to making minor editorial corrections to the current regulations, these rules amend the regulations in two substantive areas, as follow:

Establishing a Timeliness Goal for Issuing ARs

A common criticism regarding the acquiescence process has involved the length of time it has taken for us to prepare and issue an AR. As a result, we have reassessed our procedures and have decided to place in our regulations our goal to release an AR for publication in the **Federal Register** no later than 120 days from the time we receive a precedential circuit court decision for which the AR is being issued, unless further judicial review of that decision is pending. This timeframe will also not apply when publication of an AR requires such coordination with the Department of Justice and/or other Federal agencies that it becomes no longer feasible. We are adding new

paragraphs 404.985(b)(1) and 416.1485(b)(1) so that the public is fully informed of this new timeframe.

Identifying Pending Claims Which May Be Affected by an AR

When we published the 1990 acquiescence regulations, we noted that a number of commenters on the 1988 proposed regulations (53 FR 46628 (November 18, 1988)) urged that we take action to identify and list pending claims that might be affected by an AR. In the response to that comment, we stated at 55 FR at 1013:

> As a matter of operational necessity, some time will always elapse between the date of a court decision and the time that we could notify all adjudicators to begin listing cases which might be affected by its holding. Thus, a substantial number of cases would not be listed for later readjudication. The process which these comments suggest presumes instantaneous, comprehensive identification of all cases, which operationally we cannot accomplish. Therefore, despite the fact that requiring claimants to seek readjudication does require some action on their part, we have concluded that this is the most efficient and effective way to proceed and have not adopted these comments in the final regulations.

The basic facts noted in that response remain valid. Despite improved technology, it is still operationally impossible for us to identify all pending claims that might be affected by an AR. However, we have reassessed this situation and have now decided that it would be appropriate to identify pending claims that might be affected by an AR, as expeditiously as possible, even though we may not be able to identify all such claims.

Therefore, as described in paragraphs 404.985(b)(3) and 416.1485(b)(3), we are implementing the following procedures. As soon as possible after we receive a precedential circuit court decision that we find may contain a holding that conflicts with our interpretation of the Act or regulations, we will develop and provide our adjudicators with criteria that they will use to identify pending claims we are deciding within the relevant circuit that might be affected, if we subsequently determine that an AR is required. If an AR is subsequently released, a notice will be sent informing the claimants in these cases that might be affected by the AR that an AR has been issued that might affect the claim. The notice to the claimant will also explain the procedures for obtaining a readjudication of the claim under the AR. If we develop criteria and begin identifying claims, but subsequently determine that an AR is not required, the notices will not be sent.

We will notify adjudicators of the appropriate criteria to be used to identify claims no later than 10 days after we receive a circuit court decision that we determine may contain a holding which conflicts with our interpretation of the Act or regulations. Although we believe that the new procedure to identify pending claims within the relevant circuit that might be affected will greatly reduce the number of claimants who would have to learn of the issuance of the AR through the **Federal Register** publication of it or otherwise, the new procedure will likely not identify all individuals whose claims may be subject to the AR. For this reason, we have retained the readjudication procedure in paragraphs 404.985(b)(2) and 416.1485(b)(2) to ensure the protection of all claimants. Additionally, if a claimant or an adjudicator brings to our attention that a claim could potentially be affected by a circuit court decision that might become the subject of an AR, we will, if appropriate, identify that case pending a decision as to whether an AR is necessary in the circuit court decision in question.

These regulations do not apply to current and reopened claims governed by the court-approved settlement in *Stieberger* v. *Sullivan,* 801 F. Supp. 1079 (S.D. N.Y. 1992), to the extent that the regulations are inconsistent with the settlement.

Public Comments

These regulatory provisions were published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on September 18, 1997 (62 FR 48963). We provided the public a 60-day comment period. We received a total of five statements containing multiple comments in response to this NPRM, two from individuals who are attorney representatives of claimants and three from legal services organizations.

Comment: One commenter recommended that the 120-day timeframe for publishing an AR specified in the NPRM be reduced to coincide with the date of the issuance of the circuit court's mandate under Rule 41 of the Federal Rules of Appellate Procedure. The commenter stated that this would allow SSA at least 52 days to prepare and release an AR. Another commenter stated that an AR should be effective as of the date of the order of the circuit court for which the AR is being issued.

Response: We have not adopted these comments. By necessity, some time will always elapse between the date of a court decision and the date that we publish an AR for that decision, due to the practical impossibility of immediately taking all the steps necessary for implementing a circuit court decision. Because, as we note below, interpreting and applying a circuit court's holding may not be a simple matter, we have decided that 120 days from the date we receive the court's decision is the appropriate timeframe for us to thoroughly analyze the decision, determine that it contains a holding conflicting with our interpretation of the Act or regulations, and develop an AR to provide as specific a statement as possible explaining SSA's interpretation of the holding and how SSA will apply the holding when adjudicating claims within the applicable circuit. Therefore, ARs will generally continue to be effective as of the date of publication, and the readjudication procedures will continue to be available with respect to claims decided between the date of the court decision and publication of the AR. The new provision in the regulation for identifying pending claims potentially affected by the court's holding will further protect the rights of claimants whose claims are adjudicated during the period prior to the effective date of the AR. We relied on similar reasoning in not adopting a comment on the 1990 acquiescence regulations, 55 FR at 1016, which suggested that ARs should be effective as of the date of the circuit court decision.

Comment: One commenter stated that the regulations establishing the process for identifying claims affected by precedential circuit court holdings should provide a procedure for ''listing'' affected claims (including those decided beyond the 120-day timeframe if publication of an AR is delayed) and should provide our adjudicators with instructions for readjudicating these claims. The same commenter asked who would be responsible for identifying the affected claims and suggested that the regulations assign this responsibility to specific SSA personnel.

Response: The regulations establish a new process for identifying pending claims that may be affected by publication of an AR. We will begin to list identified claims no later than 10 days after the date the precedential circuit court decision is received by SSA. Identification criteria and instructions will be issued to all of our adjudicators in the circuit who will be responsible for deciding, in accordance with those criteria and instructions, whether a particular claim may be affected by the court's holding. We believe that adjudicators are best suited to identify these claims because ARs apply to all levels of adjudication, not

only to the ALJ and Appeals Council levels, unless a court holding by its nature applies to only certain levels of adjudication. If publication of an AR is delayed beyond the 120-day timeframe, the identification process will continue until the AR is issued. After an AR is published, additional instructions for each AR will be issued to all adjudicators in the circuit as needed.

Comment: One commenter stated that paragraph 404.985(b)(3) of the regulations should explicitly reflect the timeframe which was contained in the preamble to the NPRM that, within 10 days after SSA receives a circuit court decision for which it determines an AR may be required, SSA will provide instructions to adjudicators on the criteria for identifying pending claims that might be subject to readjudication if an AR is subsequently published for that court decision.

Response: Ordinarily we do not include operational processing time goals in regulations. However, because of our commitment to the timely publication of ARs, we have provided in these regulations that, in general, an AR will be released for publication in the **Federal Register** no later than 120 days from receipt of the court's decision. We believe the operational steps necessary for identifying pending claims are appropriately placed in the various detailed instructions that will be issued to adjudicators. Since the specific elements of the identification process are an operational matter, we have not placed it within the regulations. When we issue implementing instructions, they will contain the operational details necessary for us to inform adjudicators and others in the claims process of the appropriate criteria to be used to identify claims no later than 10 days after we receive a circuit court decision that we determine may contain a holding which conflicts with our interpretation of the Act or regulations.

Comment: One individual suggested that any process that does not provide for notice to all claimants, including claimants who received determinations between the date of the circuit court decision and the date we start identifying claimants who could potentially be affected by an AR (generally 10 days after our receipt of the circuit court decision), is ''wholly inadequate.''

Response: As we pointed out in the NPRM, we recognize that the new procedure may not identify all individuals who could be affected by an AR. Consequently, we have retained the readjudication procedures in paragraphs 404.985(b)(2) and 416.1485(b)(2) to ensure the protection of all claimants. We expect that, generally, very few claims that could potentially be affected by an AR will be adjudicated during the relatively short period before we begin to identify claimants. However, claimants can bring to our attention and adjudicators can identify such claims during this period. While the procedures contained in our regulations require some action on the claimant's part, we have concluded that, from an operational standpoint, we cannot always accomplish instantaneous, comprehensive identification of all claims. We believe the new procedure represents the best balance we can strike between service to claimants and operational limitations.

Comment: Two commenters suggested that we publish our decision not to issue an AR for a circuit court holding that we determine does not conflict with our interpretation of the Act or regulations. One of these commenters also suggested that we should publish a notice in the **Federal Register** whenever we are unable to meet the 120-day timeframe for publishing an AR.

Response: We have not adopted these comments. We review approximately 600 circuit court decisions each year to determine whether an AR is required. We believe that publishing notices in the **Federal Register** for each of these decisions is an inefficient and costly way to inform the public and the courts about our conclusions with respect to acquiescence. We also do not believe it would be efficient to require SSA to publish a notice whenever issuance of an AR is delayed beyond the 120-day timeframe. We believe that we will provide the highest quality service to the public by focusing our limited resources on publishing ARs within the 120-day timeframe specified in these regulations and on notifying individual claimants identified under the procedure in paragraphs 404.985(b)(3) and 416.1485(b)(3) about circuit court decisions that may affect their claims.

Comment: One commenter suggested that the regulations should not limit readjudications under an AR to the particular issue addressed by the AR but instead should allow de novo review of the entire claim.

Response: Claims pending administrative review will receive de novo review when adjudicated under an AR. Under the 1990 acquiescence regulations, which we have not changed in this regard, other claims in which administrative appeal rights have lapsed are readjudicated based upon a consideration of the issues covered by the AR. To the extent that those issues covered by the AR affect other issues in the claim, those other issues will also be addressed as part of the readjudication. However, we do not believe that the Act requires us to automatically afford lapsed claims being readjudicated the opportunity for de novo review.

Comment: One commenter suggested that the regulations should permit full appeal rights as to a finding that a claim is not subject to readjudication under an AR.

Response: This question was addressed in the preamble to the 1990 acquiescence regulations, 55 FR at 1014. We do not believe that permitting further review on the question of whether or not an AR applies to a pending claim is appropriate. Once we conclude that readjudication is not necessary, the next step should be an appeal on the substantive merits of the claim itself, not the readjudication question. When a decision is reached on appeal concerning the substantive issue(s), the readjudication issue will be resolved. In cases where a person did not appeal timely and subsequently becomes aware of an AR that may apply to his or her claim, the readjudication procedure is available. Also, claimants may request to have their lapsed claims reopened and we may do so if the grounds for reopening are met.

We continue to believe that the combination of appeal, readjudication, and reopening provides a fair process that protects the rights of claimants.

Comment: One commenter expressed the view that paragraph 404.985(b)(2) should not require claimants to identify the appropriate AR when seeking readjudication. The commenter suggests that a claimant should be allowed to seek readjudication by identifying the appropriate circuit court decision, without also identifying the AR.

Response: We have adopted this comment and modified the new paragraphs under 404.985(b)(2) and 416.1485(b)(2) to specify that the claimant may request application of the AR to his or her case by either citing the AR or, in the alternative, by specifying the holding or portion of a circuit court decision which could change the prior determination in their case. It should be noted, however, that the 1990 regulations provided under paragraphs 404.985(b) and 416.1485(b) that one way a claimant may obtain a readjudication was by submitting a statement which cited the AR; the regulations did not state that this was, and we did not intend this to be, an absolute requirement for obtaining readjudication.

Regulation paragraphs 404.985(b)(3) and 416.1485(b)(3) provide for the identification by SSA of pending claims which might be affected by the issuance

of an AR. When an AR is published, we will send individual notices for those claims. In addition, as stated in the preamble to the NPRM, a claimant or an adjudicator may bring to our attention a claim that could be potentially affected by a circuit court decision and we will, if appropriate, identify that claim pending our decision as to whether an AR is necessary for the circuit court decision in question.

Comment: One individual observed that the regulations result in the application of differing rules in different sections of the country, which is not desirable, and the regulations can cause the differing rules to continue indefinitely without restoring national uniformity. The commenter suggested that we establish a formal process to oversee litigation and to make changes in national rules whenever a district or circuit court decision conflicted with our rules.

Response: As discussed in the preamble to the 1990 acquiescence regulations, 55 FR at 1012–1013, a number of studies on the subject of Federal acquiescence have noted that nationwide adoption of the decision of the first circuit court to address an issue (intercircuit acquiescence) would preclude other circuit courts from considering the issue. In 1984, when Congress considered legislation that would have required SSA to acquiesce in circuit court decisions, the Solicitor General of the United States expressed similar concerns, stating that the practical effect of that legislation would be to require the Department of Justice to consider seeking Supreme Court review of the first adverse decision on an issue by any court of appeals. The Department of Justice reiterated these concerns in 1997 when Congress was again considering legislation to address the issue of acquiescence by Federal agencies.

An approach that would require nationwide adoption of the first circuit court decision on a particular issue would not improve SSA's adjudicatory and policy making processes, but would instead result in the first circuit that happened to rule on an issue setting SSA's national rules on that subject. In effect, the circuit court that would rule first would rule last. This result could hardly be intended by any reasonable interpretation of acquiescence and would undermine the advantages, which have been recognized by the Supreme Court, of having issues considered by more than one circuit court.

Moreover, we acquiesce only in the holdings of Federal circuit courts and not in holdings of Federal district courts within a circuit. See SSR 96–1p (61 FR 34470). This is consistent with the well-recognized principle that one district court's decision does not constitute binding precedent applicable to other claims arising within that district. There is no such thing as the ''law of the district.'' Indeed, even within the same district, one judge may disagree with the holding in a decision by another judge. Thus, despite a district court holding in a decision that may conflict with our interpretation of the Act or regulations, we will continue to apply our nationwide rules when adjudicating claims within that district court's jurisdiction unless the court directs otherwise such as may occur in a class action.

Comment: Several commenters expressed the opinion that we have not fully implemented our existing acquiescence policy because, in reviewing circuit court holdings to determine whether they conflict with our rules, we read the holdings too narrowly and, thus, incorrectly decide that an AR is not necessary. The commenters suggested that this was caused by a lack of specific standards for determining when a circuit court holding conflicts with our rules. One commenter said that it was inappropriate for us to interpret circuit court holdings and that we should be limited to merely implementing the ''policy directive'' stated by the court.

Response: We review every circuit court decision to determine whether a circuit court's holding conflicts with our interpretation of the Act or regulations. Since our acquiescence policy became effective in 1985, we have published 68 ARs. There has been a dramatic decline in litigation based on allegations that we have refused to acquiesce in specific circuit court decisions since the adoption of the 1990 acquiescence regulations.

As discussed in the preamble to the 1990 acquiescence regulations, 55 FR at 1012, the vast majority of adverse circuit court decisions do not conflict with our interpretation of the Act and regulations; they are based either on the issue of whether substantial evidence supports SSA's final administrative decision or on the issue of whether the final administrative decision adheres to established agency rules. A court holding based on the adjudicator's failure to follow established rules does not conflict with the rules themselves. Identifying the holding of a particular circuit court decision and determining whether or not the holding conflicts with our interpretation of the Act and regulations are not always clear or simple matters, and this may account for the concern expressed by these commenters about how we implement acquiescence policy.

Establishing specific standards for evaluating whether a court holding conflicts with our interpretation of the Act and regulations would be impractical because of the diversity and complexities both of the programs and policies we administer and of the court decisions concerning these programs and policies. For example, the policies and issues considered in adjudicating disability claims usually involve technical medical and vocational concepts, which are very different from the benefit computation and family relationship questions frequently considered in retirement and survivors claims. Because explaining how we will apply the circuit court holding within the circuit is also not a clear and simple matter, we do not believe that a standard for analyzing all circuit court holdings would be feasible. Consequently, we have declined to adopt this comment.

By statute, establishing rules and procedures governing SSA's programs is the responsibility of the Commissioner of Social Security. Furthermore, court decisions generally resolve individual claims and neither address similar circumstances, nor are written in a way that necessarily instructs our adjudicators how to apply the courts' holdings to other claims. We believe that to ensure uniform and consistent adjudication procedures necessary for the administration of a national program, SSA must analyze and interpret circuit court holdings that we determine conflict with SSA's nationwide rules to provide our adjudicators as specific a statement as possible of how to apply the holding in the course of adjudicating other claims.

If a person believes that we have overlooked or misconstrued a holding in a court of appeals decision, that person may bring this matter to our attention and we will respond appropriately.

Comment: Two commenters suggested that SSA should amend the current acquiescence regulations to direct adjudicators to follow circuit court precedent whether or not an AR has been issued. It was also suggested that SSR 96–1p, which sets forth a different policy from that suggested by the commenters, be withdrawn immediately.

Response: Both the preamble to the 1990 acquiescence regulations, 55 FR at 1013, and SSR 96–1p, published on July 2, 1996, explain the basis for our longstanding policy that SSA adjudicators are to follow SSA's nationwide rules until the

Commissioner determines that a circuit court holding is in conflict with our national rules and publishes an AR instructing adjudicators on how the decision is to be followed within the applicable circuit. Circuit court decisions generally resolve individual claims and are not necessarily written in a way that instructs our adjudicators on how to consistently apply the courts' holdings to other claims, particularly when the numerous possible situations to which they may apply are considered. The meaning and scope of a court holding are not always clear and can be subject to disparate interpretations.

If each of SSA's over 15,000 adjudicators were permitted to apply his or her own interpretation of a circuit court decision in resolving these difficult questions, rather than relying on guidance from the Commissioner in the form of an AR, it could result in conflicting standards being used by decisionmakers, even within the same circuit. Furthermore, the Commissioner has the responsibility by statute to administer the Social Security programs and establish the agency's rules and procedures. If the Commissioner abdicated that responsibility by allowing individual adjudicators to decide claims according to his or her individual interpretation of the law, it would be impossible for the Commissioner to carry out his responsibility to administer the Social Security programs in an effective and efficient manner on a nationwide basis, and to ensure consistent and uniform application of SSA's rules. Indeed, some adjudicators might apply the circuit court's decision in ways less favorable to claimants than the court intended. Furthermore, it would not necessarily be apparent what standard was applied by an individual adjudicator; therefore, unlike the standards established by the Commissioner in an AR, the interpretation of a circuit court decision by an individual adjudicator might not be readily susceptible to judicial scrutiny.

In addition, adjudicators at the initial and reconsideration levels of review generally do not have any legal training in interpreting and applying circuit court decisions. If authority to apply circuit court decisions in the absence of an AR was extended only to ALJs and the Appeals Council, it would further undermine uniformity in decisionmaking by creating different standards of adjudication at different levels of administrative review.

For all these reasons, we continue to believe that the AR is the fairest and most effective method to achieve uniform acquiescence in circuit court holdings that conflict with SSA's nationwide rules. This approach is consistent with the longstanding legal principle that it is the responsibility of the Commissioner, not individual adjudicators, to establish SSA's rules and policies (including how to apply a circuit court holding which conflicts with SSA's nationwide rules). Any erosion of this legal principle would represent a radical change in the Federal administrative structure, and would undermine a Federal department or agency head's accountability for the administration of the agency's programs. Therefore, it is the role and responsibility of individual adjudicators to decide claims by applying the rules and policies established by the Commissioner to the facts of an individual case.

Comment: One individual suggested that we clarify our longstanding regulatory language setting forth SSA's authority to rescind an AR when we subsequently publish a new regulation addressing an issue not previously included in our regulations.

Response: This provision has been in the regulations since 1990 and courts have not found that it has been misapplied. We do not believe there is a need for a clarifying amendment to this particular provision at this time.

Comment: One commenter questioned the legality of relitigating in the same circuit an issue addressed by an AR. Another questioned whether the regulations permit SSA to relitigate an issue within the same circuit after publication of an AR if we later publish a nationwide regulation reaffirming our original position on the issue.

Response: These final rules make no changes in our relitigation policies and procedures which were set forth in the 1990 acquiescence regulations. We do not believe that a Federal agency is legally precluded from relitigating an issue within a circuit that has previously issued a ruling adverse to the Government's position. When we published the 1990 acquiescence regulations, we discussed some of the authorities supporting our position on relitigation and stated that we would not use relitigation as a primary means for resolving conflicts in statutory and regulatory interpretation. To date, we have never used the relitigation procedures outlined in the 1990 regulations. Those regulations state that if we do decide to relitigate an issue, we will publish a notice of our intention in the **Federal Register** and also provide a notice explaining our action to all affected claimants.

As discussed in the preamble to the 1990 acquiescence regulations, 55 FR at 1015, when we determine that a circuit court holding conflicts with our interpretation of the Act and regulations, we generally expect to resolve the conflict by actively pursuing our right to seek further judicial review, revisiting the same issue in related litigation, clarifying our regulations, or seeking statutory amendments. The regulations outline a process for relitigating a court's holding within the same circuit after publication of an AR, which requires certain specific activating events. Publication of a regulation, by itself, is not an activating event for relitigation.

Based on our analysis of the comments, and for the reasons set forth above, we are publishing the proposed rules as final rules with the changes to paragraphs 404.985(b)(2) and 416.1485(b)(2) discussed above. We have also made minor editorial and technical changes for clarification and consistency.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these 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 regulations will not have a significant economic impact on a substantial number of small entities because these rules affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These regulations contain information collection requirements in paragraphs 404.985(b) and 416.1485(b). We have received approval for these requirements from OMB under OMB No. 0960–0581 which expires November 30, 2000.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.003, Social Security-Special Benefits for Persons Aged 72 and Over; 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: April 27, 1998.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons set out in the preamble, subpart J of part 404 and subpart N of part 416 of chapter III of title 20 of the Code of Federal Regulations are amended as set forth below:

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

20 CFR part 404, subpart J, is amended as follows:

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

Authority: Secs. 201(j), 205(a), (b), (d)–(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 405(a), (b), (d)–(h), and (j), 421, 425, and 902(a)(5)); 31 U.S.C. 3720A; sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note).

2. Section 404.985 is revised to read as follows:

§ 404.985 Application of circuit court law.

The procedures which follow apply to administrative determinations or decisions on claims involving the application of circuit court law.

(a) *General.* We will apply a holding in a United States Court of Appeals decision that we determine conflicts with our interpretation of a provision of the Social Security Act or regulations unless the Government seeks further judicial review of that decision or we relitigate the issue presented in the decision in accordance with paragraphs (c) and (d) of this section. We will apply the holding to claims at all levels of the administrative review process within the applicable circuit unless the holding, by its nature, applies only at certain levels of adjudication.

(b) *Issuance of an Acquiescence Ruling.* When we determine that a United States Court of Appeals holding conflicts with our interpretation of a provision of the Social Security Act or regulations and the Government does not seek further judicial review or is unsuccessful on further review, we will issue a Social Security Acquiescence Ruling. The Acquiescence Ruling will describe the administrative case and the court decision, identify the issue(s) involved, and explain how we will apply the holding, including, as necessary, how the holding relates to other decisions within the applicable circuit. These Acquiescence Rulings will generally be effective on the date of their publication in the **Federal Register** and will apply to all determinations and decisions made on or after that date unless an Acquiescence Ruling is rescinded as stated in paragraph (e) of this section. The process we will use when issuing an Acquiescence Ruling follows:

(1) We will release an Acquiescence Ruling for publication in the **Federal Register** for any precedential circuit court decision that we determine contains a holding that conflicts with our interpretation of a provision of the Social Security Act or regulations no later than 120 days from the receipt of the court's decision. This timeframe will not apply when we decide to seek further judicial review of the circuit court decision or when coordination with the Department of Justice and/or other Federal agencies makes this timeframe no longer feasible.

(2) If we make a determination or decision on your claim between the date of a circuit court decision and the date we publish an Acquiescence Ruling, you may request application of the published Acquiescence Ruling to the prior determination or decision. You must demonstrate that application of the Acquiescence Ruling could change the prior determination or decision in your case. You may demonstrate this by submitting a statement that cites the Acquiescence Ruling or the holding or portion of a circuit court decision which could change the prior determination or decision in your case. If you can so demonstrate, we will readjudicate the claim in accordance with the Acquiescence Ruling at the level at which it was last adjudicated. Any readjudication will be limited to consideration of the issue(s) covered by the Acquiescence Ruling and any new determination or decision on readjudication will be subject to administrative and judicial review in accordance with this subpart. Our denial of a request for readjudication will not be subject to further administrative or judicial review. If you file a request for readjudication within the 60-day appeal period and we deny that request, we shall extend the time to file an appeal on the merits of the claim to 60 days after the date that we deny the request for readjudication.

(3) After we receive a precedential circuit court decision and determine that an Acquiescence Ruling may be required, we will begin to identify those claims that are pending before us within the circuit and that might be subject to readjudication if an Acquiescence Ruling is subsequently issued. When an Acquiescence Ruling is published, we will send a notice to those individuals whose cases we have identified which may be affected by the Acquiescence Ruling. The notice will provide information about the Acquiescence Ruling and the right to request readjudication under that Acquiescence Ruling, as described in paragraph (b)(2) of this section. It is not necessary for an individual to receive a notice in order to request application of an Acquiescence Ruling to his or her claim, as described in paragraph (b)(2) of this section.

(c) *Relitigation of court's holding after publication of an Acquiescence Ruling.* After we have published an Acquiescence Ruling to reflect a holding of a United States Court of Appeals on an issue, we may decide under certain conditions to relitigate that issue within the same circuit. We may relitigate only when the conditions specified in paragraphs (c)(2) and (3) of this section are met, and, in general, one of the events specified in paragraph (c)(1) of this section occurs.

(1) Activating events:

(i) An action by both Houses of Congress indicates that a circuit court decision on which an Acquiescence Ruling was based was decided inconsistently with congressional intent, such as may be expressed in a joint resolution, an appropriations restriction, or enactment of legislation which affects a closely analogous body of law;

(ii) A statement in a majority opinion of the same circuit indicates that the court might no longer follow its previous decision if a particular issue were presented again;

(iii) Subsequent circuit court precedent in other circuits supports our interpretation of the Social Security Act or regulations on the issue(s) in question; or

(iv) A subsequent Supreme Court decision presents a reasonable legal basis for questioning a circuit court holding upon which we base an Acquiescence Ruling.

(2) The General Counsel of the Social Security Administration, after consulting with the Department of Justice, concurs that relitigation of an issue and application of our interpretation of the Social Security Act or regulations to selected claims in the

administrative review process within the circuit would be appropriate.

(3) We publish a notice in the **Federal Register** that we intend to relitigate an Acquiescence Ruling issue and that we will apply our interpretation of the Social Security Act or regulations within the circuit to claims in the administrative review process selected for relitigation. The notice will explain why we made this decision.

(d) *Notice of relitigation.* When we decide to relitigate an issue, we will provide a notice explaining our action to all affected claimants. In adjudicating claims subject to relitigation, decisionmakers throughout the SSA administrative review process will apply our interpretation of the Social Security Act and regulations, but will also state in written determinations or decisions how the claims would have been decided under the circuit standard. Claims not subject to relitigation will continue to be decided under the Acquiescence Ruling in accordance with the circuit standard. So that affected claimants can be readily identified and any subsequent decision of the circuit court or the Supreme Court can be implemented quickly and efficiently, we will maintain a listing of all claimants who receive this notice and will provide them with the relief ordered by the court.

(e) *Rescission of an Acquiescence Ruling.* We will rescind as obsolete an Acquiescence Ruling and apply our interpretation of the Social Security Act or regulations by publishing a notice in the **Federal Register** when any of the following events occurs:

(1) The Supreme Court overrules or limits a circuit court holding that was the basis of an Acquiescence Ruling;

(2) A circuit court overrules or limits itself on an issue that was the basis of an Acquiescence Ruling;

(3) A Federal law is enacted that removes the basis for the holding in a decision of a circuit court that was the subject of an Acquiescence Ruling; or

(4) We subsequently clarify, modify or revoke the regulation or ruling that was the subject of a circuit court holding that we determined conflicts with our interpretation of the Social Security Act or regulations, or we subsequently publish a new regulation(s) addressing an issue(s) not previously included in our regulations when that issue(s) was the subject of a circuit court holding that conflicted with our interpretation of the Social Security Act or regulations and that holding was not compelled by the statute or Constitution.

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

20 CFR part 416, subpart N, is amended as follows:

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

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b).

2. Section 416.1485 is revised to read as follows:

§ 416.1485 Application of circuit court law.

The procedures which follow apply to administrative determinations or decisions on claims involving the application of circuit court law.

(a) *General.* We will apply a holding in a United States Court of Appeals decision that we determine conflicts with our interpretation of a provision of the Social Security Act or regulations unless the Government seeks further judicial review of that decision or we relitigate the issue presented in the decision in accordance with paragraphs (c) and (d) of this section. We will apply the holding to claims at all levels of the administrative review process within the applicable circuit unless the holding, by its nature, applies only at certain levels of adjudication.

(b) *Issuance of an Acquiescence Ruling.* When we determine that a United States Court of Appeals holding conflicts with our interpretation of a provision of the Social Security Act or regulations and the Government does not seek further judicial review or is unsuccessful on further review, we will issue a Social Security Acquiescence Ruling. The Acquiescence Ruling will describe the administrative case and the court decision, identify the issue(s) involved, and explain how we will apply the holding, including, as necessary, how the holding relates to other decisions within the applicable circuit. These Acquiescence Rulings will generally be effective on the date of their publication in the **Federal Register** and will apply to all determinations, redeterminations, and decisions made on or after that date unless an Acquiescence Ruling is rescinded as stated in paragraph (e) of this section. The process we will use when issuing an Acquiescence Ruling follows:

(1) We will release an Acquiescence Ruling for publication in the **Federal Register** for any precedential circuit court decision that we determine contains a holding that conflicts with our interpretation of a provision of the Social Security Act or regulations no later than 120 days from the receipt of the court's decision. This timeframe will not apply when we decide to seek further judicial review of the circuit court decision or when coordination with the Department of Justice and/or other Federal agencies makes this timeframe no longer feasible.

(2) If we make a determination or decision on your claim between the date of a circuit court decision and the date we publish an Acquiescence Ruling, you may request application of the published Acquiescence Ruling to the prior determination or decision. You must demonstrate that application of the Acquiescence Ruling could change the prior determination or decision in your case. You may demonstrate this by submitting a statement that cites the Acquiescence Ruling or the holding or portion of a circuit court decision which could change the prior determination or decision in your case. If you can so demonstrate, we will readjudicate the claim in accordance with the Acquiescence Ruling at the level at which it was last adjudicated. Any readjudication will be limited to consideration of the issue(s) covered by the Acquiescence Ruling and any new determination or decision on readjudication will be subject to administrative and judicial review in accordance with this subpart. Our denial of a request for readjudication will not be subject to further administrative or judicial review. If you file a request for readjudication within the 60-day appeal period and we deny that request, we shall extend the time to file an appeal on the merits of the claim to 60 days after the date that we deny the request for readjudication.

(3) After we receive a precedential circuit court decision and determine that an Acquiescence Ruling may be required, we will begin to identify those claims that are pending before us within the circuit and that might be subject to readjudication if an Acquiescence Ruling is subsequently issued. When an Acquiescence Ruling is published, we will send a notice to those individuals whose cases we have identified which may be affected by the Acquiescence Ruling. The notice will provide information about the Acquiescence Ruling and the right to request readjudication under that Acquiescence Ruling, as described in paragraph (b)(2) of this section. It is not necessary for an individual to receive a notice in order to request application of an Acquiescence Ruling to his or her claim, as described in paragraph (b)(2) of this section.

(c) *Relitigation of court's holding after publication of an Acquiescence Ruling.* After we have published an Acquiescence Ruling to reflect a holding

of a United States Court of Appeals on an issue, we may decide under certain conditions to relitigate that issue within the same circuit. We may relitigate only when the conditions specified in paragraphs (c)(2) and (3) of this section are met, and, in general, one of the events specified in paragraph (c)(1) of this section occurs.

(1) Activating events:

(i) An action by both Houses of Congress indicates that a circuit court decision on which an Acquiescence Ruling was based was decided inconsistently with congressional intent, such as may be expressed in a joint resolution, an appropriations restriction, or enactment of legislation which affects a closely analogous body of law;

(ii) A statement in a majority opinion of the same circuit indicates that the court might no longer follow its previous decision if a particular issue were presented again;

(iii) Subsequent circuit court precedent in other circuits supports our interpretation of the Social Security Act or regulations on the issue(s) in question; or

(iv) A subsequent Supreme Court decision presents a reasonable legal basis for questioning a circuit court holding upon which we base an Acquiescence Ruling.

(2) The General Counsel of the Social Security Administration, after consulting with the Department of Justice, concurs that relitigation of an issue and application of our interpretation of the Social Security Act or regulations to selected claims in the administrative review process within the circuit would be appropriate.

(3) We publish a notice in the **Federal Register** that we intend to relitigate an Acquiescence Ruling issue and that we will apply our interpretation of the Social Security Act or regulations within the circuit to claims in the administrative review process selected for relitigation. The notice will explain why we made this decision.

(d) *Notice of relitigation.* When we decide to relitigate an issue, we will provide a notice explaining our action to all affected claimants. In adjudicating claims subject to relitigation, decisionmakers throughout the SSA administrative review process will apply our interpretation of the Social Security Act and regulations, but will also state in written determinations or decisions how the claims would have been decided under the circuit standard. Claims not subject to relitigation will continue to be decided under the Acquiescence Ruling in accordance with the circuit standard. So that affected claimants can be readily identified and any subsequent decision of the circuit court or the Supreme Court can be implemented quickly and efficiently, we will maintain a listing of all claimants who receive this notice and will provide them with the relief ordered by the court.

(e) *Rescission of an Acquiescence Ruling.* We will rescind as obsolete an Acquiescence Ruling and apply our interpretation of the Social Security Act or regulations by publishing a notice in the **Federal Register** when any of the following events occurs:

(1) The Supreme Court overrules or limits a circuit court holding that was the basis of an Acquiescence Ruling;

(2) A circuit court overrules or limits itself on an issue that was the basis of an Acquiescence Ruling;

(3) A Federal law is enacted that removes the basis for the holding in a decision of a circuit court that was the subject of an Acquiescence Ruling; or

(4) We subsequently clarify, modify or revoke the regulation or ruling that was the subject of a circuit court holding that we determined conflicts with our interpretation of the Social Security Act or regulations, or we subsequently publish a new regulation(s) addressing an issue(s) not previously included in our regulations when that issue(s) was the subject of a circuit court holding that conflicted with our interpretation of the Social Security Act or regulations and that holding was not compelled by the statute or Constitution.

[FR Doc. 98–11945 Filed 5–5–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0119]

21 CFR Part 801

Natural Rubber-Containing Medical Devices; User Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; interpretation.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it does not intend to apply to combination products currently regulated under human drug or biologic labeling provisions its September 30, 1997, final rule requiring certain labeling statements for all medical devices that contain or have packaging that contains natural rubber that contacts humans. FDA is taking this action, in part, in response to a citizen petition and other communications from industry that the agency has received since the publication of the final rule. FDA intends to initiate a proceeding to propose natural rubber labeling requirements for drugs and biologics, including combination products that are currently regulated under drug and biologic labeling provisions. Such a proceeding may include a combination of rulemaking and guidance and will offer opportunity for public comment.

EFFECTIVE DATE: September 30, 1998.

FOR FURTHER INFORMATION CONTACT:

Brian L. Pendleton, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5649; or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0737.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 30, 1997 (62 FR 51021), FDA published a final rule to be codified at 21 CFR 801.437 requiring certain labeling statements on medical devices that contain or have packaging that contains natural rubber that contacts humans. The labeling statements alert users that a product contains either dry natural rubber or natural rubber latex, and for products containing natural rubber latex that the presence of this material may cause allergic reactions. The final rule, which becomes effective September 30, 1998, was adopted because natural rubber may cause a significant health risk to persons who are sensitized to natural latex proteins.

In response to a comment on the proposed latex labeling regulation (61 FR 32618, June 24, 1996) about the applicability of the requirements to combination products, FDA stated in the preamble to the final rule that it intended to require combination products (i.e., drug/device and biologic/device combinations) that contain natural rubber device components to be labeled in accordance with § 801.437 (62 FR 51021 at 51026). Because the entities that comprise a combination product meet more than one jurisdictional definition, the agency may apply one or more sets of regulatory provisions to such products, as specified in the Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health and the Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and