

(ii) Subsequent Violation/Subsections (a)(1)–(3), from \$60,000 to \$60,000

(iii) Violation/Subsections (a)(4)–(5), from \$6,000 to \$5,500.

(iv) Subsequent Violation/Subsections (a)(4)–(5), from \$6,000 to \$5,500.

(v) Violation/Subsection (a)(6), from \$120,000 to \$120,000.

(8) 16 U.S.C. 973f(a), South Pacific Tuna Act of 1988, from \$300,000 to \$300,000.

(9) 16 U.S.C. 1174(b), Fur Seal Act Amendments of 1983, from \$11,000 to \$11,000.

(10) 16 U.S.C. 1375(a)(1), Marine Mammal Protection Act of 1972 (1981), from \$12,000 to \$11,000.

(11) 16 U.S.C. 1385(e), Dolphin Protection Consumer Information Act (1990), from \$110,000 to \$110,000.

(12) 16 U.S.C. 1437(d)(1), National Marine Sanctuaries Act (1992), from \$119,000 to \$120,000.

(13) 16 U.S.C. 1540(a)(1), Endangered Species Act of 1973;

(i) Knowing Violations of Section 1538 (1988), from \$30,000 to \$27,500.

(ii) Other Knowing Violations (1988), from \$14,000 to \$13,200.

(iii) Otherwise Violations (1978), from \$600 to \$550.

(14) 16 U.S.C. 1858(a), Magnuson-Stevens Fishery Conservation and Management Act (1990), from \$120,000 to \$120,000.

(15) 16 U.S.C. 2437(a)(1), Antarctic Marine Living Resources Convention Act of 1984;

(i) Knowing Violation, from \$12,000 to \$11,000.

(ii) Violation, from \$6,000 to \$5,500.

(16) 16 U.S.C. 2465(a), Antarctic Protection Act of 1990;

(i) Knowing Violation, from \$11,000 to \$11,000.

(ii) Violation, from \$5,500 to \$5,500.

(17) 16 U.S.C. 3373(a), Lacey Act Amendments of 1981

(i) Sale and Purchase Violation, from \$12,000 to \$11,000.

(ii) Marking Violation, from \$300 to \$275.

(iii) False Labeling Violation, from \$12,000 to \$11,000.

(iv) Other than Marking Violation, from \$12,000 to \$11,000.

(18) 16 U.S.C. 3606(b)(1), Atlantic Salmon Convention Act of 1982 (1990), from \$120,000 to \$120,000.

(19) 16 U.S.C. 3637(b), Pacific Salmon Treaty Act of 1985 (1990), from \$120,000 to \$120,000.

(20) 16 U.S.C. 4016(b)(1)(B), Fish and Seafood Promotion Act of 1986, from \$5,500 to \$5,500.

(21) 16 U.S.C. 5010(a)(1), North Pacific Anadromous Stocks Act of 1992, from \$110,000 to \$110,000.

(22) 16 U.S.C. 5103(b)(2), Atlantic Coastal Fisheries Cooperative

Management Act (1993), from \$110,000 to \$120,000.

(23) 16 U.S.C. 5154(c)(1), Atlantic Striped Bass Conservation Act (1990), from \$120,000 to \$120,000.

(24) 16 U.S.C. 5507(a)(1), High Seas Fishing Compliance Act of 1995, from \$109,000 to \$110,000.

(25) 16 U.S.C. 5606(b), Northwest Atlantic Fisheries Convention Act of 1995, from \$109,000 to \$120,000.

(26) 22 U.S.C. 1978(e), Fishermen's Protective Act of 1967 (1971);

(i) Violation, from \$11,000 to \$11,000.

(ii) Subsequent Violation, from \$27,500 to \$27,500.

(27) 30 U.S.C. 1462(a), Deep Seabed Hard Mineral Resources Act (1980), from \$30,000 to \$27,500.

(28) 42 U.S.C. 9152(c)(1), Ocean Thermal Energy Conversion Act of 1980, from \$30,000 to \$27,500.

■ 3. Section 6.5 is revised to read as follows:

§ 6.5 Effective date of adjustments.

The adjustments made by Sec. 6.4 of this part, of the penalties there specified, are effective on December 11, 2003, and said penalties, as thus adjusted by the adjustments made by Sec. 6.4 of this part, shall apply only to violations occurring after December 11, 2003, and before the effective date of any future inflation adjustment thereto made subsequent to December 11, 2003 as provided in Sec. 6.6 of this part.

[FR Doc. 03–30621 Filed 12–10–03; 8:45 am]

BILLING CODE 3510–17–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Regulation Nos. 4 and 16]

RIN 0960–AE97

Federal Old-Age, Survivors and Disability Insurance and Supplemental Security Income for the Aged, Blind, and Disabled; Administrative Review Process; Video Teleconferencing Appearances Before Administrative Law Judges of the Social Security Administration

AGENCY: Social Security Administration (SSA).

ACTION: Final rule.

SUMMARY: We are adopting without change the final rules that were published in the **Federal Register** on February 3, 2003, at 68 FR 5210, authorizing us to conduct hearings before administrative law judges (ALJs) using video teleconferencing (VTC). The revised rules authorized us to conduct hearings before ALJs at which a party or

parties to the hearing and/or a witness or witnesses may appear before the ALJ by VTC. The revised rules also provided that if we schedule you to appear at your hearing by VTC, rather than in person, and you object to use of the VTC procedure, we will reschedule your hearing as one at which you may appear in person before the ALJ. Under the revised rules, the ALJ will also consider any objection you may have to the appearance of a witness by VTC. The purpose of the rules is to provide us with greater flexibility in scheduling and holding hearings, improve hearing process efficiency, and extend another service delivery option to individuals requesting a hearing.

DATES: These rules were effective March 5, 2003.

FOR FURTHER INFORMATION CONTACT:

Robert J. Augustine, Social Insurance Specialist, Office of Regulations, Social Security Administration, 100 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–0020 or TTY 1–800–966–5906, for information about this notice. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at <http://www.socialsecurity.gov>.

Electronic Version

The electronic file of this document is available on the Internet at <http://www.gpoaccess.gov/fr/index.html>. It is also available on the Internet site for SSA (i.e., Social Security Online) at <http://policy.ssa.gov/pnpublic.nsf/LawRegs>.

SUPPLEMENTARY INFORMATION:

Background

On January 5, 2001, at 66 FR 1059, we published a Notice of Proposed Rulemaking (NPRM) in which we proposed to authorize our use of VTC in conducting hearings before ALJs. One provision in the proposed rules would have given claimants the right to veto use of VTC to take both their own testimony and the testimony of vocational experts (VEs) and medical experts (MEs). On February 3, 2003, after considering the public comments received on the NPRM, we published the final rules at 68 FR 5210 authorizing our use of VTC effective March 5, 2003. The final rules made a significant change from the proposed rules by giving claimants the right to veto the use of VTC only for the purpose of taking their own testimony. Accordingly, in publishing the final rules, we requested public comment on the issue of whether

claimants should or should not be empowered to veto use of VTC to take the testimony of expert witnesses.¹

Our Reasons for Proposing Rules Authorizing Use of VTC²

We receive more than 500,000 requests for hearings before ALJs each year. To accommodate the hearing requests of individuals who do not live near a hearing office, we hold approximately 40% of hearings at remote sites, which are generally at least 75 miles from the hearing office.

To make travel to remote hearing sites as cost effective as possible, hearing offices wait until they have a sufficient number of requests for hearing to schedule a full day or, if travel to a remote hearing site requires an overnight stay, several days of hearings. Because of the need to accrue a docket, ALJs travel to some remote hearing sites infrequently. Because many remote hearing sites are in less-populous areas, it can be difficult to find a needed medical and/or vocational expert witness(es) to travel to these sites, and this difficulty may further delay scheduling a hearing. ALJs also travel from their assigned hearing offices to assist other hearing offices when the need arises.

We proposed rules to authorize use of VTC in conducting hearings based on testing conducted in the State of Iowa beginning in 1996 that demonstrated that VTC procedures can be effectively used where large scale, high quality VTC networks exist and claimants want to participate in VTC procedures because doing so reduces the distances they must travel to their hearings. In a survey of participants in the Iowa test, a large percentage of the respondents rated hearings using VTC procedures as "convenient" or "very convenient," and overall service as either "good" or "very good." Test data showed that processing time for these hearings was substantially less than for hearings conducted in person at remote sites during the same time period, and that the ratio of hearings held to hearings scheduled was significantly higher for hearings using VTC procedures than for hearings

conducted in person. Being able to hold hearings as scheduled increases our efficiency because we do not have to recontact the individual to determine why he or she did not appear at a scheduled hearing nor reschedule the hearing (which can be time consuming, especially when an expert witness(es) has been scheduled to testify). Further, an ALJ does not spend time waiting for someone who does not appear, as would be the case in a hearing conducted in person at a remote site.

Based on all these factors—claimant satisfaction, ability to provide more timely hearings, savings in ALJ travel time, faster case processing, and higher ratio of hearings held to hearings scheduled—we decided that conducting hearings by VTC would be an efficient service delivery alternative. We also decided that scheduling a hearing for use of VTC, rather than asking someone to elect a hearing using VTC, as we did in our testing of VTC, would improve hearing office efficiency and would permit us to provide faster access to a hearing for some individuals.

Final Rules With Request for Comment

In the final rules with request for comment published February 3, 2003, we revised several sections of our regulations. We revised §§ 404.929 and 416.1429 to state that you may appear at your hearing in person or by VTC. We revised §§ 404.936 and 416.1436 to state that we may schedule your appearance or that of any individual appearing at the hearing to be by VTC and that, if we schedule you to appear by VTC and you tell us that you want to appear in person, we will schedule a hearing at which you may appear in person. We revised §§ 404.938 and 416.1438 to state that if we schedule you or anyone to appear at your hearing by VTC, the notice of hearing will tell you that and provide information about VTC appearances and about how you can tell us that you do not want to appear by VTC. Finally, we revised §§ 404.950(a) and (e) and 416.1450(a) and (e) to state that a party or a witness may appear at a hearing in person or by VTC.

The final rules with request for comment included a number of changes we made in response to the public comments we received on the NPRM, including changes to §§ 404.936 and 416.1436 to clearly reflect the authority of the ALJ to determine how hearings are conducted with respect to the use of VTC to conduct appearances.³ The final

rules with request for comment also set forth, in §§ 404.936(c) and 416.1436(c), specific policies that direct how that authority is to be exercised. Those sections specify that—

"In setting the time and place of the hearing, the administrative law judge determines whether your appearance or that of any other individual who is to appear at the hearing will be made in person or by video teleconferencing. The administrative law judge will direct that the appearance of an individual be conducted by video teleconferencing if video teleconferencing technology is available to conduct the appearance, use of video teleconferencing to conduct the appearance would be more efficient than conducting the appearance in person, and the administrative law judge does not determine that there is a circumstance in the particular case preventing use of video teleconferencing to conduct the appearance."

As previously noted, the final rules with request for comment also made changes in the rules proposed in the NPRM relative to the issue of whether claimants should have veto authority over the use of VTC for the appearances of VEs and MEs. We made these changes in response to the comments of ALJs who commented on the NPRM, all but one of whom strongly opposed the proposal to allow claimants to veto the use of VTC to conduct the appearances of expert witnesses. (The comments of the remaining ALJ dealt with matters that were not within the scope of the NPRM.) The ALJs who opposed this provision included five ALJs who conducted hearings in the Iowa test and the Association of Administrative Law Judges.

The commenters opposed the proposal to allow claimants to veto VTC appearances by expert witnesses for several reasons. One was that it would defeat the purpose of using VTC as a way to obtain expert testimony when it is impractical for the expert to appear in person, and that it could force ALJs to forgo needed testimony or to take testimony through the time consuming and unwieldy method of written interrogatories. The commenters also expressed concern that the right to veto the appearance of an expert by VTC could be used to prevent the taking of expert testimony that might be adverse to the claimant and to facilitate "expert shopping." It was pointed out that claimants can already object to witnesses based on bias or qualifications. The view was also expressed that due process is fully accorded to the claimant if the claimant can see and cross-examine the expert

¹ The final rules published on February 3, 2003, were designated as "[f]inal rules with request for comment." This current preamble deals with three sets of rules: (1) The proposed rules published in the NPRM of January 5, 2001; (2) the final rules were requested for comment published February 3, 2002, and (3) these current final rules that adopt the final rules with request for comment without change.

² We are summarizing our reasons for proposing rules to authorize use of VTC. For a more detailed review of the history of the development of these rules, see the preamble to the NPRM of January 5, 2001 (66 FR 1059–1062).

³ For a detailed review of the comments on the NPRM, and of all the changes that the final rules with request for comment made in the proposed rules, see the preamble to the final rules with

and confront the expert with documentary evidence.

The ALJs who commented based on their experience in the Iowa test strongly emphasized the practical problems that allowing claimants to veto VTC appearances by experts would cause. These ALJs stated that using VTC to take the testimony of VEs is necessary to utilize these experts effectively because the cost of a VE's appearance can be reduced if, as is possible using VTC procedures, a docket of multiple appearances can be arranged for the expert. They also emphasized the value of VTC in reducing the problems involved in scheduling hearings, citing the example of how much easier it is to make arrangements for one VE to appear by VTC in four hearings occurring on a given day at four different sites than it is to arrange for four VEs to make in-person appearances, at odd times in their workdays, at four sites.

The ALJs who participated in the Iowa test also emphasized that the practical problems in not using VTC to take VE testimony are greatly compounded when it comes to securing the testimony of MEs. They reported that it is only through use of VTC that they are able to provide ME testimony for hearings being held in remote sites, and that MEs will not travel to remote sites when it is technically possible to testify in hearings being held at such sites via VTC. These ALJs also reported that it was their experience that it is almost impossible to get MEs to testify in the larger urban areas where the hearing offices are located, and that it is sometimes necessary to rely on MEs testifying from the medical centers in Ames and Iowa City even in cases being heard in the West Des Moines area.

In explaining our response to these comments (*i.e.*, the decision we made in the final rules with request for comment to deny claimants veto authority over whether hearings will be conducted with a witness or witnesses appearing by VTC), we said—

The claimant may state objections to a witness appearing by VTC, just as they may state objections to any aspect of the hearing, and they may object to a witness on the basis of perceived bias or lack of expertise. However, a claimant's objection to a witness appearing by VTC will not prevent use of VTC for the appearance, unless the ALJ determines that the claimant's objection is based on a circumstance that warrants having the witness appear in person.

The analysis of the commenting ALJs concerning the impracticalities of giving claimants veto power over the medium whereby expert witnesses make their appearance has caused us to reevaluate our proposal in that regard. We believe these commenters are correct in indicating that

giving claimants that power would undermine one of the primary practical benefits of using VTC procedures and adversely impact our ability to use those procedures effectively to improve the hearings process. The commenters also effectively emphasize the significance of the positive practical benefits that can flow from relying on VTC procedures in scheduling and conducting the appearances of expert witnesses.

An important point made in this comment is that implementation of VTC procedures reduces the readiness of experts to travel to remote sites. This is a result that might be expected logically, we believe, and the experience of the ALJs in the Iowa test bears out its occurrence.

Unless we ensure ALJ authority to use VTC to take expert testimony by not empowering claimants to veto its use for that purpose, the reduced readiness of expert witnesses to travel when VTC appearances are technologically possible will adversely affect our ability to preserve a reasonable opportunity for claimants to appear in person if they choose to opt out of scheduled appearances by VTC. If the authority of ALJs to secure expert testimony by VTC is not ensured, the reduced willingness of experts to travel when VTC technology is available could also reduce the efficiency with which we are able to schedule the appearances of experts at the hearings of individuals who live near hearing offices in urban areas and appear in person in those offices for their hearings.

MEs and VEs testify as impartial witnesses. They testify based on the evidence entered into the record and not based on any examination or personal evaluation of the claimant. Where they testify by VTC and their testimony is adverse to a party's claim, the party and his or her representative, if any, will have a complete opportunity to confront and examine the witness regarding the matters that are important with respect to expert testimony—*i.e.*, the expertise of the witness and the accuracy of his or her testimony.

Affording claimants the power to veto the appearance of expert witnesses by VTC would be inconsistent with our existing practices and instructions regarding use of interrogatories to secure the testimony of expert witnesses. While emphasizing the preferability of securing live testimony where feasible, and requiring the ALJ to consider and rule on any claimant objection to the use of interrogatories, our instructions do not mandate non-use of interrogatories merely because a claimant objects to their use. See Hearings, Appeals, and Litigation Law Manual (HALLEX), sections I-2-5-30, I-2-5-42, and I-2-5-57, at <http://www.ssa.gov/OP-Home/hallex/hallex.html>. Thus, allowing claimants to veto the live testimony that experts can give by VTC would invest claimants with an authority that they do not currently have with respect to interrogatories.

Under these final rules, ALJs have discretion to determine that the appearance of any individual must be conducted in person. Thus, to the extent that circumstances could arise in which it would be advisable to schedule an in-person

appearance by an expert witness even though a VTC appearance would be possible technologically, the ALJ may schedule such an appearance. That action could be appropriate, for example, where the claimant alleges personal bias or dishonesty on the part of the expert and the ALJ determines that the claimant should have the opportunity to cross-examine the witness in person because of the greater immediacy of an in-person confrontation.⁴

Use of VTC

At present, 15 of our 138 hearing offices and 1 regional office use VTC to conduct hearings. Appearances by VTC are occurring from 12 different remote sites and 2 state networks.

We plan to gradually roll out use of VTC nationally. We will begin to use VTC facilities in the servicing area of a hearing office when the Associate Commissioner for Hearings and Appeals determines that appearances at hearings conducted in the area can be conducted more efficiently by VTC than in person.

We foresee initially scheduling VTC appearances where absent use of VTC:

- We would need to accrue a docket for a remote hearing site.
- An ALJ would need to travel to assist another hearing office.
- An expert witness(es) or appropriate medical specialist(s) would not be available for a hearing site. (In such a case, all participants could be at different locations; for example, the ALJ at a hearing office, the individual at a remote hearing site or another hearing office, and the expert witness(es) at a third location.)

Initially, we plan to locate most remote sites for using VTC to conduct appearances either in space where we have a long-term lease or in another federal building. We are investigating sharing VTC facilities with other federal agencies and states, and, if we can ensure privacy, we may eventually rent commercial space to expand use of VTC as a service delivery option. Calling into SSA's VTC network from private facilities, such as facilities owned by a law firm, may also be possible. Regardless of the type of facility, we will make certain that:

- The individual has the same access to the hearing record when appearing by VTC as he or she would have if appearing in person before the ALJ.
- There is a means of transmitting and receiving additional evidence between all locations and all participants.
- An assistant is present at the VTC site to operate the equipment and provide other help, as required.

⁴ 68 FR 5215-5216 (2003).

- The audio/video transmission is secure and the individual's privacy is protected.

We will follow the same procedures for making audio recordings of hearings using VTC that we do for hearings where all the participants appear in person. We have no plans to videotape hearings in which a party or a witness appears by VTC. If there is a problem with the VTC equipment, before or during a hearing, we will reschedule the hearing as we do now when unforeseen circumstances require us to reschedule a hearing: At the earliest time possible based on the request for hearing filing date.

We reserve the right not to schedule an appearance by VTC for someone who asks to appear by VTC. In many locations, especially in the near term, we may not have the capability to accommodate the request, and the ALJ may determine that an appearance must be conducted in person even where VTC capability exists. As access to VTC expands, we will generally accommodate requests to appear by VTC as space and time permit.

Although use of VTC to conduct hearings has the potential to improve service, we will not require any individual to appear at his or her hearing by VTC if the individual objects to that procedure at the earliest possible opportunity before the time scheduled for the hearing. Under these final rules, if a party timely objects to making his or her appearance by VTC, we will reschedule the hearing as one at which the individual may appear in person.

When we reschedule a hearing because a party objects to making his or her appearance by VTC, we will reschedule the hearing at the earliest time possible based on the date the request for hearing was filed. Where necessary, to expedite the rescheduling, we will give the party the opportunity to appear in person at the hearing office or any other hearing site within the service area of the hearing office at which we are first able to schedule a hearing. The party's travel expenses to the remote site or to the hearing office, and the travel expenses of his or her appointed representative, if any, and the travel expenses of any unsubpoenaed witnesses we determine to be reasonably necessary, will be reimbursed in accordance with the provisions of §§ 404.999a–404.999d and 416.1495–416.1499.

To ensure that a party fully understands the right to decline to appear by VTC, a notice scheduling an individual to appear at his or her hearing by VTC will clearly state:

- What it means to appear by VTC;
- That we have scheduled the individual's appearance to be by VTC;
- That we will schedule a hearing at which the individual may appear in person if the individual tells us that he or she does not want to appear by VTC; and
- How to tell us that.

We will evaluate hearings using VTC procedures to ensure that there is no significant difference in the outcome of hearings conducted using VTC and those conducted in person and that we maintain a high degree of accuracy in decisions made based on hearings using VTC. We will also ensure that individuals:

- Understand that they are not required to appear at their hearings by VTC;
- Understand that a witness is appearing by VTC, when appropriate;
- Know how to tell us if they do not want to appear by VTC;
- Receive a full and fair hearing; and
- Are satisfied with the VTC process in relation to their appearance and the appearances of any witnesses, including the appearances of witnesses who may appear by VTC notwithstanding an objection by the claimant to use of VTC for the appearance.

Public Comments

The final rules with request for comment that were published on February 3, 2003, provided the public with a 60-day comment period. We received a total of ten comments.

Because some of the comments were detailed, we have condensed, summarized, or paraphrased them below. However, we have tried to summarize the commenters' views accurately and to respond to all of the significant issues raised by the commenters that were within the scope of this rulemaking action.

We have not limited ourselves to responding only to those comments that addressed the specific issue on which we solicited comment (*i.e.*, whether claimants should have veto authority over VTC appearances by witnesses as well as veto authority over their own appearances by VTC). Many of the other comments received addressed issues previously addressed or touched on in the comments received in response to the NPRM. However, since the additional comments generally offered some different perspective on the issues, we are responding to those comments as well.

None of the comments we received opposed the change to deny claimants the right to veto use of VTC to conduct the appearance of a witness. However,

a number of the comments suggested that we expand our rules to provide more specific guidance regarding the consideration of objections to the use of VTC for taking expert testimony and the factors that could interfere with use of VTC to conduct the appearance of a witness.

Comment: The Railroad Retirement Board (RRB), which had noted in commenting on the proposed rules that it would be interested in making use of SSA's VTC facilities on a fee basis, wrote to again state its interest in exploring the possibility of the RRB using our VTC facilities.

Response: We are exploring the possibilities of sharing VTC facilities with the RRB and other agencies.

Comment: The Association of Administrative Law Judges (AALJ) wrote to restate its strong support for our decision to have the ALJ decide whether to have expert witnesses appear by VTC and to deny claimants the right to veto use of VTC for that purpose.

Response: We considered the AALJ's comments in deciding to change the proposed rules in this respect. The AALJ's restatement of its prior comments supports adoption of the rules published February 3, 2003, without change.

Comment: Noting that we cited the difficulty of finding MEs in remote sites in sparsely populated areas as one justification for using VTC, one commenter suggested that another possible solution would be to increase ME compensation.

Response: We believe that we can increase our ability to secure ME (and VE) services in remote areas by using VTC, and that it will be productive to use VTC for this purpose even if we also identify other ways to ameliorate the problems we have experienced in securing expert testimony in remote areas. VTC use can increase the incentives for an expert witness to appear in remote-site hearings by reducing or eliminating the adverse effect on the expert's professional schedule that can occur if the expert is required to travel to a remote site. Use of VTC can also increase the incentive of experts to appear in Social Security hearings by facilitating the scheduling of multiple appearances for the expert within a limited period.

Comment: In the mistaken belief that we plan to videotape hearings in which appearances are made by VTC, a commenter asked a number of questions about access to and the costs of the videotapes that would result under such a procedure, and about whether the Appeals Council might use these videotapes and the visual clues they

provide regarding credibility to make credibility findings over and beyond those of the ALJ.

Response: As we stated above, and in the preambles to the NPRM and the final rules with request for comment, we have no plans to videotape hearings in which a party or witness appears by VTC. We will make audio recordings of these hearings using the same procedures we use in hearings in which all of the participants appear in person. The role of the Appeals Council in considering cases should not be affected by whether VTC was used in conducting an appearance or appearances at the hearing.

Comment: This same commenter asked what savings in real days we project to occur as a result of the use of VTC.

Response: As we noted above and in the prior preambles concerning these rules, the Iowa test results showed that processing time for hearings using VTC procedures was substantially less than for hearings conducted in person at remote sites. The processing time savings achieved by different hearing offices will vary depending on multiple factors, including the rate at which the office uses VTC in the hearings it conducts. Nationally, we expect that the overall effect of using VTC in reducing processing times will increase as we gradually rollout VTC and develop more effective VTC networks.

Comment: A commenter expressed the opinion that VTC is a viable alternative for hearings, provided it remains a choice and not a requirement, and that use of VTC should speed up the hearing process and save money.

Response: We agree with these views. We understand the aspect of this comment that deals with the maintenance of "choice" to be concerned with the claimant's retention of choice regarding the mode of his or her appearance, rather than the specific issue of whether the claimant should have veto authority over VTC appearances of expert witness. We discuss that issue in response to other comments.

Comment: Two commenters questioned whether claimants would find appearing by VTC satisfactory. One commenter thought that the ALJ hearing was already stressful enough for claimants and that adding a camera to the process will only make matters worse. Another thought that the camera "may not cut it" and that represented claimants will want to look the ALJ in the eye and tell their story in person.

Response: Our testing of VTC does not support the conclusion that claimants will find appearing by VTC to be

intimidating or unsatisfactory for the purpose of projecting their own credibility. As previously discussed (above and in the prior preambles for these rules), in our testing of VTC in Iowa a large percentage of claimants rated hearings using VTC procedures as "convenient" or "very convenient" and overall service as "good" or "very good." We also note that in commenting on the NPRM, a national organization of claimant representatives reported that one of its members who had represented several hundred claimants in the Iowa test now preferred VTC to in-person hearings because, among other benefits, VTC has a calming effect on his clients.

One of the reasons we retained the right of claimants to opt out of appearing personally by VTC in the final rules with request for comment was to promote claimant satisfaction with the hearing experience. As we noted in the preamble to those rules, claimants may have strong opinions about whether they can best project their own credibility by appearing in person or by VTC. Preserving an option for claimants to appear in person should increase their comfort level in appearing by VTC and help to ensure that they perceive the hearing process as fair.

Comment: Two commenters expressed concerns about the effectiveness of VTC proceedings for the purposes of inquiring fully into the facts. One thought that a "flickering and disembodied" view is no substitute for in-person observation at the hearing and that use of VTC will deprive hearing proceedings of the solemnity that encourages truth telling. Another commenter thought that the decisionmaker would lose the personal contact with the claimant that the commenter believes is needed to assess credibility.

Response: Under the final rules with request for comment, the ALJ has discretion to require in-person appearances, by the claimant or witnesses, in any case in which the ALJ determines that the immediacy of an in-person appearance is needed to inquire fully into the facts. Thus, the rules provide a mechanism to prevent use of VTC where an in-person appearance would be more appropriate.

We believe that any problems in assessing credibility in VTC proceedings would generally be associated with possible instances of inadequate VTC transmission. That was the case, for example, in the incident reported in a comment on the NPRM in which a claimant representative was dissatisfied with a VTC experience because the quality of the VTC transmission was not sufficient to allow the ALJ to perceive

the claimant's sweating and shortness of breath. We believe we can generally avoid problems of this type by assuring that our VTC facilities are of high quality. As we noted above and in the prior preambles for these rules, we plan to implement use of VTC in the servicing areas of hearing offices after the Associate Commissioner for Hearings and Appeals determines that appearances at hearings conducted in those areas can be conducted more efficiently by VTC than in person. Where problems do occur, we believe that it will frequently be possible to reach satisfactory solutions on an ad hoc basis, such as happened in the above noted example when the ALJ stipulated to the claimant's sweating and shortness of breath based on the representative's statement describing these conditions. Where technical problems occur and cannot be overcome, the hearing will be rescheduled, as happens when a problem in the audio recording equipment prevents the recording of a hearing.

Comment: One commenter opposed use of VTC on the basis that its use is complicated by technical issues, including problems involved in making the claim file available for review by the claimant and the additional costs associated with having dual staffs at two sites.

Response: The technical problems of concern to this commenter involve matters that we assessed in deciding that using VTC to conduct hearings is an efficient service delivery option. Our judgment in this regard included consideration of the need to establish VTC facilities and to have hearing monitors available at VTC sites to assist in the hearing proceedings. The technical issues we have considered also include the problems involved in ensuring that claimants who appear by VTC will have access to the record that is sufficient and equal to that of claimants who appear in person. We have addressed these problems by establishing procedures to provide the claimant and the representative a copy of the evidence of record or an opportunity to review the file at their local Social Security FO before the hearing is conducted, and/or through use of document cameras to display documents on the day of the hearing.⁵

⁵ We address these procedures, together with changes we are making in our standardized notices of hearing to advise claimants concerning the procedures, in HALLEX guidance that we have issued to implement our use of VTC procedures (HALLEX TI 1-5-1-16). (See <http://www.ssa.gov/OP-Home/hallex/I-05/I-5-1-16.html>, TI 1-5-1-16 ILE, and Attachment 3.)

Comment: One commenter proposed that we should limit the use of VTC to cases in which the ALJ determines that there is “good cause” to use VTC procedures because the claimant is prevented from traveling by illness or other good reasons. Another commenter expressed the view that use of VTC should be limited to situations in which its use is necessary to allow the appearance of a witnesses who would be unable to appear except by VTC.

Response: Using VTC would not be efficient or cost effective if we limited its use to the relatively small number of cases in which the claimant is unable to travel or there is another factor requiring the use of VTC. The advantages in efficiency and costs savings involved in using VTC accrue where a hearing office is able to use VTC in many of its cases.

We see no basis for making the use of VTC contingent upon the ALJ finding “good cause” to use it in a particular case. As we stated in the preamble to the final rules with request for comment, we believe that the hearing proceedings we conduct using VTC will be fundamentally fair and fully protective of the claimant’s right to procedural due process. Based on that belief, we further believe that the best overall policy is to schedule use of VTC to conduct hearings in all instances in which VTC technology is available and would be an efficient means for conducting the appearance(s) of the claimant and/or a witness or witnesses,⁶ and the ALJ does not determine that there is a circumstance in the particular case preventing use of VTC to conduct an appearance.

Comment: One commenter expressed concern about unspecified provisions of the final rules with request for comment that “prohibit a right to object to the appearance of an expert witness by VTC.”

Response: The final rules with request for comment included no provision prohibiting claimants or their representatives from stating objections on any matter, including the appearance of a witness by VTC. As we noted in the preamble to those rules, claimants may state objections to a witness appearing by VTC, just as they may state objections to any aspect of the hearing.⁷

⁶ Concerning the assessment of the efficiency of using VTC, see our response below to the comment recommending that the ALJ consider certain factors when scheduling VTC appearances.

⁷ HALLEX TI I-5-1-16 has changed our standardized notices of hearing to notify claimants when a witness will appear by VTC and to advise claimants explicitly that they may object not only with respect to issues, but also “to any other aspect of the scheduled hearing.” (TI I-5-1-16, Attachment 3.)

Comment: Noting that it generally supports the use of VTC provided the right to a full and fair hearing is adequately protected and the technical quality of the hearings is assured, an organization of individuals who represent claimants commented that we should provide guidance for circumstances that warrant having a witness appear in person. For that purpose, the commenter suggested that we should include in our rules language from the preamble to the final rules with request for comment in which we specified that a claimant’s objection to a witness appearing by VTC will not prevent the use of VTC “unless the ALJ determines that the claimant’s objection is based on a circumstance that warrants having the witness appear in person.”⁸

Response: We are not adopting this comment because the provisions of the final rules with request for comment encompass the point made in the preamble language cited in the comment. Sections 404.936(c) and 416.1436(c) of our rules require us to schedule a VTC appearance for the claimant or any other individual “if [VTC] technology is available to conduct the appearance, use of [VTC] to conduct the appearance would be more efficient than conducting the appearance in person, and the [ALJ] *does not determine that there is a circumstance in the particular case preventing use of [VTC] to conduct the appearance.*” (Emphasis added.) A “circumstance preventing use of [VTC]” for an appearance necessarily exists where the ALJ “determines that the claimant’s objection is based on a circumstance that warrants having the witness appear in person”; therefore, deciding if there is a circumstance that warrants having a witness appear in person is requisite to deciding if there is a circumstance preventing use of VTC to conduct an appearance.

Comment: This commenter further recommended that our rules should include a requirement that the ALJ consider other factors, such as limitations of the claimant or the representative, that could affect how the hearing is conducted. In this respect, the commenter suggested that we consider including in our rules guidance like that in language from the preamble to the final rules with request for comment indicating that, in deciding whether the claimant’s appearance should be scheduled to occur in person or by VTC, the ALJ “will consider any stated preference of the claimant or the representative for or against appearing by VTC, as well as the availability of

VTC technology and other factors, such as a claimant’s loss of visual and auditory capacities, that may affect how the appearance should be conducted.”⁹ Another commenter, a claimant’s representative who personally has a hearing loss that would interfere with his ability to understand and to question a witness appearing by VTC, made a similar comment.

Response: We are making no change in response to these commenters because our rules already include provisions to require consideration of any factors that would compromise the integrity or fairness of the hearing or make it inappropriate to use VTC for any reason. These provisions are reinforced by provisions that require the ALJ to consider the efficiency of scheduling an appearance to occur by VTC.

In setting the time and place for the hearing, the ALJ is required under §§ 404.936(c) and 416.1436(c) to determine whether the appearance of the claimant or any other individual appearing at the hearing will be made in person or by VTC. To make that determination, the ALJ is required by the provisions of these sections to determine if there is a circumstance preventing use of VTC for the appearance. As the cited preamble language reflects, determining if there is such a circumstance requires the ALJ to consider if there is any factor or factors, such as an auditory loss on the part of one of the participants, that would interfere with using VTC for the appearance. The factors considered will necessarily include any visual or auditory limitations on the part of the claimant’s representative that could compromise the ability of the representative to participate effectively in observing, understanding, and questioning the expert if VTC is used to take the expert’s testimony.¹⁰

Under §§ 404.936(c) and 416.1436(c) of the final rules with request for comment, the efficiency of using VTC for an appearance is one of the factors the ALJ must consider in deciding if an appearance should be scheduled to occur by VTC or in person. As we explained above and in the prior preambles to these rules, we plan to use VTC in the service area of a hearing

⁹ 68 FR 5213 (2003).

¹⁰ Our HALLEX instructions implementing VTC procedures specify that the circumstances that might cause the ALJ to require an in-person appearance include that in which the claimant or the representative has a visual or auditory impairment of a type that could adversely affect his or her ability to appear and participate in the hearing through VTC, either for the purpose of interacting with the ALJ or another participant in the hearing. (TI I-5-1-16 III.B.)

⁸ 68 FR 5215 (2003).

office when the Associate Commissioner for OHA determines that appearances at hearings conducted in the areas can be conducted more efficiently by VTC than in person. However, while the Associate Commissioner makes the decision about the general efficiency of using VTC in an area, the ALJ is responsible for determining if using VTC for any appearance in a particular case will be efficient.

Comment: The same organization also commented that our rules should require the hearing notice to include a statement that a ME and/or a VE will appear by VTC and provide an opportunity to object.

Response: Sections 404.938(b) and 416.1438(b) of the final rules with request for comment specify that the claimant "will also be told if [his/her] appearance or that of any other party or witness is scheduled to be made by [VTC] rather than in person." We reflect these requirements in HALLEX guidance that modifies our standardized notices of hearing to notify claimants that a witness will appear by VTC and to advise them explicitly of their right to object to any aspect of the hearing (see Footnote 7 above).

Regulatory Procedures

Executive Order 12866, As Amended by Executive Order 13258

We have consulted with the Office of Management and Budget (OMB) and determined that this final rules document meets the criteria for a significant regulatory action under Executive Order 12866, as amended by Executive Order 13258. Thus, it was reviewed by OMB.

Regulatory Flexibility Act

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

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 says that no persons are required to respond to a collection of information unless it displays a valid OMB control number. In accordance with the PRA, SSA is providing notice that the Office of Management and Budget has approved the information collection requirements contained in §§ 404.929, 404.936(d), (e) & (f), 404.938(c) (HA-504), 404.950(a), 416.1429, 416.1436(d), (e) and (f), 416.1438(c) (HA-504), and 416.1450(a) of these final rules. The OMB control

number for this collection is 0960-0671, expiring November 30, 2004.

(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, Aged, Blind, 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: October 3, 2003.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ Accordingly, the final rules with request for comment amending 20 CFR parts 404 and 416 that were published at 68 FR 5210 on February 3, 2003, are adopted as final rules without change.

[FR Doc. 03-30691 Filed 12-10-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. 2000N-1652]

RIN 0910-AB91

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing the format in which certain labeling is required to be submitted for review with new drug applications (NDAs), certain biological license applications (BLAs), abbreviated new drug applications (ANDAs), supplements, and annual reports. The final rule requires that certain labeling content be submitted electronically in a

form that FDA can process, review, and archive. Submitting the content of labeling in electronic format will simplify the drug labeling review process and speed up the approval of labeling changes.

DATES: The rule is effective June 8, 2004.

FOR FURTHER INFORMATION CONTACT:

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Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 3, 2002 (67 FR 22367), FDA published a proposed rule to require the submission of the content of labeling for human prescription drugs and certain biologics in electronic format in a form that FDA can process, review, and archive. This electronic submission requirement would necessitate the amendment of FDA's regulations under §§ 314.50(l) (21 CFR 314.50(l)), 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii)), 314.94(d)(1) (21 CFR 314.94(d)(1)), and the addition of § 601.14 (21 CFR 601.14).

Under current regulations, as noted in the preamble to the proposed rule, labeling for the archival copy of an NDA must be submitted to the agency on paper, labeling for the archival copy of an ANDA may be submitted in any form that FDA and the applicant agree upon, and the current regulations for BLA labeling do not specify a format for submission to the agency. The term "labeling" used in §§ 314.50, 314.94, 314.81, and § 601.12 is defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(m)) to mean both labels¹ and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. Thus, requiring the submission of "labeling" entails submission of the label (i.e., the label on the immediate container) and labeling. Labeling consists of the comprehensive prescription drug labeling directed to health care practitioners (i.e., the labeling required under § 201.100(d)(3) (21 CFR 201.100(d)(3)), commonly referred to as the "package insert" or

¹ Under section 201(k) of the act, the term "label" means a display of written, printed, or graphic matter upon the immediate container of any article.