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Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852-20201

Docket No. 2004S-0270

To Whom It May Concern:

1. INTRODUCTION

The Center for Medicare Advocacy, Inc., founded in 1986, is a national non-partisan education and advocacy organization that identifies and promotes policy and advocacy solutions to ensure that elders and people with disabilities have access to Medicare and quality health care.

The Center represents thousands of individuals in appeals of Medicare denials at all levels of the administrative process. **From July 1, 1990 through March 31, 2003, we received a total of 8848 administrative law judge (ALJ) decisions, 79% of which (7022) were favorable. In addition to our own cases, we provide advice to attorneys and other advocates in their representation of Medicare beneficiaries through the Medicare appeals process.**

From our perspective as beneficiary representatives, the current ALJ system, over all , works well for the Medicare beneficiaries it was designed to protect. We want to ensure that, in transferring ALJs from the Social Security Administration (SSA) to the Department of Health and Human Services (HHS), nothing is done that interferes with the ability of Medicare beneficiaries to continue to have access to fair, impartial administrative law judge hearings.

We file these comments to the *Plan for the Transfer of Responsibility for Medicare Appeals* on behalf of our clients and on behalf of the Arizona Center for Disability Law, the Medicare Rights Center, the National Academy of Elder Law Attorneys, Senior Citizens Law Project of Vermont Legal Aid, and the Vermont Long Term Care Ombudsman Project. These organizations also represent older people and people with disabilities and want to protect access to a fair, impartial administrative law judge process.

2. THE PROPOSED PLAN FAILS TO ADDRESS THE TWO PRIMARY STATUTORY PROTECTIONS FOR MEDICARE BENEFICIARIES.

Section 931 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) includes two primary protections to assure that Medicare beneficiaries continue to have access to an appeals process that is easy to use and that meets due process requirements. The statute requires that the transition plan address two specific concerns:

- ?? To ensure the independence of ALJs from CMS, Section 931(a)(2)(H), (b)(2), and
- ?? To provide for an appropriate geographic distribution of ALJs throughout the United States, Section 931(a)(2)(I), (b)(3).

The proposed transition plan fails to address these protections adequately.

A. The plan does not identify the steps that will be taken to assure that ALJs are separate from the Centers for Medicare & Medicaid Services.

1. Questions remain about how independence will be maintained. The statute requires that the ALJs be transferred to HHS and be in an office that is separate from the Centers for Medicare & Medicaid Services (CMS) and its contractors. They are to report to, and be under the supervision of, the Secretary of HHS, and not any other officer of the Department. The reason for this protection is simple: Congress wanted to prevent CMS from exerting any undue influence on ALJs in their analysis of the facts and the law pertinent to individual appeals. Congress' concerns are not speculative. The actions by the CMS Administrator to prevent the Chief Medicare Actuary from providing requested information to Congress in 2003 demonstrate that undue interference with the work of an independent office, including an office overseeing the appeals process, is indeed possible.

However, the proposed plan gives no details on how HHS intends to keep the Medicare ALJs independent from the agency that oversees the Medicare program and is responsible for management of its costs. In fact, the plan does nothing more than parrot the statute. Among other things, the plan fails to name:

- ?? The new office or agency in which the ALJs will be placed;
- ?? Firewalls that will be put in place to assure independence;
- ?? Procedures for reporting and oversight by the Secretary; and
- ?? Standards against which independence will be measured.

Questions also remain about ALJ performance standards, and how the Secretary will assure that the number of cases resolved in favor of beneficiaries and against CMS is not taken into consideration.

2. HHS' plans for training of Medicare ALJs give rise to concerns that CMS may,

through training modalities and materials, attempt to sway the way ALJs handle Medicare appeals. Reports by the Office of Inspector General and other entities have documented that beneficiaries who reach the ALJ level of review have a greater success rate than they do at lower appeal levels, often because ALJs apply the federal regulations and statute. They are not bound by CMS manuals and other policy guidance while Medicare contractors are required to apply CMS Policy. All too often the CMS policies are more restrictive than the statute and regulations. These reports imply that, because ALJs don't follow the policy manuals utilized by Medicare contractors, they are not applying the proper standards. However, ALJs currently do not apply these rules because they do not have the same force and effect as the Medicare statute and regulations.¹

The proposed transfer plan states, without further elucidating, that training will focus on improving decisional accuracy. We are concerned the training will focus on CMS policy manuals and local contractor rules, rather than on the statute, regulations, and case law, to encourage ALJs to abide by policy guidelines that conflict with, and do not have the weight of, the statute and regulations. To assure that the training protects the independence of ALJs to apply the law to the facts of each claim, the training should include information about the requirements of the Administrative Procedures Act and case law relating to deference to agency policies. The trainings should be open to the public, and the agenda, materials, and transcripts should be available on the Medlearn folder of the CMS web site, www.cms.hhs.gov/medlearn.

3. HHS' plan to locate the central hearing support office in the Baltimore/Washington area raises red flags about independence. As will be discussed in more detail below, HHS' plan for location of the central office raises further questions. Placement of the central hearing support office in Washington, D.C. in HHS headquarters allows for close proximity to the secretary. Placement in the Falls Church, Virginia, Social Security Office of Hearings and Appeals allows for coordination with Social Security ALJs. Placement of the office in CMS headquarters in Baltimore is unacceptable, as that would place the ALJs in direct contact with the Medicare agency, without any buffer, and far from the office of the Secretary to whom they are to report.

4. Outside assistance may be necessary to assure independence. To assist with implementation and monitoring of the independence requirement, HHS should consider utilizing the American Bar Association Administrative Law Section, the National Conference of Administrative Law Judiciary of the American Bar Association Judicial Divisions, the Association of Administrative Law Judges, the Federal Administrative Law Judge Conference, and the National Association of Administrative Law Judges, non-governmental entities with an interest in the integrity of the federal ALJ system. Representatives of these groups could be appointed to a committee within HHS that acts as a watchdog over the independence of the Medicare ALJs. The committee could also establish guidelines for the operations of the Medicare ALJs that focus on measures that assure their independence.

¹ See *Public Citizen v. Department of Health and Human Services*, 332 F.3d 654 (D.C. Cir. 2003).

B. The transfer plan promotes centralization of ALJs rather than geographic diversity.

1. The plan includes no details on how HHS will comply with the statutory requirement to provide for an appropriate geographic distribution of ALJs performing ALJ functions throughout the country to ensure timely access. Again, the plan simply repeats the statute without giving any explanation. Among the unanswered questions are the following:

- ?? How will regions be identified?
- ?? Will ALJs be housed permanently in one location, or will they ride circuit?
- ?? Will hearing sites be at least as geographically accessible as they currently are, or will beneficiaries have to travel greater distances?
- ?? What safeguards will be available to beneficiaries in rural areas to assure they have the same access to ALJ hearings as beneficiaries in urban areas.

These questions are critical for low income Medicare beneficiaries, who may have greater difficulty traveling long distances to have the face-to-face hearing required by due process. In addition, many of the beneficiaries who bring appeals have chronic and other conditions that make traveling long distances difficult. Moreover, because in our experience many beneficiaries desire to have in-person contact with the ALJ after having gone through several impersonal stages of appeal, easy geographic access to an in-person hearing is of paramount importance and concern in assuring the integrity of the ALJ hearing process.

2. The issue of a centralized office raises concerns about geographic distribution. In addition to concerns about the location of the centralized office raised earlier, the emphasis of discussion on a centralized office, rather than on offices spread throughout the country, raises the issue of whether HHS is even considering having offices other than in the Baltimore/Washington region.

More local offices are critical to assure that beneficiaries continue to have the opportunity for fair and full hearings. They and their advocates need to have access to the hearing records before the date of the hearing to assure that the record is complete and to determine what additional evidence, if any, is necessary to provide. In addition, ALJs are supposed to assist unrepresented beneficiaries develop the record for their case. They will be unable to do so if they operate from Washington, D.C. Finally, ALJs who are assigned to particular regions become familiar with the issues in those areas of the country, and may be better attuned to systemic problems.

3. The availability of teleconferencing and video-teleconferencing is not an adequate response to the issue of geographic distribution. The proposed move towards increased use of video-teleconferencing to conduct hearings raises concerns that HHS will concentrate more on new technology than on assuring geographic distribution of ALJs. VTC cannot be used as a substitute for a local, face-to-face hearing in all circumstances. Many beneficiaries will not be able to participate with such equipment. There are also situations in which the ALJ needs a face-to-face meeting to understand the beneficiary's situation and condition, or in which a beneficiary will want a face-to-face meeting to engage in a clear exchange with the ALJ.

In 1988 the Office of Inspector General (OIG), in a report investigating the use of telephone conferences for Part B hearings, found that telephone hearings may be less costly and less time consuming, and may provide additional access to homebound individuals. However, they also found that telephone hearings should not be used in all cases. They recommended that safeguards be in place that consider

- ?? The preference of the beneficiary,
- ?? The issue involved,
- ?? The physical condition of the beneficiary,
- ?? The type of equipment used, and
- ?? Due process requirements for notice, opportunity to examine the record before the hearing, and opportunity to cross-examine witnesses.²

The factors enumerated by the OIG apply equally to VTC. If VTC is to be used in cases involving beneficiaries, it should only be used at the option of the beneficiary, after the beneficiary has been provided a full explanation of how VTC works and where it will be made available, as well as information about a reasonable and local alternative for a live in-person hearing.

3. THE TRANSFER PLAN RAISES ISSUES THAT ARE BEYOND THE SCOPE OF THE STATUTORY MANDATE CONCERNING THE TRANSFER OF ALJS.

The statute only requires that the ALJs be transferred to HHS and that they be independent of CMS. It does not state that HHS should make major changes in the ALJ process.

Yet the report discusses proposed regulations issued in November 2002 that substantially revise the conduct of ALJ hearings to make them less accessible to and less user-friendly by Medicare beneficiaries. The Center for Medicare Advocacy and other consumer groups submitted comments to these proposed regulations to outline the ways in which the proposed changes violate due process and make the system impossible to use for beneficiaries. See comments from the Center for Medicare Advocacy, January 13, 2003, filed in response to 67 Fed. Reg. 69312 (Nov. 15, 2002).

We repeat, however, that the appeals system is often used by Medicare beneficiaries who are unrepresented or under represented. Evidentiary and procedural rules designed to make the adjudication of “big box” and other cases brought by providers only work to exclude beneficiaries from an appeals system that should be designed to assist them.

IV TIMETABLE FOR TRANSITION.

² OIG, *Appeals by Telephone: Appellant Reactions and Implications for Appeals Processing* (June 1988).

The timetable for transition and resolution of backlogged cases seems overly ambitious. We encourage HHS and SSA to seek adequate funding to assure that the time table is met. In addition, adequate resources need to be provided so that the new core of Medicare ALJs will be able to complete their workload within the statutory time frames adopted in BIPA.

V USE OF ELECTRONIC TRANSMISSIONS

The problems beneficiaries encounter with the current ALJ process usually stem from administrative breakdowns. Medicare contractors may not transfer records on a timely basis, or the records they transfer may not be complete. The use of electronic case tracking systems may help to reduce some of these administrative difficulties, and should be developed as expeditiously and carefully as possible to promote a smooth transition and appeals system.

The plan also discusses CMS' efforts to allow the Medicare beneficiary population to access their own personal Medicare data via the Internet, in anticipation of allowing beneficiaries to file appeals electronically.

We remind HHS that, according to the Kaiser Family Foundation, only 20% of current Medicare beneficiaries have access to the Internet, and only 3% have used the Medicare web site. We urge HHS to continue to provide for paper appeals until such time as every household in America has Internet access.

VI CONCLUSION

The current ALJ process provides Medicare beneficiaries with the opportunity for a face-to-face hearing with an impartial, independent decision-maker in the beneficiary's geographical locale, who applies Medicare law to the facts of each individual case. Beneficiaries without access to a representative may use the system with assurance that they will be accorded the due process protections to which they are entitled.

The MMA only mandates that the transfer of ALJs from SSA to HHS. It does not require any change to the current process; nor should it be interpreted as reducing the process that is due to the beneficiaries for whom it is designed. In implementing the statutory change, SSA and HHS must be cognizant of the beneficiary protections included in MMA and of the need to assure that a system which helps beneficiaries is not made less effective.

We thank you for the opportunity to submit these comments.

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Center for Medicare Advocacy, Inc.

On behalf of

Arizona Center for Disability Law
Medicare Rights Center

Medicare Advocacy Project, Greater Boston Legal Services, on behalf of its clients
National Academy of Elder Law Attorneys
National Organization of Social Security Claimants' Representatives
Senior Citizens Law Project of Vermont Legal Aid
Vermont Long Term Care Ombudsman Project
Vermont Legal Aid