UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BEVERLY HEALTH & REHABILITATION SERVICES, Inc., *et al*.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 99-02367 (ESH)**
TOMMY G. THOMPSON, Secretary of Health and Human Services, *et al*.,	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiffs are Beverly Health and Rehabilitation Services, Inc., which owns and operates 300 nursing homes nationwide, and its subsidiary Beverly Enterprises – Florida, Inc., the licensee in the State of Florida for Beverly Health and Rehabilitation – Spring Hill ("Spring Hill"). Prior to June 2, 1998, Spring Hill had contracts with the Health Care Financing Administration ("HCFA"), a subagency of the Department of Health and Human Services ("HHS"), and the State of Florida, to provide nursing home services to beneficiaries of the federal Medicare program and the Florida Medicaid program, pursuant to sections 1819 and 1919 of the Social Security Act, 42 U.S.C. §§ 1395i-3, 1396r.

On June 2, 1998, the Secretary of HHS terminated Spring Hill's contract to participate in the Medicare and Medicaid programs. This termination decision was upheld by an Administrative Law Judge, and thereafter affirmed by the Appellate Panel, Departmental Appeals Board, HHS. Plaintiffs have now sued Tommy Thompson, in his official capacity as the Secretary of HHS, and Thomas A.

Scully, in his official capacity as Administrator of CMS.[1/]

Plaintiffs' challenge to the Spring Hill termination extends far beyond the particular decision in this case. Plaintiffs seek the invalidation of the federal nursing home enforcement regulations and the standard survey protocol used by state and federal surveyors to monitor compliance with substantive statutory and regulatory requirements for nursing home participation in the Medicare and Medicaid programs.[2/] Plaintiffs also challenge the termination decision as being arbitrary and capricious. In addition to opposing these arguments, defendants argue that plaintiffs lack standing to assert injury from a survey protocol that allegedly has not been validated, and that the question of whether the Secretary has validated the survey protocol is not reviewable but has been committed to agency discretion. In addressing the myriad of issues raised by the parties, the Court will begin its analysis in Section I by tracing the relevant legislative and regulatory history, as well as HHS' development of the Long-Term Care ("LTC") Survey Protocol that is at the center of this litigation. Thereafter, the Court will address the legal arguments raised by the parties by answering the following questions:

[1/] The Complaint, filed on September 3, 1999, was originally brought against Donna E. Shalala, the former Secretary of HHS, and Nancy-Ann Min DeParle, the former Administrator of HCFA, which has, as of July 1, 2001, changed its name to the Centers for Medicare and Medicaid Services ("CMS"). Since the relevant actions were taken by HCFA, this Memorandum Opinion refers only to HCFA.

[2/] The American Health Care Association ("AHCA"), a long-term care trade association, has filed an *amicus* brief in support of plaintiffs, arguing that the survey and enforcement system is too vague and ambiguous to provide fair notice to nursing home providers. In opposition to the nursing home industry's assault on the current enforcement system, the National Citizens' Coalition for Nursing Home Reform ("NCCNHR") and the American Association of Retired Persons ("AARP") have also filed an *amici* briefs which advocates upholding the current regulatory system, but argues that the termination decision should be remanded due to the unique facts of this case.

Section II: Do Plaintiffs Have Standing to Challenge the Survey Protocol?
Section III: Does Defendants' Use of the Survey Protocol Violate the Statute, the APA, or the Fifth Amendment?
Section IV: Can the Survey Protocol Be Used as An Enforcement Tool If It Was Not Promulgated Through Notice and Comment Rulemaking Proceedings?
Section V: Are Defendants' Enforcement Regulations Invalid Because of a Failure to Respond to Comments Regarding the Invalidity of the Survey Protocol or to Disclose the Abt Study?
Section VI: Was the Termination Decision Arbitrary and Capricious, Not in Accordance with Law, or In Violation of Plaintiffs' Rights to Due Process and Equal Protection under the Law?

As explained more fully below, the Court will not reverse defendants' decision to terminate Spring Hill, enjoin the agency's use of the protocol, or invalidate the agency's enforcement regulations. Therefore, plaintiffs' motion for summary judgment will be denied, and summary judgment is entered in favor of defendants.

I. BACKGROUND: THE HISTORY OF NURSING HOME LEGISLATION AND REGULATION

A. Pre-OBRA '87 History

Congress has maintained a longstanding, continuing concern with the well being of America's elderly population, and today the nursing home industry is heavily regulated and monitored by the government through HHS and its subagency HCFA. The government began its attempts to regulate nursing homes in 1935 with the passage of the Social Security Act. (R.R.[3/] at 253, Institute of

[3/] Materials from the rulemaking record are attached to Pls.' Mem. as Appendix 1, Rulemaking Record and will be referred to hereinafter as "R.R. at ___."

Medicine, *Improving the Quality of Care in Nursing Homes* (1986).)[4/] The creation of Medicare and Medicaid in 1965 changed the landscape regarding regulation of nursing homes, as federal funding and agency oversight of nursing homes expanded. (*See id.* at 256.) Ultimately, a major overhaul of the nursing home regulatory system occurred in 1987 with the passage of the Omnibus Budget Reconciliation Act of 1987 ("OBRA '87"), H.R. Rep. No. 100-391(I), at 452 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-272. It is this Act and the regulations promulgated thereunder, as well as the survey protocol used to monitor compliance with the regulations, that is at issue here.

However, before the Court can address these legislative and regulatory developments, it is necessary to digress momentarily to discuss the protracted litigation in *Smith v. Bowen* that took place beginning in the 1970s and lasted through the 1990s. In 1975, Medicaid recipients filed a class action lawsuit seeking to require the agency to meet its statutory duty to provide residents of nursing homes with adequate care. *See Estate of Smith v. O'Halloran*, 557 F. Supp. 289 (D. Colo. 1983), *rev'd sub. nom., Estate of Smith v. Heckler*, 747 F.2d 583 (10th Cir. 1984). In 1984, the Tenth Circuit reversed the district court's decision and held that the agency had failed to meets its statutory duty of examining whether facilities were providing adequate care. *See Estate of Smith*, 747 F.2d at 589-90. The Tenth Circuit concluded:

> The Secretary of Health and Human Services ha[d] a duty to establish a system to adequately inform herself as to whether the facilities receiving federal money are satisfying the requirements of the Act. These requirements include providing high quality patient care. This duty to be adequately informed is not only a duty to be informed at the time a facility is originally certified, but is a duty of continued

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[4/] A more detailed history of nursing home regulation from 1935 through the early 1980s is provided in Appendix A to the Institute of Medicine Report. (*See* R.R. at 253-64.)

> supervision. Nothing in the Medicaid Act indicates that Congress intended the physical facilities to be the end product. Rather, the purpose of the Act is to provide medical assistance and rehabilitative services. 42 U.S.C. § 1396. The Act repeatedly focuses on the care to be provided, with facilities being only part of that care.

Id. at 589. The Tenth Circuit issued an order requiring the Secretary "to promulgate regulations which will enable her to be informed as to whether the nursing facilities receiving federal Medicaid funds are actually providing high quality medical care." *Id.* at 591. As to implementation of the remedy, the Court, however, recognized that it was not a "super agency" and could not control "the specifics of how the Secretary satisfie[d] the duty." *Id.*

Thereafter, on remand in 1985, the district court ordered the Secretary of HHS to "develop and publish a notice of proposed rule making, consistent with the requirements of the APA, regarding a new survey system which will enable the Secretary to perform the duty prescribed by the Tenth Circuit Court of Appeals." *Estate of Smith v. Heckler*, 622 F. Supp. 403, 411 (D. Colo. 1985). In March 1987, the court required the Secretary to publish a Notice of Proposed Rule Making ("NPRM") that included the guidelines and forms of the survey protocol. *Estate of Smith v. Bowen*, 656 F. Supp. 1093 (D. Colo. 1987). In response, the Secretary published an NPRM on July 1, 1987. *See* 52 Fed. Reg. 24752 (July 1, 1987). In December 1987, upon plaintiffs' motion for contempt, alleging that the NPRM was defective because it contained only substantive standards of care, the court concluded that the agency was technically in contempt of court and must "promulgate regulations to effectuate the congressional purpose. . . . Under the Act, the states are responsible for establishing health standards and for determining whether institutions meet and continue to satisfy the requirements for participation in the Medicaid program." *Estate of Smith v. Bowen*, 675 F. Supp. 586, 589 (D. Colo. 1987). The

court stated:

> To exercise the discretion granted by Congress, the Secretary must remain informed, on a continuing basis, whether facilities receiving federal money are meeting the requirements of the Act. To become and remain informed, *the Secretary must establish uniform standards for facility performance and a uniform methodology for evaluating that performance to ensure the delivery of high quality health care*. Thus, the regulations required for these purposes must be prescriptive and legislative.

Id. at 589 (emphasis added).

As the *Smith* litigation was proceeding, the legal landscape was shifting throughout the 1980s. Congress and HCFA increased their focus on remedying the serious deficiencies in the nursing home regulatory system. In 1983, HCFA contracted with the Institute of Medicine to conduct a study on nursing home care in America and how it could be improved. HCFA was concerned that nursing homes were not providing a sufficient level of care and that the enforcement system was too lax. As a result, IOM published its report in 1986, entitled *Improving the Quality of Care in Nursing Homes* ("IOM Report"), which concluded that "[t]here is broad consensus that government regulation of nursing homes, as it now functions, is not satisfactory, because it allows too many marginal or substandard nursing homes to continue in operation." (R.R. at 17.) The IOM Report noted that too many government certified nursing homes provided "very inadequate -- sometimes shockingly deficient -- care." (*Id.*) It also indicated that many studies of nursing home care, which were conducted in the 1970s and 1980s, identified "both grossly inadequate care and abuse of residents." (*Id.* at 18.)[5/] The

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[5/] "The deficient conditions included neglect and abuse leading to premature death, permanent disability, and unnecessary fear and suffering on the part of residents. . . . Residents are often treated with disrespect; they are frequently denied any choices of food, of roommates, of the time they rise and go to sleep, of their activities, of the clothes they wear, and of when and where they may visit with

IOM Report reached the following conclusions:

> (1) quality of care and quality of life in many nursing homes are not satisfactory;
> (2) more effective government regulation can substantially improve quality in nursing homes and a stronger federal role is necessary;
> (3) specific improvements are needed in the regulatory system;
> (4) there are opportunities to improve quality of care independent of changes in Medicaid payment policies or bed supply;
> (5) regulation is necessary but not sufficient for high-quality care;
> (6) a system to obtain standardized data on residents is essential; and
> (7) the regulatory system should be dynamic and evolutionary in outlook.

(*Id.* at 36-39.)

With respect to the regulatory system, the IOM Report recommended that the requirements imposed on nursing homes to participate in the Medicare and Medicaid programs be strengthened. IOM concluded that the three central requirements needed to provide sufficient nursing home care were: "(1) a competently conducted, comprehensive assessment of each resident; (2) development of a treatment plan that integrates the contributions of all relevant nursing home staff, based on the assessment findings; and (3) properly coordinated, competent, and conscientious execution of all aspects of the treatment plan." (*Id.* at 63.) Among its recommendations for improving the regulatory system, IOM proposed a two-stage survey process with a standard and an extended survey taking place after a preliminary assessment. (*Id.* at 129-30.)

B. OBRA '87

On December 22, 1987, Congress passed OBRA '87, Pub. L. No. 100-203, which imposed strict new requirements on nursing homes and enacted measures to improve the enforcement process.

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family and friends. . . . The quality of medical and nursing home care also leaves much to be desired." (*Id.*)

In an effort to improve the quality of care that Medicare and Medicaid recipients were receiving in such facilities, Congress adopted many of the recommendations of the IOM Report and revised the conditions it required for facilities to participate in the Medicare and Medicaid programs, the survey and certification process used to oversee participating facilities, and the sanctions that were to be imposed on noncompliant facilities. In enacting OBRA '87, "the central purpose . . . [wa]s to improve the quality of care for Medicaid-eligible nursing-home residents, and either to bring substandard facilities into compliance with Medicaid quality of care requirements or to exclude them from the program." H.R. Rep. No. 100-391(I) at 452, *reprinted in* 1987 U.S.C.C.A.N. at 2313-272.

In OBRA '87, Congress established over 100 conditions for facilities to receive Medicare and Medicaid funds. To monitor compliance with these conditions, nursing homes have to enter into provider agreements that permitted unannounced annual standard surveys under 42 U.S.C. §§ 1395i-3(g) and 1396r(g). Pursuant to contracts with state agencies, state surveyors have to conduct yearly surveys to determine whether nursing homes are meeting their statutory requirements. *See id.* §§ 1395aa, 1395i-3(g), 1396r(g). Surveyors must use a "case-mix stratified sample of residents," and conduct "a survey of the quality of care furnished" by the facility as measured by various quality of life and of care indicators, an evaluation of resident assessments, and a review of the facility's compliance with residents' rights. *Id.* §§ 1395i-3(g)(2)(A)(ii), 1396r(g)(2)(A)(ii). If surveyors conclude that a nursing home provides "substandard quality of care," then an extended survey is done immediately. *See id.* §§ 1395i-3(g)(2)(B), 1396r(g)(2)(B).

Under OBRA '87, state "surveyors" must conduct these surveys using a "survey protocol" that has been "developed, tested, and validated." 42 U.S.C. §§ 1395i-3(g)(2)(C), 1396r(g)(2)(C). The

survey protocol consists of the forms, procedures, and guidelines that state surveyors use in assessing compliance by nursing homes with their statutory obligations. The survey is to be conducted by a "multidisciplinary team of professionals," which must include a registered professional nurse. *Id.* §§ 1395i-3(g)(2)(E), 1396r(g)(2)(E). The Secretary must provide for "the comprehensive training of State and Federal surveyors in the conduct of standard and extended surveys." *Id.*[6/]

With respect to the requirements of the survey protocol, OBRA '87 specifies that:

> Standard and extended surveys shall be conducted–
>
> **(i)** based upon a protocol which Secretary has developed, tested, and validated by not later than January 1, 1990, and
>
> **(ii)** by individuals, of a survey team, who meet such minimum qualifications as the Secretary establishes by not later than such date.
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> The failure of the Secretary to develop, test, or validate such protocols or to establish such minimum qualifications shall not relieve any State of its responsibility (or the Secretary of the Secretary's responsibility) to conduct surveys under this subsection.

Id. §§ 1395i-3(g)(2)(C)(i), 1396r(g)(2)(C)(i). OBRA '87 also specifies that: "Each State shall implement programs to measure and reduce inconsistency in the application of survey results among surveyors." *Id.* §§ 1395i-3(g)(2)(D), 1396r(g)(2)(D).

C. Post-OBRA '87 Agency Action

Given OBRA '87's sweeping substantive changes to the regulatory framework governing nursing homes, defendants were required to publish substantive rules regarding participation and enforcement requirements.[7/] The rules containing participation requirements, which are located at 42

[6/] "No individual shall serve as a member of a survey team unless the individual has successfully completed a training and testing program that has been approved by the Secretary." *Id.*

[7/] The enforcement regulations, which are discussed *infra* Section V, became effective on June 1, 1995.

C.F.R. §§ 483.1-483.75, became fully effective on October 1, 1990. *See* 54 Fed. Reg. 5316; *see also* 56 Fed. Reg. 48826 (Sept. 26, 1991) (containing rules effective April 1, 1992, which contained changes following comment period). They were much more outcome-oriented than the pre-OBRA '87 regulations, and they changed the focus to how services are provided to residents and the actual or potential effect on residents rather than on a facility's capacity to provide services. *See* 56 Fed. Reg. at 48826. The new regulations contained a host of new substantive provisions enacted pursuant to OBRA '87 and its emphasis on quality of life concerns. For example, the regulations require facilities to respect dignity, privacy, and the right of self-determination and to provide for medically-related social services. *See* 42 C.F.R. § 483.15. In short, the post-OBRA '87 regulatory scheme was far more comprehensive in scope than its predecessor.

After passage of OBRA '87, but before its effective date on October 1, 1990, HCFA sought relief from the 1987 court orders in *Smith* requiring promulgation of survey forms, guidelines, and procedures through notice and comment proceedings. The agency argued that congressional action had mooted any need for formal rulemaking. On February 18, 1988, the district court denied the agency's Motion To Vacate Judgment and Order In Light Of New Legislation. *Smith v. Bowen*, 1988 WL 235574, at *1 (D. Colo. Feb. 18, 1988). Since the court appreciated that there would be a substantial period of time before the pertinent OBRA '87 amendments would be effective, it concluded that there was no reason to allow the agency to delay implementation any longer. *Id.* In response, on June 17, 1988, the Secretary published regulations that contained the forms, procedures, and guidelines in use at the time. *See* 53 Fed. Reg. 22,850 (June 17, 1988) (codified at 42 C.F.R. Part 488, Subpart C).

Pursuant to OBRA '87, the agency promulgated its participation regulations through notice and comment rulemaking proceedings. These regulations became effective as of OBRA '87's effective date -- October 1, 1990. Given the fundamental changes to the system brought about by OBRA '87, the agency again sought relief from the district court with respect to its prior orders. In response, the court found on September 27, 1990, that it was "necessary to permit the Secretary to implement the survey forms, procedures, and interpretive guidelines . . . without requiring notice and comment rulemaking pursuant to the Administrative Procedures Act . . . ." in order to "facilitate the implementation of the nursing home reforms of OBRA '87 without final resolution of the issues before the Court." (Pls.' Mem. Ex. 33, *Smith v. Sullivan*, Order at 2 (Sept. 27, 1990).) Based on this finding, the court held that "[e]ffective October 1, 1990, the Secretary shall be permitted on an interim basis to require the use of the new survey forms, procedures, and interpretive guidelines . . . ." (*Id.*) The court also held that the survey and certification forms and guidelines located at 42 C.F.R. Part 488, Subpart C "shall be suspended but not repealed pending further orders of this Court regarding the appropriateness of the relief sought by the Defendant's Motion." (*Id.*) Since this order in 1990, the court has not again taken up this issue, and the protocol that was passed without notice and comment, has now been in effect since October 1, 1990.

Consistent with the court's order, the agency has used this new survey protocol based on the duly promulgated participation regulations and the requirements of OBRA '87, and it has required that it be used by all surveyors to investigate nursing homes. Thereafter, it released revised procedures to

the survey protocol in the April 1992 State Operations Manual ("SOM"). (*See* A.R. at 14349.)[8/] The agency also subsequently released two revised versions of the survey protocol, Appendix P to the SOM, released in 1995 (*see* Pls.' Mem. Ex. 21), and Appendices P and PP to the SOM, released in 1999. (*See* Defs.' Mem. Exs. 6 and 7.)[9/]

Section 2712 of the SOM, "Use of the Survey Protocol in the Survey Process," notes that:

> Survey protocols are established to provide you with guidance in conducting surveys to assess the compliance of providers and suppliers participating in the Medicare and Medicare programs with certain regulatory requirements. . . . [Their purpose] is to provide instructions, check lists, and other tools for use both in preparation for the survey and when you are on-site performing the survey.

(Pls.' Mem. Ex. 21 at 2-137.) The SOM further indicates that:

> Survey protocols identify relevant areas and issues to be surveyed as specified in each regulation, and, in some cases, the methods to be used to survey those areas and issues. These protocols promote consistency in the survey process. They also assure that a facility's compliance with the regulations is reviewed in a thorough, efficient, and consistent manner.

(*Id.*)

Part I of the survey protocol -- "Survey Procedures for Long Term Care Facilities" -- outlines the survey tasks:

> Task 1: Offsite Survey Preparation (*see id.* at P-5 - P-7);
> Task 2: Entrance Conference/Onsite Preparatory Activities (*see id.* at P-7 - P-10);
> Task 3: Initial Tour (*see id.* at P-10 - P-13);
> Task 4: Sample Selection (*see id.* at P-13 - P-19);

[8/] Materials from the administrative record compiled in *Beverly Health and Rehab.-Spring Hill*, DAB No. CR553 (1998), *available at* 1998 WL 839612 (Oct. 27, 1998), *aff'd*, DAB No. 1696 (1999), *available at* 1999 WL 482433 (Jul. 1, 1999), are attached to Pls.' Mem. as Appendix 2, Administrative Record and will be referred to as "A.R. at ___."

[9/] Citations throughout are to the survey protocol in existence at the time the survey at issue took place unless otherwise noted. (Pls.' Mem. Ex. 21.)

Task 5: Information Gathering (General Observations of the Facility; Kitchen/Food Service Observation, Resident Review, Quality of Life Assessment, Medication Pass, and Quality Assessment and Assurance Review) (*see id.* at P-20 - P-41);
Task 6: Information Analysis for Deficiency Determination (*see id.* at P-41 - P-46); and
Task 7: Exit Conference. (*See id.* at P-46 - P-48.)

Part I describes the steps that surveyors must take when performing each task. Appendix P also contains instructions for conducting extended and partial extended surveys. (*See id.* at P-46.) It also instructs surveyors on writing the statement of deficiencies, noting that the statement should:

- Specifically reflect the content of each requirement that is not met;
- Clearly identify how/why the requirement is/was not met;
- Identify the extent of the deficient practice, including systemic practices, where appropriate;
- Identify the source(s) of evidence (*e.g.*, interview, observation, or record review); and
- Identify the impact or potential impact of the facility's noncompliance on the resident, and how it prevents the resident from reaching his/her highest practicable physical, mental, or psychosocial well-being.

(*Id.* at P-48.) The Appendix also addresses deficiency categorizations and provides guidance on severity and scope levels (*see id.* at P-49), and it discusses confidentiality and respect for resident privacy. (*See id.* at P-54).

Part II of the survey protocol, "Guidance to Surveyors -- Long Term Care Facilities," provides surveyors with multiple forms designed to provide guidance on various regulations. Each form is organized in three tabular columns. The first column identifies the tag number, the second provides the text of the regulation, and the third contains guidelines, procedures, and probes.

LEGAL ANALYSIS

II. DO PLAINTIFFS HAVE STANDING TO CHALLENGE THE SURVEY PROTOCOL?

Before addressing the merits of plaintiffs' claims, the Court must first determine whether plaintiffs have standing to challenge the validity of the survey protocol. The question of standing involves both constitutional limitations on federal court jurisdiction, as well as prudential limitations on its exercise. *See Bennett v. Spear*, 520 U.S. 154 (1997); *see also Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1323 (D.C. Cir. 1996). Article III constitutional standing limits judicial intervention to genuine disputes between adverse parties which are "'in a form . . . capable of judicial resolution,'" *Florida Audubon Society v. Bentsen*, 94 F.3d 658, 663 (D.C. Cir. 1996) (quoting *Flast v. Cohen*, 392 U.S. 83, 101 (1968)), and therefore, it "'is an essential and unchanging predicate to any exercise of [federal] jurisdiction.'" *Id.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)).

To meet the "irreducible constitutional minimum" requirements for Article III standing, plaintiffs bear the burden of showing that: (1) they have suffered an injury which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; (2) there is a causal connection between the alleged injury and conduct that is fairly traceable to defendants, and not the result of the independent action of some third party not before the court; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *See Lujan*, 504 U.S. at 561-62. Because the elements of standing are "not mere pleading requirements, but rather an indispensable part of the plaintiff's case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Id.* at 561. If "plaintiffs' standing does not

adequately appear from all materials of record, the complaint must be dismissed." *Warth v. Seldin*, 422 U.S. 490, 502 (1975).

A. Injury In Fact

Plaintiffs first bear the burden of establishing an injury in fact. *See Lujan*, 504 U.S. at 561. Plaintiffs must show that they suffer a "concrete and particularized" injury that is "actual or imminent." *Id.* at 560. Defendants argue that the "thrust of [plaintiffs'] evidence is that, if there is any problem with the nursing-home enforcement process, it is that it does not uncover as many violations as it could." (Defs.' Reply at 5.) According to defendants' argument, plaintiffs are not injured from "underenforcement," and thus, they have no standing to challenge the validity of the survey protocol. Plaintiffs respond that their injury is concrete and particularized, since they have suffered two distinct types of injuries. First, they argue that the Spring Hill facility was terminated and incurred substantial civil penalties based on an invalid instrument that has not been tested or validated as required by Congress and that produces arbitrary and inconsistent results in violation of federal law. Second, plaintiffs argue that they are injured because they will continue to be subjected to this illegal protocol in the future. (*See* Pls.' Opp. at 5-11.)

It is beyond dispute that plaintiffs have suffered injury and will continue to suffer injury in the future, because their 300 nursing homes nationwide will be subjected to an allegedly illegal survey at least every fifteen months, pursuant to 42 U.S.C. §§ 1395i-3(g)(2), 1396r(g)(2), and "an agency rule . . . is typically reviewable without waiting for enforcement." *Chamber of Commerce v. FEC*, 69 F.3d 600, 604 (D.C. Cir. 1995). Moreover, plaintiffs convincingly compare this case to *Abbott Laboratories v. Gardner*, 387 U.S. 136, 153-54 (1967); *Bristol-Myers Squibb Co. v. Shalala*, 91

F.3d 1493 (D.C. Cir. 1996); and *Chamber of Commerce*, 69 F.3d at 604. In all three cases, the Courts held that plaintiffs had standing to challenge rules that had a continuous or future impact on them. For instance, in *Abbott Laboratories*, the Supreme Court granted standing to drug companies challenging the Food and Drug Administration's regulation, since "the regulation [wa]s directed at [drug companies] in particular; it require[d] them to make significant changes in their everyday business practices; [and] if they fail[ed] to observe the Commissioner's rule they [we]re quite clearly exposed to the imposition of strong sanctions." 387 U.S. at 154. *See also Bristol-Myers Squibb Co.*, 91 F.3d at 1498 (challenged regulations create "threat of recurring harms"); *Chamber of Commerce*, 69 F.3d at 604.

Here, there can be no dispute that the survey protocol is directed at nursing homes, it substantially impacts plaintiffs' everyday practices, and they were exposed to sanctions, including termination and fines, after use of the survey. Moreover, defendants mischaracterize plaintiffs' claims by trying to suggest that they are only complaining about the protocol's failure to identify more violations. Rather, plaintiffs are challenging the agency's failure to use a tested and validated survey protocol and the resultant sanctions that flow from application of this allegedly illegal enforcement tool. (Pls.' Opp. at 10-11.) Thus, plaintiffs have met their burden of establishing that they have suffered an injury in fact.

B. Causation

Plaintiffs' alleged injury is also "fairly traceable" to defendants. *Lujan*, 504 U.S. at 560 (requiring causal connection between alleged injury and conduct "fairly traceable" to defendant). "A court may act only to redress injury that fairly can be traced to the challenged action of the defendant,

and not injury 'that results from the independent action of some third party not before the court.'" *Northwest Airlines, Inc. v. FAA*, 795 F.2d 195, 203-04 (D.C. Cir. 1986) (citation omitted); *see also Mideast Systems and China Civil Construction Saipan Joint Venture, Inc. v. Hodel*, 792 F.2d 1172, 1177 (D.C. Cir. 1986) ("The presence of an independent variable between either the harm and the relief or the harm and the conduct makes causation sufficiently tenuous that standing should be denied.").

Here, plaintiffs allege that defendants' actions are arbitrary and capricious. Plaintiffs challenge "the validity of the regulations and the process used by the Secretary to survey nursing facilities because the standards applied are too vague and surveyors are given too much discretion, because the Secretary has failed to test and validate the procedure as directed by Congress, and because a study commissioned by HCFA to evaluate the survey process demonstrated that the process is unreliable and inconsistent." (Compl. ¶ 24(b).) Furthermore, it is defendants who require their surveyors to use the survey protocol alleged to be invalid, and the use of the survey protocol can result in sanctions. *See* 42 U.S.C. §§ 1395i-3(g)(2)(C), 1396r(g)(2)(C).

C. Redressability

Plaintiffs have shown that there is a "substantial likelihood" that their injuries would be redressed by a favorable decision on the merits. "[Plaintiffs] need not show to a certainty that a favorable decision will redress [their] injury. A mere likelihood will do." *Nat'l Wildlife Fed. v. Hodel*, 839 F.2d 694, 705 (D.C. Cir. 1988). In their Complaint, plaintiffs have requested several remedies, including:

(1) that defendants' decision to terminate plaintiffs from the Medicare and Medicaid

> programs be vacated and given no legal effect;
> (2) that defendants be required to design a valid survey process conforming to statutory requirements;
> (3) that defendants be required to refrain from using invalid survey forms;
> (4) that 42 C.F.R., Part 488, Subpart C be properly amended or repealed; and
> (5) that defendants refrain from employing nursing home law enforcement regulations.

While it may be true, as argued by defendants (Defs.' Mem. at 32-33), that invalidation of the existing protocol would not redress the problem of underenforcement, this argument does not accurately represent plaintiffs' claim of injury. Moreover, it is clear that if plaintiffs were to succeed in invalidating the survey protocol, their injuries would be redressed, for they would not be exposed to an allegedly invalid protocol.

D. Prudential Standing and Statutory Authority to Bring Suit

Lastly, defendants claim that plaintiffs lack prudential standing, arguing that plaintiffs fall outside the required "zone of interests," because Congress intended to protect nursing home residents and not the nursing homes when enacting the survey and certification provisions of OBRA '87. (*See* Defs.' Mem. at 33-34.) Defendants, however, provide no case law in support of this argument; moreover, their reply does not even address plaintiffs' argument that they do not need to establish prudential standing, for when Congress has authorized a party to bring an action, such action "'eliminates any prudential standing limitations[.]'" *FEC v. Akins*, 524 U.S. 11, 20 (1998) (quoting *Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997)); *see also Bennett*, 520 U.S. at 163-64 (statutory provision stating "any person may commence a civil suit" negates prudential standing requirement).

To establish statutory authority to sue, plaintiffs rely upon the Supreme Court's decision in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 20-21 (2000), which involved a

strikingly similar and recent attempt by nursing homes to challenge the Secretary's enforcement regulations. In *Illinois Council*, an association of nursing homes brought suit against the Secretary, alleging, *inter alia*, that Medicare-related regulations violated OBRA '87. Specifically, they claimed that (1) certain terms, *e.g.*, "substantial compliance," were unconstitutionally vague; (2) the regulations and manual violated the statutory requirement seeking enforcement consistency, 42 U.S.C. § 1395i-3(g)(2)(D); (3) the regulations violated due process; and (4) the manual and agency publications created legislative rules not promulgated with necessary "notice and comment" and a statement of "basis and purpose," pursuant to 5 U.S.C. § 553. 529 U.S. at 6. The association "complain[ed] that a host of procedural regulations unlawfully limit the extent to which the agency itself will provide the administrative review channel leading to judicial review, for example, regulations insulating from review decisions about a home's level of noncompliance or a determination to impose one, rather than another, penalty." *Id.* at 23 (citing 42 C.F.R. §§ 431.153(b), 488.408(g)(2), 498.3(d)(10)(ii)).

While the Supreme Court held that there was a lack of federal question jurisdiction so that the association was unable to make an anticipatory challenge to the validity of the Medicare regulations, it nonetheless provided guidance as to how nursing home facilities should proceed in order to obtain judicial review by directing parties to proceed through the special review channel created by the Medicare statute (*see* 529 U.S. at 20-22), which is exactly what plaintiffs have done here:[10/]

[10/] The Medicare Act's special review provision states that a nursing home "dissatisfied . . . with a determination . . . is 'entitled to a hearing . . . to the same extent as is provided in' the Social Security Act, 42 U.S.C. § 405(b)," and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) . . . ." 42 U.S.C. § 1395cc(h)(1). Section (b)(2) of the Social Security Act relates to the administrative hearing to which a "dissatisfied" home is entitled, and section 405(g) of the Act enables the nursing home to obtain judicial review in this Court of the Secretary's "final

> The [association]'s members remain free, however, after following the special review route that the statutes prescribe, to contest in court the lawfulness of any regulation or statute upon which an agency determination depends. The fact that the agency might not provide a hearing for that particular contention, or may lack the power to provide one . . . is beside the point, because it is the "action" arising under the Medicare Act that must be channeled through the agency . . . . *After the action has been so channeled, the court will consider the contention when it later reviews the action. And a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide,* . . . including, where necessary, the authority to develop an evidentiary record. Proceeding through the agency in this way provides the agency the opportunity to reconsider its policies, interpretations, and regulations in light of those challenges.

Id. at 23-24 (emphasis added) (citations omitted). Thus, under *Illinois Council*, plaintiffs have statutory authority to bring suit.[11/]

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decision" after the hearing. *See Illinois Council*, 529 U.S. at 20-21.

[11/] It is furthermore clear that even if plaintiffs do not have statutory standing, their interests "arguably fall within the zone of interests protected or regulated by the statutory provision . . . invoked in the suit." *Bennett*, 520 U.S. at 162-63. The "zone of interests" test requires a court to discern the interests "arguably to be protected" by the statutory provision and then to determine if plaintiffs' interests are among them. *Nat'l Cred. Union Admin. v. First Natl. Bank & Trust Co.*, 522 U.S. 479, 492 (1998); *see also Grand Council of the Crees (of Quebec) v. FERC*, 198 F.3d 950, 956 (D.C. Cir. 2000). This test, however, does not require a showing of congressional intent to benefit plaintiffs. *See Nat'l Cred. Union Admin.*, 522 U.S. at 492. Plaintiffs must show only that the interests affected by the agency action are arguably protected under the statute. *Id.* Prudential standing does not exist where plaintiffs' interests are so "marginally related to . . . the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit" or if plaintiffs are only incidental beneficiaries of a statutory provision. *Clarke v. Securities Industry Ass'n*, 479 U.S. 388, 399, 414 (1987). Indeed, plaintiffs have prudential standing as parties that are "'regulated by the particular regulatory act being challenged'" and have "'the incentive to guard against any administrative attempt to impose a greater burden than contemplated by Congress.'" *Building Industry Ass'n of Superior Cal. v. Babbitt*, 979 F. Supp. 893, 900 (D.D.C. 1997) (quoting *Hazardous Waste Treatment Council v. Thomas*, 885 F.2d 918, 922 (D.C. Cir. 1989)).

III. DOES DEFENDANTS' USE OF THE SURVEY PROTOCOL VIOLATE THE STATUTE, THE APA, OR THE FIFTH AMENDMENT?

Plaintiffs argue that the decision to terminate Spring Hill from the Medicare program must be set aside. First, they argue that the agency's determination to terminate was predicated on findings based on an invalid survey protocol, because it has never been "tested[] and validated," as required by statute. Second, plaintiffs argue that the survey process produces arbitrary, inaccurate, and inconsistent results in violation of the Social Security Act, the Administrative Procedure Act ("APA"), and the Fifth Amendment to the Constitution.

With respect to plaintiffs' first argument, they cite to the statutory language requiring that surveys "shall be conducted . . . based upon a protocol which the Secretary has developed, tested, and validated by not later than January 1, 1990." 42 U.S.C. §§ 1395i-3(g)(2)(C), 1396r(g)(2)(C). Plaintiffs argue that this language requires that the survey protocol "produce accurate, reliable and consistent results" (Pls.' Mem. at 10), but despite this mandate, plaintiffs claim that:

> Year after year, defendants are ordered to adopt a survey protocol that produces accurate and consistent assessment of care. Time and again, defendants promise to develop and utilize valid and reliable measurements of the quality of care. Yet, the survey process still continues to be found inaccurate, unreliable and inconsistent in independent studies, in defendants' own studies, in studies performed by other government agencies and, in fact, by participants at every level in the delivery and receipt of nursing home care. The history of nursing home regulation is characterized by nothing so much as defendants' broken promises and obdurate failure to comply with the law, whether announced by courts or imposed by Congress.

(*Id.* at 14.)

With respect to their second argument, plaintiffs claim "[t]he mandate to measure and reduce inconsistency on a going forward basis sets forth Congress' requirement that the Secretary articulate

clearly and apply uniformly the standards and principles that govern his discretionary survey and enforcement decisions." (*Id.* at 47-48.) While conceding that the level of consistency and accuracy is not specified in the statute (*see id.* at 48), plaintiffs rely on studies, including a 2001 IOM Report (*id.* Ex. 14) and GAO and OIG Reports (*id.* Exs. 6, 9), that they claim demonstrate "substantial," "wide" and "considerable" variation of an unacceptable nature in the pattern of deficiency citations across states. (*Id*. at 52.) They argue that the survey and enforcement process is at odds with the goals of OBRA '87, because the protocol is not a credible tool to promote quality medical care. (*Id.* at 63) (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1988)). Lastly, plaintiffs and *amicus* AHCA argue that the protocol is so vague as to deny due process.

Based on these arguments, plaintiffs claim that the inspection findings are invalid and cannot be used to impose sanctions against nursing homes generally and Spring Hill in particular. They also contend that the survey protocol is an invalid instrument that cannot be used as an enforcement tool in the future.

At the outset, the Court must reject plaintiffs' attempt to reverse Spring Hill's termination on the grounds that the survey is "invalid." Contrary to plaintiffs' argument, the surveyors' inspection findings remain valid regardless of whether the survey protocol has been tested and validated, for OBRA '87 makes clear that the lack of a validated protocol does not discharge defendants of their statutory obligation to conduct surveys:

> Standard and extended surveys shall be conducted:
>
> > **(i)** based upon a protocol which Secretary has developed, tested, and validated by not later than January 1, 1990, and
> > **(ii)** by individuals, of a survey team, who meet such minimum qualifications as the Secretary establishes by not later than such date.

> *The failure of the Secretary to develop, test, or validate such protocols or to establish such minimum qualifications shall not relieve any State of its responsibility (or the Secretary of the Secretary's responsibility) to conduct surveys under this subsection.*

42 U.S.C. §§ 1395i-3(g)(2)(C), 1396r(g)(2)(C) (emphasis added).

Plaintiffs quote selectively from this statutory language by focusing only on the language requiring that the survey shall be conducted based upon a "protocol which the Secretary has developed, tested, and validated by not later than January 1, 1990," omitting the subsequent language. (*See, e.g.*, Pls.' Mem. at 9.) The statutory language, however, unambiguously states that the Secretary and States must conduct surveys, irrespective of whether the protocol has been validated, and as defendants observe, this language does not limit defendants' obligation to conduct surveys to the specific time period that elapses on January 1, 1990. Plaintiffs' interpretation would also contravene the remedial nature of OBRA '87 and its central purpose of "improv[ing] the quality of care." H.R. Rep. No. 100-391(I) at 452, *reprinted in* 1987 U.S.C.C.A.N. 2313-272. As the legislative history states: "[T]he failure of the Secretary to develop such protocols would not relieve the States or the Secretary of their responsibilities to conduct standard and extended surveys. It is the Committee's expectation that the use of protocols will enable facilities, residents, and residents' families and advocates to know how surveys will be conducted and how data will be analyzed to reach conclusions about the quality of care at a facility." *Id.* at 468, *reprinted in* 1987 U.S.C.C.A.N. 2313-288.

The Secretary correctly interpreted this same language in 1994 when deciding to implement 42 C.F.R. § 488.305(b), which states in relevant part, "[t]he State survey agency's failure to follow the procedures set forth in this section will not invalidate otherwise legitimate determinations that a facility's

deficiencies exist." *See* Fed. Reg. at 56,133-56,134. In responding to comments suggesting deletion of this provision and questioning whether it was sanctioned by Congress, the Secretary stated the belief that "the provision accurately reflects the intent of the Act . . . ." and reasoned:

> To invalidate legitimate determinations of noncompliance and leave them unaddressed would be in opposition to the mandate of OBRA '87 that all requirements be met and enforced, and would lead to inconsistent application of the law. Sections 1819(g)(2)(C) and 1919(g)(2)(C) of the Act reveal the intent of the Act very clearly. *These sections state that standard surveys must be conducted based upon a protocol, but add that the failure of the Secretary to develop, test or validate such a protocol will not relieve any State or the Secretary of the responsibility to conduct surveys. Because the Congress intended for survey results to be binding even when surveys were conducted in the absence of a formal protocol, it is clear that the Congress views the substance of survey findings to be of greater importance than the process used to identify them*. . . . [S]ince the source of noncompliance will not rest on whether the survey protocol was rigorously followed, but *on whether a requirement of the Act or the regulations has been violated*. . . . [W]hether or not a surveyor follows protocols must be subordinate in importance to whether or not a facility meets Federal participation requirements. Violations must be recognized and remedied appropriately if resident interests are to be protected and integrity is to remain in the enforcement system.

Id. (emphasis added). Thus, Spring Hill cannot avoid responsibility for its deficiencies based on an allegedly invalid protocol.

A. Standard of Review

With respect to plaintiffs' facial challenge to the protocol, they argue that it is fundamentally flawed, because it produces arbitrary, inaccurate, and inconsistent results. The Court must first determine if, as argued by defendants, this matter is committed to agency discretion, and if not, what is the appropriate standard of review.

Defendants argue that the Secretary's decision regarding the validation of the protocol is

unreviewable, because the contested agency action has been committed to agency discretion by law. *See* 5 U.S.C. § 701. There is, however, a strong presumption favoring judicial review of agency actions, *see, e.g.*, *Abbott Laboratories*, 387 U.S. at 140, which can be rebutted only by showing that "'(1) the statutes preclude judicial review; or (2) agency action is committed to agency discretion by law.'" *Natural Resource Defense Council, Inc. v. SEC*, 606 F.2d 1031, 1043 (D.C. Cir. 1979) (quoting 5 U.S.C. § 701(a)). It is undisputed that the statute does not expressly preclude judicial review. With respect to the second inquiry, the Court concludes that there is law to apply in a meaningful manner, and thus, it may exercise at least a limited power of review.

The exception to the general presumption favoring judicial review that defendants seek to invoke can apply only in "those rare instances where 'statutes are drawn in such broad terms that in a given case there is no law to apply.'" *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 410 (1971) (citation omitted). For instance, in *Heckler v. Chaney*, 470 U.S. 821, 830 (1985), the Supreme Court held that an agency's decision not to take an enforcement action was not reviewable.[12/] The instant facts, however, are distinguishable from *Chaney*, for they do not directly involve an agency's decision regarding whether to undertake an enforcement action; rather, plaintiffs challenge whether defendants have met their statutory mandate to "validate" the survey protocol. Thus, the statutory requirement is sufficiently removed from the enforcement and investigation process to fall outside of the

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[12/] *See also Robbins v. Reagan*, 780 F.2d 37, 46 (D.C. Cir. 1985) ("The 'committed to agency discretion' provision is a 'very narrow exception.' . . . The requirement of a heightened level of discernible standards controlling discretion to rebut the presumption of nonreviewability applicable in decisions not to take enforcement action must not be applied outside of that context. To do so would be to frustrate Congress's clear intention, and the long tradition, of allowing judicial review when it can carry out an effective function.") (citations omitted).

enforcement arena.[13/]

In determining what standard to apply, this Circuit's reasoning in *Robbins* is instructive:

> Even when there are no clear statutory guidelines, courts often are still able to discern from the statutory scheme a congressional intention to pursue a general goal. If the agency action is found not to be reasonably consistent with this goal, then the courts must invalidate it. The mere fact that a statute grants broad discretion to an agency does not render the agency's decision completely nonreviewable under the 'committed to agency discretion by law' exception unless the statutory scheme, taken together with other relevant materials, provides absolutely no guidance as to how that discretion is to be exercised.

Robbins, 780 F.2d at 45. As noted by the Circuit Court, "courts have a clear role to play in ensuring

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[13/] The Court would reach a similar result even if it were to conclude that this case falls within the enforcement arena and is thus committed to agency discretion, because there is still law to apply. *See Giacobbi v. Biermann*, 780 F. Supp. 33, 37 (D.D.C. 1992), *aff'd*, 1992 WL 309042 (D.C. Cir. Oct. 6, 1992), where this Court concluded that an investigation, like the final decision whether to undertake enforcement action, falls within the "enforcement arena" and therefore, was committed to agency discretion, but permitted review, because there was law to apply in a meaningful manner. The *Giacobbi* plaintiffs had challenged the Department of Labor's method of carrying out an investigation required by statute that was to occur prior to any enforcement decision. *See* 41 C.F.R. § 60-741.26(e). Because there was a statutory command, the Court rejected the government's "cramped" interpretation that it had no obligation to complete a "prompt investigation" within any time frame. *Giacobbi*, 780 F. Supp. at 38. Plaintiffs' reliance on *Giacobbi* (Pls.' Mem. at 24) supports this Court's power of review, but it must be construed as an implicit recognition that such review is severely constrained, for in *Giacobbi*, the Court limited its review to determining whether the investigation was "reasonable, i.e., so cursory or conducted in such an irresponsible manner that the intent of the statute and the regulation would not have been carried out." 780 F. Supp. at 38. The Court held:

> While the Court acknowledges that the statute does leave the agency considerable discretion to conduct the investigation in the manner it sees as appropriate, the statute does require that an investigation be undertaken promptly, be completed in a reasonable amount of time, and not be so cursory as to be a sham.

Id.

that an agency's practical implementation of its program is consistent with its own declared intentions and goals. Courts often have invalidated agency action because it simply did not comport with standards of rational decisionmaking given the agency's uncontested goal." *Id.* at 46 (citing *Telocator Network of America v. FCC*, 691 F.2d 525, 537 (D.C. Cir. 1982)). Thus, unless the presumption of reviewability is rebutted by an "affirmative showing that the statute's allocation of discretion is so broad that the Courts simply have no standards to apply," *Robbins*, 780 F.2d at 47, the agency's action must be reviewable.

Here, "the statutory scheme, taken together with other relevant materials, provides . . . guidance as to how the discretion is to be exercised." *Id.* at 46. The statutory language, 42 U.S.C. §§ 1395i-3(g)(2)(C), 1396r(g)(2)(C), mandates that surveys "*shall* be conducted . . . based upon a protocol which Secretary has developed, tested, and validated by not later than January 1, 1990." (emphasis added). Defendants attempt to avoid this statutory requirement by arguing that the word "shall" does not modify the word "validate" (*see* Defs.' Mem. at 36), but their argument is unpersuasive. Congress' language is plainly that "of obligation rather than discretion," *Bennett*, 520 U.S. at 172, and such mandatory language is evidence that Congress intended that the statute be subject to judicial review. *See, e.g.*, *Armstrong v. Bush*, 924 F.2d 282, 293 (D.C. Cir. 1991) (finding there was "law to apply" in a statute providing that agency heads "shall establish and maintain" records management programs and "shall establish safeguards against the removal or loss of records[.]") The mandatory nature of this requirement is also made clear by the House Committee Report's language summarizing statutory guidelines -- upon which defendants rely (*see* Defs.' Reply at 10) -- which states that the Secretary "must establish standard [and] extended survey protocols and min[imum]

qualifications for surveyors." H.R. Rep. No. 100-391(I) at 481, *reprinted in* 1987 U.S.C.C.A.N. at 2313-301. Thus, the presence of the word "shall" makes it mandatory for surveys to be conducted "using a tested and validated" protocol.

Under the familiar "arbitrary and capricious" standard in the APA, requiring a court to review whether the agency actions are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), the Court must determine here whether the agency's actions in fulfilling the statutory mandate to "validate" the survey "comport with standards of rational decisionmaking" given the goals of OBRA '87. *Robbins*, 780 F.2d at 45-46. In conducting such a review, it is, however, "well settled that the Secretary's decisions interpreting the Medicare Act are entitled to 'great deference.'" *Hampton General Hosp. v. Sullivan*, 980 F.2d 749, 755 (D.C. Cir. 1992). *See also Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994) ("The Supreme Court has made clear that courts must give heightened deference to the Secretary's interpretation of a 'complex and highly technical regulatory program' such as Medicare.") (quoting *Thomas Jefferson Univ. v. Shalala*, 114 S.Ct. 2381, 2387 (1994)); *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981) ("The Social Security Act is among the most intricate ever drafted by Congress."); *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1016 (D.C. Cir. 1999) ("In marking off the metes and bounds of our review under the second step of *Chevron*, we accord particular deference to the Secretary's

interpretation . . . 'given the tremendous complexity of the Medicare statute.'") (quoting *Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1054 (D.C. Cir. 1997)).

B. Legal Analysis

Applying this deferential standard of review to the record, the Court finds that the agency has complied with the requirements of the statute and the APA. As demonstrated below, plaintiffs' argument for invalidation is unsound and contrary to the substantial evidence that the agency has engaged in a continual and lengthy process of rational decisionmaking, consistent with the goals of OBRA '87, in an effort to develop, test, revise, and improve the survey protocol so as to validate it.

1. Flaws in Plaintiffs' Argument

a. There is no standard for judging accuracy and consistency

If one were to accept plaintiffs' argument, the Court would have to make decisions that Congress did not authorize it to make. It is not for the Court to determine what is the acceptable level of accuracy or consistency, for neither the statute nor its legislative history defines how much inconsistency or inaccuracy is too much.[14/] Congress appreciated the complexity and enormity of the agency's task of developing an enforcement process to ensure that nursing homes provide an adequate level of care to the elderly -- and it did not expect perfection. Instead, it demanded the agency to take its charge seriously, but it anticipated that improvements would occur gradually. Congress acknowledged that there would be a certain level of inconsistency, and that even training would not eliminate the problem, so it required that "each State and the Secretary shall implement programs to

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[14/] Even plaintiffs concede that "the level of consistency and accuracy required by OBRA '87 is not specified in the statute." (Pls.' Mem. at 48.)

measure and reduce inconsistency in the application of survey results among surveyors." 42 U.S.C. §§ 1395i-3(g)(2)(D), 1396r(g)(2)(D). *See also* H.R. Rep. No. 100-391(I), at 468 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-288.[15/]

Even the dictionary definition of the term "validate" that plaintiffs offer does not require perfection or establish permissible levels of consistency and accuracy.[16/] Rather, it implies an ongoing process that will result in changes and refinements. Plaintiffs concede as much: "[T]he amendments did not merely obligate defendants to test and validate the survey protocol on a one-time basis, *i.e.*, prior to implementation. To the contrary, the statute requires on-going actions to assure accurate and consistent survey results." (Pls.' Mem. at 11.)

Plaintiffs nonetheless continually complain that the survey findings and sanctions are unacceptably inconsistent (*see, e.g.*, *id.* at 50), but they rely on vague generalities -- "[e]very study of the survey process . . . demonstrates that survey findings and enforcement sanctions continue to be unacceptably inconsistent . . . ." (*id.*); "[s]urvey results . . . are arbitrary and are characterized by gross

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[15/] Congress' emphasis on training to help reduce inconsistency is consistent with the IOM Report, which noted that in addition to improving surveyor consistency through better design of survey instruments and procedures, "better training, monitoring, and evaluation of surveyor performance" would also reduce inconsistency. (R.R. at 144.) In fact, the IOM Report concluded: "The importance of adequate training for surveyors to achieve consistency cannot be overemphasized. Such training should focus on the development among surveyors of a common language for describing what is observed during the course of a survey and the conclusions that are reached, techniques of eliciting relevant and useful information while surveying a facility
. . . . This training should not only increase the reliability and consistency of surveys, but also enhance the credibility of surveyors as a group with facility managers." (*Id.*)

[16/] Plaintiffs cite various dictionaries that define the word "validate" to mean "to corroborate or support on a sound basis or authority; verify; substantiate; to examine for correctness or bias; to confirm or check the correctness of; capable of being justified, supported, or defended." (Pls.' Opp. at 28.)

inconsistency . . . ." (*id.* at 51); "'variability . . . in consistency . . . is problematic . . . .'" (*id.*) (citing Pls.' Mem. Ex. 14, IOM 2001 Report); "inconsistencies" are "'substantial', 'wide' and 'considerable.'" (*id.* at 52); "'the pattern of citations suggest that states probably vary widely . . . .'" (*Id.* at 53) (quoting Pls.' Mem. Ex. 13, 1998 Report to Congress.) Plaintiffs, however, provide no yardstick for determining an acceptable level of variation, but leave it for the Court to decide, even though this is a matter within the agency's -- and not the Court's -- discretion and expertise.

b. Plaintiffs have failed to prove that the protocol is invalid

Plaintiffs have failed to present sufficient evidence that the survey protocol has not been validated, as required by statute. Although defendants acknowledge the validity of much of the data and criticisms presented by plaintiffs, they correctly argue that there is no conclusive evidence as to the cause of these problems. (*See* Defs.' Mem. at 38-39.) Correlation does not necessarily mean causation, for there are many other factors that contribute to the survey results.

For instance, there could be differences in the quality of care. In its 1998 Report to Congress, the agency identified the problem:

> Enforcement is inherently difficult to measure. Although there is considerable variation among states in degree of enforcement, as measured by rates of deficiency or substandard quality of care determination, it is difficult to separate what proportion of behavior is due to true differences in nursing home quality and what proportion is attributable to differences in surveyor behavior.

(Pls.' Mem. Ex. 13 at 41.) In fact, variability in results is desirable as long as it accurately reflects the differential quality of care that is being provided in different locales.

Second, resident populations could differ in size or could have different characteristics that would impact the results. Additionally, surveyor performance could vary, and there could be legitimate

differences in professional judgment, which by definition can lead to varying results. As to the latter, the system requires some level of professional judgment. (*See* Defs.' Mem. Ex. 1 at 20) ("[P]rofessional judgment is an essential component in identifying poor care.")[17/] States also devote different levels of time and resources to the survey process or may have varying degrees of success in conducting unannounced surveys. (*See* Pls.' Mem. Ex. 28 at 31.)

Additionally, much of the critical data upon which plaintiffs rely relates to the problem of underreporting of deficiencies.[18/] (*See, e.g.*, Pls.' Mem. Ex. 28 at 10, 32-33, Testimony of William Scanlon; Pls.' Opp. Ex. 2 at 5, 2001 RFP.) However, underreporting does not necessarily result from an invalid survey protocol, nor does it mean that the protocol is not being used to find legitimate violations. It could be due to other factors, such as lax enforcement.

In sum, the evidence does not permit one to conclude that defects in the protocol are to blame for the inconsistencies and inaccuracies.

c. Plaintiffs' factual presentation regarding the survey protocol is inaccurate and incomplete

Plaintiffs mischaracterize both the agency's efforts to validate the protocol and the studies that have been undertaken to review the protocol. Plaintiffs also ignore studies that reach positive conclusions about the protocol, and they fail to acknowledge the improvements that have been made in

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[17/] As the IOM Report acknowledged, "[e]limination of professional judgment -- and the inconsistencies that are inescapably associated with it -- will never be possible, but some steps to introduce more objectivity and reliability into the regulatory system are possible." (R.R. at 86.)

[18/] Under *Heckler v. Chaney*, it is clear that the extent of defendants' enforcement efforts is unreviewable by a court. *See* 470 U.S. at 830.

the protocol since it was first used in the early 1990s.

For instance, plaintiffs do not take into account the studies published in the 1990s, which indicate that survey results are generally reliable. For example, in 1995 and 1996, the Center for Health Systems Research and Analysis ("CHSRA") at the University of Wisconsin concluded that independent researchers disagreed with only five percent of the deficiencies cited by the state surveyors considered. (*See* Defs.' Mem. Ex. 5 at 12.)[19/] A 1999 GAO Report examined 107 randomly selected survey reports, which spanned all ten regions, and relied on the fact that ninety-eight percent of surveys documented actual harm to residents to conclude that HCFA should increase its use of the existing survey by targeting repeat violators. (*See* Defs.' Mem. Ex. 3 at 2, 5-6.) Another 1999 GAO Report concluded that appropriate regulatory action had been taken in all eight examples that *amicus* AHCA had submitted to Congress as examples of allegedly inaccurate citations. (*See* Defs.' Ex. 4 at 2.)[20/]

Plaintiffs also misrepresent defendants' 1998 Report to Congress, focusing on its admission that "the new enforcement regulation does not appear to be working as intended[.]" (*See* Pls.' Mem. at 37) (quoting Pls.' Mem. Ex. 13 at 540.) But plaintiffs ignore the context of such a statement and the report's general conclusions noting progress: "With respect to . . . the existing system of survey and certification, evidence was produced that the OBRA '87 reforms implemented in October 1990 resulted in improved

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[19/] These researchers would have cited at least the same levels of scope and severity in nearly ninety percent of the surveys (20 of 23). (*Id.* at 12-13, 17.) Furthermore, the researchers indicated that there was significant underreporting of deficiencies, as the independent researchers would have cited more deficiencies in seventy-eight percent of the surveys. (*Id.*)

[20/] "[I]n each of the eight cases for which there was sufficient information for an objective assessment, we believe that appropriate regulatory action was taken." (*Id.*)

resident outcomes. Also, there is some suggestive but inconclusive evidence that the more recent enforcement provisions resulted in improvements in resident outcomes, although many of the enforcement processes we examined are not working as intended." (*Id.* at xiii.) Plaintiffs also rely on seven other studies (four GAO Reports from July 1998, March 1999, June 1999, and November 1999 and three reports issued by OIG) and the testimony of Dr. Scanlon before the Senate's Special Committee on Aging, but these materials merely point to the obvious fact that a complex, nationwide regulatory system that must rely on human beings for its implementation cannot be expected to be infallible. They do not prove that the protocol is invalid.

Plaintiffs reliance on defendants' Request for Proposal ("RFP"), published on July 12, 2001, to study "the effectiveness of enforcement" is misguided. (Pls' Opp. Ex. 2.) What plaintiffs point to as troubling is defendants' concession that "[a]lthough many aspects of this system have been studied, there is little empirical evidence supporting the most fundamental assumptions of this system, including a consensus of what the system has achieved or is expected to achieve." (Pls.' Opp. at 35) (quoting Pls.' Opp. Ex. 2 at 4, 10.)[21/] While this statement reflects significant agency concern with the oversight of nursing homes, the RFP nonetheless presents a far more nuanced picture than plaintiffs are willing to

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[21/] In the RFP, the agency admits:

> Finding out whether any enforcement action ultimately enures from this compliance determination is not only problematic, but to date not completely reported in any singular data repository open to empirical investigation. . . . Strange as this may seem, the amount of enforcement in the system is unknown. Consequently, the impact of this system on quality is unknown.

(*Id.* at 15.)

admit:

> During the last few years, there have been countless news reports, articles, and public hearings reporting the widespread occurrence of resident abuse, neglect, and problems of dehydration, malnutrition, and pressure ulcers. In response, beginning with HCFA's July Report to Congress . . ., there have been several studies and investigatory reports on various aspects of the system of survey and certification. *The HCFA study found that the OBRA '87 reforms implemented in October 1990 through July 1995 resulted in improved resident outcomes*. However, many of the enforcement processes, *e.g.*, the identification of serious problems, were not working as intended.

Id. (emphasis added).

Contrary to plaintiffs' slant, the RFP represents an effort to evaluate "an evolving package of reforms," the President's 1998 Nursing Home Initiative ("NHI"), which was instituted in response to HCFA and GAO reports. The NHI "centers on improving nursing home inspections by placing a stronger emphasis on looking for care problems related to pressure sores, dehydration, nutrition, and the use of restraints and strengthening state and federal enforcement efforts." (*Id.*) It is exactly the type of reform that Congress would have expected the agency to undertake to fulfill its statutory mandate. As noted in the RFP, in reviewing the effectiveness of the reforms, results have been mixed: "The GAO found some improvement, considerable remaining problems, and they were not prepared to make a final judg[]ment." (*Id.*) The agency's goals for the RFP are (1) "[to] conduct a study on . . . previously unstudied aspects of enforcement", (2) "[to] assess the overall effectiveness of the system"; and (3) "[to] identify policy issues and options for improvement." (*Id.* at 9.) Defendants should not be penalized for their candor, nor is the RFP a concession that the protocol is invalid. Rather, it constitutes compelling evidence that defendants are continuing their efforts to validate the protocol.

d. Plaintiffs' reliance on the Abt Report is misplaced

Plaintiffs' use of the Abt Report is likewise flawed and factually misleading. In September 1991, the agency contracted with Abt Associates, Inc. to evaluate the long-term survey care process. The purpose of this work was to test and validate the protocol -- to provide HCFA with "[a] full scale evaluation of the new survey process [that] is required under OBRA '87. P.L. 100-203, 42 U.S.C. § 1819(g)(2)." (A.R. at 14349.) In July 1993, defendants received a preliminary report from Abt, and the final report was released in December 1996.

Abt conducted its review in the early and mid-1990s and based its findings on an early version of the protocol. Therefore, any criticisms are outdated and do not reflect the agency's efforts to date to examine and refine the protocol. Furthermore, the results of the Abt Report were not as negative as plaintiffs claim. The report was critical of the enforcement system and made numerous suggestions as to how to improve the system to produce greater consistency,[22/] but plaintiffs fail to mention Abt's findings that:

[22/] The Abt Report, released in December 1996, stated:

> This evaluation has identified several areas in which improvements are necessary to achieve the desired goal of a resident-centered, outcome-oriented survey that is implemented consistently nationwide. A significant concern is that the exercise of surveyor discretion can lead to harmful facility practices not being cited, or practices being inappropriately cited, in both quality of care and quality of life domains . . . . In general, the evaluation found that the survey guidelines developed by HCFA, which reflect current regulations, conform to the expectations of the IOM Report. However, the structure of the survey, the instruments employed, the training of surveyors, and the inclinations of many surveyors, do not readily result in the resident-centered, outcome-oriented process that the IOM envisioned. The evaluation results suggest that the survey process currently employed is in need of restructuring.

(*Id.* at 14331, 14332.)

> The current resident-centered, outcome oriented survey process represents a major step toward what the IOM had envisioned. The HCFA should be commended for implementing the changes it has made thus far. However, it should be noted that the process is very complex; surveyors must make judgments not only about outcomes that have been achieved, but also about outcomes that might have been achieved. It is difficult for individuals to exercise professional judgments consistently.

(*Id.* at 14319.) Thus, the Abt Report's results were mixed. "HCFA should be commended," but there was still much work to be done. The report recognized that there were numerous ways in which the survey process could be improved and included several recommendations that the agency subsequently adopted. The evaluation also concluded that the survey guidelines generally "conform to the expectations of the IOM Report." (*Id.* at 14331.)

Plaintiffs make much of the fact that the Abt Report specifically expressed concern with "quality of life" guidelines, but ignore the fact that Abt concluded that its quality of life study was "generally supportive of the content of the quality of life regulations and guidelines." (Defs.' Mem. Ex. 1, Decl. of Toby Edelman, Attachment C at 3.) Plaintiffs also mischaracterize defendants' response to the report, which reflected a genuine commitment to improving the survey process. Most noteworthy were defendants' efforts to implement Abt's recommendations regarding quality of life issues.[23/] HCFA's response to the Abt Report led directly to the introduction of revised quality of life

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[23/] In response to the Abt Report, HCFA worked with Abt and numerous organizations to improve the protocol regarding quality of life issues. After developing new protocols in conjunction with an Abt researcher, the agency designed a series of pilot tests of proposed improvements. Abt provided the subsequent "Report on the Pilot Studies for the Quality of Life Protocol" in which it affirmed the agency's new protocol, indicating that improvements were noticeable in investigations and documentation and that there were a larger number of quality of life citations. (*See* Defs.' Mem. Ex. 1, Decl. of Toby Edelman.) The agency also engaged in comprehensive training efforts to ensure proper implementation, and throughout the process, the agency continued to solicit the comments of interested

investigative protocols in 1995, which plaintiffs blithely dismiss as relating only to the quality of life portion of the protocol. But nonetheless, the circumstances surrounding the Abt Report confirm that validation has been an ongoing and sincere process.

e. The relief sought by plaintiffs contravenes OBRA '87's goals

Lastly, plaintiffs' requested remedies would eviscerate Congress' efforts to "improve the quality of care for . . . nursing home residents, and . . . to bring substandard facilities into compliance with . . . quality of care requirements . . . [,]" H.R. Rep. No. 100-391(I) at 452 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-272, for invalidating the protocol would cripple the inspection and enforcement process. The solution to fixing problems of underreporting and inconsistency is not, as plaintiffs suggest, to dismantle an imperfect enforcement system; rather, it is to continue to make improvements. As *amici* AARP and NCCNHR document, the essential purpose of the enforcement system under OBRA '87 was to protect some of the most vulnerable people in America. If anything, the government studies and investigations reveal the need for "stricter enforcement efforts, not elimination of the system." (AARP and NCCNHR *Amici* Br. at 15.) Therefore, plaintiffs' requested course of action would be contrary to the goal of protecting "[nursing home] residents [who] are the beneficiaries of the Medicare and Medicaid programs," which was the "motivating force behind

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parties, including, for example, representatives of AHCA and the American Health Information Management Association. (*See id.* Attachment A at 2.) Additionally, the agency followed the recommendations of Abt and others that HCFA develop numeric quality indicators that could be used to predict the overall quality of care so as to streamline the initial stage of the survey process. (*See* A.R. at 14338-14339.) After it developed these indicators, it trained surveyors and began using them in 1999. (*See* Defs.' Mem. Ex. 6, SOM, App. P (1999) at 5-11, 18-19.)

OBRA '87 and these regulations." 59 Fed. Reg. 56,116, 56,157 (Nov. 10, 1994).[24]

2. The Record Supports a Finding that Defendants Have Complied with the Statute's Mandate

Based upon a review of the record, it is clear that defendants have fulfilled their statutory mandate. Indeed, the agency has engaged in an ongoing and continual process of analysis and self-criticism in order to improve the instrument's reliability and accuracy.

Defendants developed the protocol only after extensive consultation.[25] They commissioned

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[24] As recognized by the Second Circuit:

> With regard to the substantiality of the government interest in the state and federal regulation of nursing homes, it can hardly be doubted that the interest is of the highest order. Many patients at nursing homes are helpless, and their physical and mental well-being and quality of life are often at the mercy of the operators and staff. . . . Mistreated patients may find it difficult or impossible to contact regulatory officials or to rebut denials by the operator or staff regarding conditions of care. Unannounced on-site inspections are thus essential to the regulatory scheme.

Blue v. Koren, 72 F.3d 1075, 1080-81 (2d Cir. 1995).

[25] Wayne Smith, the Director of HCFA's Office of Survey and Certification, avers that in developing its survey materials, HCFA desired to "maximiz[e] public participation in the drafting process. The plan . . . was to enlist the help of a myriad of consumer, industry, and government groups for the purpose, first of developing the outlines of a survey material package and second, to permit these groups to comment upon the drafts of the materials that were, in fact, developed." (Pls.' Opp. Ex. 1 ¶ 5, Decl. of Wayne Smith.) In his declaration, dated May 17, 1990, Dr. Smith further states:

> This public process took many months to complete and included the opportunity for 80 organizations and individuals to provide comments before the new survey materials were completed including the opportunity to be heard at a number of public meetings on the issues. . . . Additionally, once the materials were finalized, they were widely circulated not only to state survey agencies and HCFA regional offices, but to provider and consumer organizations as well.

(*Id.* ¶ 7.)

the Abt Report and took its conclusions seriously. Pilot tests, meetings, and revisions to the quality of life protocols resulted from the report. The agency has also made a major commitment to training of surveyors to reduce inconsistency, including use of the Principles of Documentation, which help to make uniform the writing of deficiencies and to ensure that surveyors collect necessary information.[26/] The agency commissioned the CHSRA study in 1995, which concluded that surveyor findings did not detect all deficiencies, but were generally accurate. (Defs.' Mem. Ex. 5.) In 1996, HCFA established a "national review team

. . . to conduct reviews of Statements of Deficiencies" in an effort to "clarify on-going survey process issues." (Pls.' Mem. Ex. 16.) In 1998, they issued guidance to regional offices. (*See id.*)

Significantly, the 1998 NHI focused on making improvements to nursing home inspections and strengthening state and federal enforcement efforts. As a result of the NHI, the revised 1999 protocol contained new investigative protocols. (*See* Defs.' Mem. Ex. 6 at 33-55.) In June 1999, the GAO recognized that HCFA had "undertaken about 30 initiatives intended to improve nursing home oversight and quality of care [between July 1998 and June 1999]." (Pls.' Mem. Ex. 4 at 18.) These initiatives were broadly categorized by the GAO as "improving the survey process to better detect noncompliance with federal nursing home requirements through strengthening annual surveys and complaint investigations; stricter enforcement to ensure that poorly performing nursing homes are identified and appropriate sanctions are imposed to achieve sustained compliance with federal nursing

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[26/] Defendants "have organized numerous educational sessions for Federal and State surveyors, held regional training conferences in the HCFA regions and produced the 'Principles of Documentation' which is an attempt to standardize the writing of deficiency citations." 59 Fed. Reg. at 56145.

home requirements; and better information to track homes' compliance and assess quality of care as well as to educate consumers and nursing home administrators."[27/] (Pls.' Mem. Ex. 4 at 18.) Lastly, in 2001, the agency issued an RFP to evaluate the initiative in an effort to improve and refine the survey protocol. (*Id.*)

Indeed, the fact that the implementation of the survey protocol has not yielded perfect results does not mean that the agency has abdicated its responsibility or acted recalcitrantly, as it may have

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[27/] In its June 1999 Report, GAO noted that HCFA sought to make improvements to the survey process in the following ways:

> (i) staggering or otherwise varying the scheduling of surveys to reduce predictability;
> (ii) taking stratified random samples of resident cases and reviewing sufficient numbers and types of resident cases to establish prevalence of problems;
> (iii) inspecting 100 nursing homes with poor compliance histories more frequently without decreasing inspection frequency for other homes;
> (iv) providing training and other assistance to States, or terminating funding to States with inadequate survey functions; and
> (v) enhancing HCFA review of state surveys;
> (vi) provide clearer guidance to surveyors on key quality-of-life/quality-of-care issues to assist in identifying nutrition, hydration, and pressure sore care problems;
> (vii) adding the survey task of assessing resident abuse intervention systems;
> (viii) developing standards for investigating allegations of actual harm;
> (ix) strengthening federal oversight of state complaint investigations; and
> (x) requiring substantiated complaints to be entered into federal data system.

(*See* Pls.' Mem. Ex. 4 at 18-19.) Specifically, as to efforts to make the timing of the protocol more unpredictable, HCFA began instructing States in 1999 to conduct 10% of the annual surveys on weekends or outside of normal working hours. As to HCFA's efforts to inspect homes with poor track records more often, HCFA identified two "special focus" homes per state in 1999, and surveys of these homes were to be done every six months. (*Id.* at 18.) *Amici* AARP and NCCNHR note that the NHI "helped reverse the declining numbers of deficiencies cited by survey agencies," for the average number of deficiencies per survey began to increase in 1999 from 5.2 to 5.7, and as noted by Professor Charlene Harrington, this rise was due to HCFA's "'growing emphasis on improving the survey and enforcement process.'" (AARP and NCCNHR *Amici* Br. at 22) (citation omitted.)

done during the *Smith* litigation. On the contrary, the agency's actions exemplify rational decisionmaking designed to further the goals of OBRA '87. Accordingly, the Court concludes that the use of the protocol is consistent with the statute and is not arbitrary and capricious within the meaning of the APA.

C. Plaintiffs' Constitutional Argument is Without Merit

The due process arguments raised by plaintiffs and *amicus* AHCA must also be rejected. First, plaintiffs fail to specify any regulations that they believe are too vague, nor do they explain how such regulations fail to provide "fair warning of what is proscribed." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 503 (1982). Additionally, plaintiffs are unable to challenge the regulations, because "'one to whose conduct a statute clearly applies may not successfully challenge it for vagueness.'" *Hastings v. Judicial Conference of the United States*, 829 F.2d 91, 105 (D.C. Cir. 1987) (citation omitted).

In addition to these legal reasons for rejecting plaintiffs' Fifth Amendment claim, it is noteworthy that even with respect to the eight examples that had been cited to the Chairman of the Special Senate Committee on Aging by *amicus* AHCA in support of its argument that the regulatory scheme is arbitrary and inconsistent, a 1999 GAO report found that appropriate action had been taken in all cases. (Defs.' Mem. Ex. 4 at 2.) Thus, their constitutional claim collapses, given its lack of any legal or factual support.

IV: CAN THE SURVEY PROTOCOL BE USED AS AN ENFORCEMENT TOOL IF IT WAS NOT PROMULGATED THROUGH NOTICE AND COMMENT RULEMAKING PROCEEDINGS?

Plaintiffs seek to invalidate the survey protocol on the grounds that it was not promulgated in accordance with the APA's notice and comment rulemaking requirements.

5 U.S.C. § 553(b). They base this argument on two grounds: (1) the survey protocol established substantive rules, and (2) the survey protocol amended or repealed duly promulgated regulations, 42 C.F.R. Part 488, Subpart C (hereinafter "Subpart C"). As demonstrated below, neither ground has merit.

A. The Survey Protocol is Substantive and Not Procedural

1. Legal Standard

Plaintiffs argue that Appendix P to the SOM (Pls.' Mem. Ex. 21) and Appendix Q (Pls.' Mem. Ex. 20) constitute "a compendium of substantive, legislative rules that may be adopted only through notice and comment rulemaking." (Pls.' Mem. at 64.) To decide this issue, the Court must determine whether the agency's guidelines set forth in Appendices P and Q are substantive or procedural. Substantive rules not promulgated in accordance with notice and comment rulemaking proceedings are invalid and will not be enforced. *See* 5 U.S.C. § 553(b); *see also Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 523-24 (1978). However, notice and comment rulemaking is not required under the APA for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice."

5 U.S.C. § 553(b)(3).

While "[t]he distinction between a substantive rule and an interpretive rule can be less than clear-cut," *Air Transp. Ass'n of America, Inc. v. FAA*, 291 F.3d 49, 55 (D.C. Cir. 2002); *General*

Motors Corp. v. Ruckelshaus, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (*en banc*) (distinction "enshrouded in considerable smog"), the Court must nonetheless determine "whether the agency action . . . encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior." *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987). Substantive rules create law, whereas interpretive rules are "'statements as to what an administrative officer thinks the statute or regulation means.'" *Id.* at 1044. Thus, the question is whether the agency guidelines located in Appendices P and Q "'grant rights, impose obligations, or produce other significant effects on private interests'" or "'effect a change in existing law or policy,'" in which case they are substantive. *Id.* at 1045 (citations omitted). Whereas, interpretive rules "'are those which merely clarify or explain existing law or regulations,' . . . are 'essentially hortatory and instructional,' . . . and 'do not have the full force and effect of a substantive rule but [are] in the form of an explanation of particular terms.'" *Id.* (citations omitted). *See also Paralyzed Veterans v. D.C. Arena L.P.*, 117 F.3d 579, 588 (D.C. Cir. 1997) ("We must look to whether the interpretation itself carries 'the force and effect of law,' . . . or rather whether it spells out a duty fairly encompassed within the regulation that the interpretation purports to construe.") (citations omitted)). Making such a determination is "an extraordinarily fact-specific endeavor" and analogies to other cases may be of only limited help. *American Hosp. Ass'n*, 834 F.2d at 1045.

2. Legal Analysis

Based on the Court's review of the guidelines located at Appendices P and Q to the SOM, it must conclude that they do not contain substantive rules that may only be adopted through notice and comment rulemaking. *See* 42 U.S.C. § 1395hh(a)(2)- (b); 5 U.S.C. §§ 551, 553(b)-(c). They are

procedural in nature, for Appendices P and Q merely "borrow[] the substantive standards of the statute and seek[] to channel agency enforcement resources toward ferreting out violations of the statute." *American Hosp. Ass'n,* 834 F.2d at 1057 n.4.

In reaching this conclusion, the Court is persuaded by the reasoning of *Vencor Nursing Ctrs., L.P. v. Shalala*, 63 F. Supp. 2d 1, 12 (D.D.C. 1999), where the Honorable Ricardo M. Urbina concluded at the preliminary injunction stage that the survey protocol constituted procedural rules that were not subject to notice and comment rulemaking. In *Vencor*, an owner of a nursing home facility that participated in the Medicare and Medicaid programs contested HCFA's actions, including its use of survey forms and procedures, as violative of the notice and comment requirements of APA. *Id.* at 11. The Court rejected this argument, finding that it "was not substantially likely to find that the SOM survey provisions are substantive rules subject to notice-and-comment requirements of the APA and the Medicare Act." *Id.* Here, as in *Vencor*, the "procedures complained of may 'relate to' a facility's eligibility to be paid under Medicare/Medicaid, but they do not 'govern' eligibility." *Id.* Rather, the standard governing eligibility "is set forth in regulations which have passed through the requisite process of publication and notice and public comment." *Id*. "[The SOM's] provisions on procedures specify the means by which the [survey agency] should collect and analyze information about a facility's compliance with regulatory standards. The SOM's forms, in turn, set forth the format in which the [surveyors] should summarize the information gathered and report its conclusions to HHS." *Id.* And, there is no evidence that the rules do "more than 'announce[ ] how the agency believes the [Medicare] statute should be enforced.'" *Id.* (quoting *American Society of Cataract & Refractive Surgery v. Bowen*, 725 F. Supp. 606 (D.D.C. 1989)).

This conclusion is also supported by this Circuit's analysis in *American Hospital Association*, which involved a challenge by an association of hospitals to certain directives and transmittals that contained instructions, guidelines, and procedures regarding a peer review organization ("PRO") program.[28/] The Court of Appeals concluded that HHS manuals containing procedures for the peer review program imposed "no new burdens on hospitals" and thus did not require agency rulemaking. *See* 834 F.2d at 1051. PROs were "essentially . . . enforcement agent[s] of the federal government for purposes of the regulations . . . . Hired pursuant to a contract with the government, a PRO monitors compliance with the HHS' strictures of the private hospitals who seek compensation from the agency." *Id.* at 1048. In commenting on one manual, the Court concluded that the agency had in effect issued an "enforcement plan," which imposed no additional burdens on hospitals, except that the manual made "it more likely that their transgressions from Medicare's standards w[ould] not go unnoticed" and it "impos[ed] on them the incidental inconveniences of complying with an enforcement

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[28/] In 1982, Congress amended the Medicare Act to implement a new method of reviewing the quality and appropriateness of the health care provided by these medical providers to Medicare. *See* 42 U.S.C. § 1320c. The new process required HHS to contract with "peer review organizations" ("PROs"), composed of doctors who would monitor "some or all of the professional activities of the provider of Medicare services in their areas." 42 U.S.C. § 1320c-3(a)(1). "In passing the 1982 amendments, Congress painted with a broad brush, leaving HHS to fill in many important details of the workings of peer review." *American Hosp. Ass'n*, 834 F.2d at 1041. Specifically, Congress had required HHS "to designate geographic areas generally corresponding to each state, to be served by individual peer review organizations," 42 U.S.C. § 1320c-2(a), and to enter into an agreement with peer review organizations in each area. 42 U.S.C. § 1320c-2(b)(1) and (c)(3). *See American Hosp. Ass'n*, 834 F.2d at 1041. The agency, however, had significant flexibility in fashioning the terms of each contract "to encourage PROs to be responsive to distinctive community needs and practices." *Id.* Under the 1982 amendments, hospitals were to enter into contracts with their area's PRO and agree to allow it to review the professional activities of physicians, hospitals, and other providers of health care to check whether they "conform[] with the substantive standards of the Medicare Act." *Id.* at 1042.

scheme." *Id.* at 1051.

The instant facts compel the same result as reached in *American Hospital Association*. The survey protocol merely "sculpt[s] the enforcement activity" of surveyors, who are HHS's agents. *Id.* at 1052. Here, the regulations at issue involve "monitoring the quality . . . [of care] provided," *id.* at 1050, and the protocol imposes "no new burdens on [nursing homes]." *Id.* at 1051. The only additional burdens imposed by the survey protocol are that it is "more likely that [plaintiffs'] transgressions from Medicare's standards will not go unnoticed" and "[the protocol] impos[es] on [nursing homes] the incidental inconveniences of complying with an enforcement scheme." *Id.* Thus, notice and comment rulemaking is not necessary.

In addition to the above case law, analysis of Appendix P shows that it is procedural. Part I of the protocol provides information that surveyors should use prior to and during their survey visit, and Part II offers surveyors forms that provide guidance on various regulations, including the text of the regulation and instructions regarding guidelines, procedures, and probes. There is no change to existing law or policy, as they are "written guidelines developed by an agency to aid their discretion" and therefore "are not binding rules." *Md. Dep't of Human Resources v. Sullivan*, 738 F. Supp. 555, 560 (D.D.C. 1990). Moreover, the agency has merely exercised the "'latitude [it retains] in organizing [its] internal operations.'" *American Hosp. Ass'n*, 834 F.2d at 1047 (citation omitted). Indeed, the protocol is an enforcement tool that aids surveyors in investigating nursing home compliance, and as recognized in *American Hospital Association*, "[e]nforcement plans by agencies to direct their enforcement activity warrant considerable deference." *Id.* at 1050.

The instant protocol is also similar to many agency guidebooks or handbooks that have been

held to be exempt from notice and comment proceedings. Essentially, the survey protocol is a compliance handbook issued to federal and state officials charged with conducting the surveys in compliance with OBRA '87's requirements. *See Cmty. Nutrition Institute v. Young*, 818 F.2d 943, 949 (D.C. Cir. 1987) (recognizing that agencies may develop written guidelines without the risk of "having a court transmogrify those guidelines into binding norms"); *see also United States Dep't of Labor v. Kast Metals Corp.*, 744 F.2d 1145, 1152 n.13 (5th Cir. 1984) ("[A]gency instructions to agency officers are not legislative rules.").[29/]

While plaintiffs attempt to cite examples of allegedly "substantive standards" (*see* Pls.' Mem. at 74-81), a review of even a few of these examples shows the weakness in their position. For example, plaintiffs provide no evidence that the identified survey tasks impermissibly impose new substantive requirements, but rather, plaintiffs state that "the survey tasks structure the nursing home survey, dictating what will be done during the inspection, what will be examined and how that examination will be conducted." (Pls.' Mem. at 75.) But, as the above case law demonstrates, providing specific tasks and instructions to surveyors does not transform the protocol into a substantive rule.

[29/] *Kast Metals Corp.* cites *Schweiker v. Hansen*, 450 U.S. 785, 789 (1981) (SSA Claims Manual without legal effect); *Roberts v. Cameron-Brown Co.*, 556 F.2d 356, 362 & n.11 (5th Cir. 1977) (HUD handbook not intended to have force of law); *Gatter v. Nimmo*, 672 F.2d 343, 347 (3d Cir. 1982) (VA manuals without force of law); *First State Bank of Hudson County v. United States*, 599 F.2d 558, 564 (3d Cir. 1979), (FDIC Manual setting up agency procedure not substantive); *Concerned Residents of Buck Hill Falls v. Grant*, 537 F.2d 29, 38 (3d Cir. 1976) (Soil Conservation Service manuals for internal operating procedures not binding on agency); *Brennan v. Ace Hardware Corp.*, 495 F.2d 368, 376 (8th Cir. 1974) (field operations handbooks without force of law).

Additionally, the survey protocol's guidance on use of physical restraints is tied to regulatory language. *See* 42 C.F.R. § 483.13. With respect to directions as to sampling standards, plaintiffs' allegation that the protocol "dictates the size of the sample relative to the size of the nursing home" (Pls.' Mem. at 75) is similarly unavailing, for there is no evidence that defendants have altered or added any statutory or regulatory language.[30/] Moreover, such sampling methods have consistently been found to be procedural. *See American Hosp. Ass'n*, 834 F.2d at 1049; *see also Md. Dep't of Human Resources v. Sullivan*, 738 F. Supp. at 559; *Kast Metals Corp.*, 744 F.2d at 1152.

Plaintiffs' complaint that Appendix P and Q "provide the only standards for surveyors to determine whether observations merit a deficiency citation" (Pls.' Mem. at 76) is likewise lacking in support. Section 2712 of the SOM provides that surveyors must "look to the substantive requirements in the statute and regulations to determine whether a citation of non-compliance is appropriate" and "base any deficiency on a violation of the statute or regulations." (Defs.' Mem. Ex. 8 at 2-137; Pls.' Mem. Ex. 21 at 2-137.) Surveyors must determine deficiencies not based on the survey protocol, but rather "the critical factor is whether or not the evidence directly relates to the language of the regulation." (*Id.* at 2-138.)

Plaintiffs' reference to the "over five pages of standards setting forth the decision-making process for making deficiency determinations" (Pls.' Mem at 72) ignores the fact that the term

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[30/] *Compare* Pls.' Mem. Ex. 21, Appendix P at P-13 (instructing surveyors "to select a case-mix stratified sample of facility residents in order to assess compliance with the resident-centered long term care requirements") *with* 42 U.S.C. § 1395i-3(g)(2)(A)(ii), 1396r(g)(2)(A)(ii) (mandating use of "case-mix stratified sample of residents" and requiring "a survey of the quality of care furnished" by the facility).

"deficiency" is merely defined as "a facility's failure to meet a participation requirement specified in the Social Security Act or in Part 483, Subpart B (*i.e.*, 42 CFR 483.5 - 42 CFR 483.75) [the regulations]." (Pls.' Mem. Ex. 21, Appendix P, at P-43.) *See also* 42 C.F.R. § 488.301. The protocol instructs surveyors that "[t]o help determine if a deficiency exists, look at the language of the requirement." (Pls.' Mem. Ex. 21, Appendix P at P-43.) Plaintiffs also selectively quote Appendix Q's characterization that an immediate and serious threat "'could be *perceived* as something which will result in *potentially* severe' injury, disability, or death." (Pls.' Mem. at 76) (emphasis in original). The full quote in Appendix Q's "Guiding Principles" reveals that "[1.] An immediate and serious threat need not result in <u>actual</u> harm to the patient. The threat of probable harm is perceived as being as serious or significant[; 2.] The threat could be perceived as something which will result in potentially severe temporary or permanent injury, disability, or death, and must be perceived as something which is likely to occur in the very near future." (Pls.' Mem. Ex. 20 at Q-3.) Plaintiffs contrast this to the fact that the regulation requires that "[i]mmediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation *has caused, or is likely to cause,* serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. (emphasis added). Plaintiffs raise a distinction without a difference, for the guiding principles of Appendix Q in no way alter the regulations. Appendix Q's definitions are "not intended to be all inclusive, nor are they intended to inhibit your professional judgment." (Pls.' Mem. Ex. 20, Appendix Q at Q-2.) They merely offer interpretive guidance.

Plaintiffs also claim that the protocol contains clinical standards for assessing the actual provision of care and determining appropriate outcomes. (*See* Pls.' Mem. at 78.) Plaintiffs, however,

do not show how any protocol obligations impose requirements that have not also been imposed by statute or regulation. Nor does the protocol impermissibly provide definitions for the terms "unavoidable," "pressure sores," and "necessary treatment," even if the regulations do not define these terms. *See* 42 C.F.R. § 483.25(c). Instead, the guidance in Appendix P does no more than provide clarification; it refers surveyors to a booklet ("Pressure Ulcers in Adults: Prevention and Treatment, Public Health Service Agency for Health Care Policy and Research") and provides a nonexhaustive list of risk factors for developing pressure sores. (Pls.' Mem. Ex. 21 at PP-93 - PP-94.)

Contrary to plaintiffs' contention, the regulations -- not the protocol -- set forth what constitutes a "significant change in the resident's . . . status" in 42 C.F.R. § 483.10(b)(11), which provides that a "significant change" is a "deterioration in health, mental, or psychosocial status un either life-threatening conditions or clinical complications." *Id.* With respect to "parameters of nutritional status," the protocol merely provides "suggested" parameters for evaluating weight loss and a reasonable, common-sense approach for calculating weight loss. Plaintiffs' allegation that the SOM "provides the only criteria for assessing the 'scope' and 'severity' of deficiencies" (Pls.' Mem. at 77) is likewise meritless, since the language directly quotes the regulations. (*See* Pls.' Mem. Ex. 21, Appendix P at P-48).

It is also noteworthy that the agency describes the protocol as "Interpretive Guidelines [that] merely define or explain the relevant statutes and regulations and do not impose any requirements that are not otherwise set forth in the statute or regulations." (Pls.' Mem. Ex. 21 at 2-137; Defs.' Mem. Ex. 8 at 2-137.) While by no means dispositive, the agency's view of the guidelines is not insignificant, for "it is well established that a court, in determining whether notice and comment

procedures apply to an agency action, will consider the agency's own characterization of the particular action," *American Hosp. Ass'n*, 834 F.2d at 1056, and will "generally given[] deference' to the agency's views." *British Caledonian Airways Ltd. v. Civil Aeronautics Bd.*, 584 F.2d 982, 991 (D.C. Cir. 1978).[31/]

B. Subpart C Did Not Have to Be Modified or Repealed by Notice and Comment

Finally, there is no merit to plaintiffs' second argument that defendants impermissibly repealed or modified Subpart C, which had been codified in the Code of Federal Regulations, and thereby violated the APA's requirements (5 U.S.C. §§ 551, 553(b)-(c)) that existing rules can be modified or repealed only through notice and comment rulemaking. (*See* Pls.' Mem. at 65.)[32/] While it is not disputed that Appendix P modified Subpart C (*see* Defs.' Reply at 25 n.27), this does not

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[31/] Additionally, administrative law judges and the DAB have treated the protocol as containing only procedural rules without the impact of binding law. *See, e.g.*, *Ruth Taylor Institute*, DAB No. CR430, *available at* 1996 WL 493107 (Aug. 21, 1996) ("[The SOM is] an interpretive guideline issued by HCFA. It is not a regulation, and it does not have the force and effect of law."); *see also Beverly Health and Rehab. of Williamsburg*, DAB No. CR653 *available at* 2000 WL 303011 (Mar. 8, 2000); *Golden State Manor and Rehabilitation Ctr.*, DAB No. 1507, *available at* 1996 WL 599831 (Sept. 16, 1996).

[32/] This rule is, of course, subject to the exception that notice and comment rulemaking requirements "do not apply -- (a) to interpretative rules, general statements of policy, or rules of agency organization or practice." 5 U.S.C. § 553. Obviously, since Subpart C and Appendix P are similar in content, it follows that § 553's exception should apply, despite the contrary ruling in the *Smith* litigation. *Estate of Smith v. Heckler*, 656 F. Supp. at 1097. However, as argued by defendants (*see* Defs.' Mem. at 78 n.58), that holding could be rejected on the grounds that it relied on the district court's ruling in *American Hospital Association* (*see* 640 F. Supp. 453 (D.D.C. 1986)), and that decision was reversed by the Circuit. *But see Estate of Smith*, 675 F. Supp. at 589-90 (rejecting this argument on the grounds that *American Hospital Association* dealt with a different factual context and was inconsistent with the Tenth Circuit ruling in *Estate of Smith*, 747 F.2d at 583, which was binding on the Colorado district court).

mean that the protocol had to be subjected to formal rulemaking given the fact that OBRA '87 and its regulations essentially eclipsed Subpart C, rendering it effectively obsolete.

Reference to the final chapter of the complex and protracted *Smith* litigation reveals that the court's requirement that Subpart C be subject to formal rulemaking was imposed prior to the effective date of OBRA '87 under a very different regulatory scheme for nursing homes. *See Estate of Smith*, 622 F. Supp. at 411, but that after OBRA '87 became effective, Subpart C was suspended and the new protocol was permitted to be used without notice and comment.

As documented in the orders in *Smith* (*see* 656 F. Supp. at 1095; 675 F. Supp. at 591), prior to the passage of OBRA '87, the Secretary was ordered to publish a Notice of Proposed Rulemaking, which included the survey forms and guidelines of the protocol. After passage of OBRA '87 but prior to its effective date and the implementation of its regulations, the district court rejected the agency's attempt to avoid notice and comment, and in early 1988, it entered an order again requiring that the survey procedures contained in Subpart C be published. *See Smith v. Bowen*, 1988 WL 235574, at *1 (D. Colo. Feb. 8, 1988). As explained by the court, this result was necessary because of the "substantial period of time before pertinent OBRA amendments must be implemented . . . ." *Id.* Pursuant to this order, in June 1988, the Secretary adopted as formal regulations the survey protocol composed of forms, procedures and guidelines, and codified such regulations at 42 C.F.R. §

Part 488, Subpart C.[33] In this way, Subpart C protected class litigants until OBRA '87's improved regulatory and enforcement scheme became effective on October 1, 1990.

In 1989, pursuant to OBRA '87, the Secretary also published proposed participation regulations that were to be subjected to notice and comment proceedings. *See* 54 Fed. Reg. 5316. The Secretary also developed new survey guidelines and procedures to monitor compliance with those requirements. Prior to the effective date of the regulations -- October 1, 1990 -- the agency returned to the court to revisit the issue of whether the new protocol had to be subject to notice and comment by filing a Motion for Relief. In support of its efforts, the agency argued that the new survey materials, now known as Appendix P, did not need to be published, given the fact that the new statute and regulations were considerably different from their predecessors. (*See* Pls.' Opp at 47 and Ex. 1, Decl. of Wayne Smith.) Ruling on this motion just prior to the effective date of OBRA '87, the court

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[33] At the time of passage, the agency noted: "The regulation define[d] the principles on which Medicare and Medicated survey methodologies are based and the required elements of a skilled nursing facility ("SNF") or intermediate care facility (ICF") survey. Th[is] rule [wa]s in response to a court order." 53 Fed. Reg. 22,850 (June 17, 1988). When publishing the final rule, the agency expressed its limited application:

> In the *Smith v. Bowen* case, the court ordered that we publish the final survey process rules by June 17, 1988. We continue to believe that, since the survey instrument measures compliance with the conditions of participation, changes to the conditions of participation are necessary to fully establish a resident-oriented system. We are developing final rules on conditions of participation for long term care facilities to accomplish this. In the meantime, we are complying with the court order by publishing these regulations, and we are planning additional revisions to the survey process rules at a later date after we issue a final rule that revises the conditions of participation.

Id. at 22,850-22,851.

entered an order on September 27, 1990, that it was necessary "to permit the Secretary to implement the survey forms, procedures, and interpretive guidelines . . . without requiring notice and comment rulemaking" in order to "facilitate the implementation of nursing home reforms of OBRA '87 without final resolution of the issues before the Court." (Pls.' Mem. Ex. 33, *Smith v. Sullivan*, Order at 2 (Sept. 27, 1990).)

Based on this conclusion, the court held that "[e]ffective October 1, 1990, the Secretary shall be permitted *on an interim basis* to require the use of the new survey forms, procedures and interpretative guidelines" and thus the court "suspended" Subpart C and "reserve[d] judgment on whether [the Secretary's] new survey materials should be promulgated as rules pursuant to notice and comment rulemaking . . . ." (*Id.*) (emphasis added.) Since this September 27, 1990 order, the district court has not issued a further ruling, even in the face of a motion for contempt filed after defendants adopted Appendix P to the SOM in 1992.

As this unusual and convoluted history makes clear, by court order in *Smith*, Subpart C was suspended, and for the past decade the agency has been permitted to use Appendix P, at least on an interim basis, without engaging in notice and comment rulemaking. The agency did not amend or repeal Subpart C, nor did it have to do so. Rather, Congress enacted a new statute (OBRA '87) that amended the existing statute, thereby rendering Subpart C obsolete and eliminating the need to undertake the useless exercise of repealing Subpart C by notice and comment. *See Hadson Gas Sys., Inc. v. FERC*, 75 F.3d 680, 684 (D.C. Cir. 1996) (where Congress enacts a new statute or amends an existing one, administrative regulations may be rendered unnecessary or obsolete and the prior

regulations need not be repealed by notice and comment).[34/] Thus, given the substantial and substantive changes that were embodied in OBRA '87 and the current nursing home participation regulations, the *Smith* rulings prior to 1990 have no bearing on the question before the Court.

V. ARE DEFENDANTS' ENFORCEMENT REGULATIONS INVALID BECAUSE OF A FAILURE TO RESPOND TO COMMENTS REGARDING THE INVALIDITY OF THE SURVEY TOOL OR TO DISCLOSE THE ABT REPORT?

Plaintiffs contend that OBRA '87's enforcement regulations should be vacated,[35/] because the agency did not "respond in a reasoned manner to the comments received, to explain how the agency

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[34/] This result is also consistent with DAB and ALJ decisions, which have addressed this very issue. For instance, in *Golden State Manor and Rehabilitation Ctr.*, DAB No. 1507 (1996), *available at* 1996 WL 599831 (Sept. 16, 1996), the DAB discussed the relevant history at great length and concluded that "[t]he survey procedures set out in 42 C.F.R. Part 488, Subpart C do not reflect the new and expanded requirements created by OBRA '87 . . . [,] and Subpart C is inconsistent with and does not implement the OBRA '87 revisions to the health and safety requirements that a long-term care facility must meet to participate in the Medicare and Medicaid programs." *Id.* Furthermore, the DAB held that: "Subpart C pertains to survey methodology and conditions of participation which became *obsolete with the implementation of the new conditions of participation and survey processes mandated by OBRA '87*, which did not go into effect until October 1990." *Id.* (emphasis added.) With respect to HCFA's failure to withdraw Subpart C and formally publish revised protocols in formal regulations, the DAB concluded that HCFA "was not legally required to formally withdraw or repeal Subpart C in order for this subsection to be rendered inoperative by the passage of OBRA '87, the provisions of which became effective on October 1, 1990." *Id*. *See also Hermina Traeye Memorial Nursing Home*, DAB No. 1810 (2002), *available at* 2002 WL 125185 (Jan. 18, 2002). ("[T]he Subpart C process was rendered inapplicable by the Omnibus Budget Reconciliation Act of 1987 and . . . the State Operations Manual provided the only appropriate survey guidelines for State survey agencies."); *Manor Care of Largo, Inc*., DAB No. CR746 (2001), *available at* 2001 WL 358743 (Feb. 23, 2001) ("[T]he nursing home provisions of the Omnibus Budget Reduction Act of 1987 have effectively made inoperative Subpart C of 42 C.F.R., Part 488.")

[35/] These rules were proposed on August 28, 1992 (*see* R.R. at 427, 57 Fed. Reg. at 39,279), and the Secretary issued the final enforcement regulations on November 10, 1994. (*See* R.R. at 465-601, 59 Fed. Reg. at 56,116-56,252.)

resolved any significant problems raised by the comments, and to show how the resolution led the agency to the ultimate rule . . . ." (Pls.' Mem. at 84) (quoting *Roadway v. Dep't of Agric.*, 514 F.2d 809, 817 (D.C. Cir. 1975).)

The gravamen of plaintiffs' complaint is that defendants did not adequately address comments regarding the problems with the survey protocol. Plaintiffs cite to a variety of comments (*see* Pls.' Mem. at 83-94), and claim that these comments "call into question a basic premise -- that the agency has in place a consistent and accurate citation system." (*Id.* at 94.)

The evidence in the Federal Register, however, reveals that the agency made a significant effort to respond to the comments submitted regarding the proposed enforcement regulations, and it explained the reasons why it was accepting or rejecting the recommendations. (*See* R.R. at 465-580, 59 Fed. Reg. at 56,116-56,229.) For instance, during the comment period, the agency reviewed over 28,000 comments, and as a result of the comments, the agency adopted the concept of "substantial compliance."[36/] Additionally, HCFA responded to comments that "increased surveyor training and testing would enhance surveyor consistency" by noting that it "ha[d] implemented an exhaustive surveyor training and testing program that will ensure that surveyors are adequately trained and competent performing surveys." (R.R. at 490, 59 Fed. Reg. at 56141.) The agency stated that a

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[36/] *See, e.g.*, 59 Fed. Reg. at 56153:

> After carefully considering the matter, we are accepting the commenters' suggestion to incorporate the concept of substantial compliance in the regulation as the standard that prospective providers and existing providers must meet in order to begin or continue to participate in the Medicare and Medicaid programs.

(R.R. at 502.)

"few commenters stressed the importance of consistency being sought in the application of enforcement remedies as well as the survey procedures." (*Id.*) In response, the agency agreed, noting that "the final regulation requires that State survey agencies conduct programs designed to enhance consistency in the application of enforcement remedies as well as in survey results." (*Id.*)

Ultimately, plaintiffs have produced no evidence that the agency failed to respond to any comments that addressed the actual provisions of the proposed enforcement rules. Rather, plaintiffs' complaint amounts to a rehash of their argument that the survey protocol has not been shown to be sufficiently validated to comply with the statute.

As an alternative, plaintiffs claim that the enforcement regulations were not duly promulgated, because defendants failed to disclose the Abt study, thereby violating the requirements that an agency is not permitted to "promulgate rules based on data known only to the agency," (Pls.' Mem. at 99) (citing *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 55 (D.C. Cir. 1997)), and "[w]hen a proposed rule is based on scientific data, the agency should identify the data and methodology used to obtain it." *Lloyd Noland Hosp. and Clinic v. Heckler*, 762 F.2d 1561, 1565 (11th Cir. 1985). According to plaintiffs, the agency failed to identify a "basic component" of the proposed regulation, because it failed to mention that the agency had already commissioned the Abt study when it published a Notice of Proposed Rulemaking in 1992 "to complete the execution of the long term care survey and certification process mandated under OBRA '87." (Pls.' Mem. at 100) (citing R.R. at 431, 57 Fed. Reg. at 39,283.) Furthermore, plaintiffs allege that in July 1993, the agency had a preliminary report from Abt but failed to mention it, even though the final rule and the enforcement rules would not be in effect for over a year. (*Id.*)

There are several problems with plaintiffs' argument. First, both sides agree that the agency did not even have the preliminary results of the Abt Report prior to the comment period for the Notice of Proposed Rulemaking. (Pls.' Mem. at 100.) Plaintiffs nonetheless argue that the agency should have reopened the comment period (*see* Pls.' Opp. at 42), even though there is no evidence that the plaintiffs or anyone else requested that the period be reopened after the preliminary results were released in July 1993.[37/]

Second, and more importantly, the Abt Report did not relate to the proposed enforcement regulations. The report addressed the survey and certification protocol, which was in existence in 1992, not the proposed enforcement regulations that went into effect on July 1, 1995. Thus, the Abt Report was relevant to the survey protocol and its results did in fact lead to changes in the protocol. (*See* discussion *supra* Section III(B)(1)(d).) Thus, there was no reason for HCFA to reopen the notice and comment period for consideration of this report.

VI. WAS THE TERMINATION DECISION ARBITRARY AND CAPRICIOUS, NOT IN ACCORDANCE WITH LAW OR IN VIOLATION OF PLAINTIFFS' RIGHTS TO DUE PROCESS AND EQUAL PROTECTION UNDER THE LAW?

[37/] According to defendants, AHCA and other nursing-home representatives received the preliminary Abt Report in 1993 and participated in numerous briefings and discussions regarding it. (*See, e.g.*, Defs.' Reply at 28.) Moreover, as defendants note (*see* Defs.' Mem. at 82 n.60), the study received publicity in 1993 and 1994 in numerous magazine articles that were targeted to providers. *See, e.g.*, *Surveys Stymied by Survey Criteria, Researchers Find*, Nursing Homes, May 1, 1994, *available at* 1994 WL 2887923; *Consultant Calls Federal LTC Survey Too Complicated*, Long Term Care Management Faulkner & Gray, Inc., Sept. 29, 1993, *available at* 1993 WL 2822305; *HCFA Modifies Survey Protocols to Ease Inspection Burden*, Long Term Care Management Faulkner & Gray, Inc., Dec. 8, 1993, *available at* 1993 WL 2822305.

In addition to plaintiffs' global attack on the defendants' use of the survey protocol, plaintiffs challenge the agency's decision to terminate Spring Hill. Defendants' decision, which was effective June 2, 1998, was upheld by the Administrative Law Judge ("ALJ") and affirmed on appeal on July 1, 1999, by the HHS Departmental Appeals Board ("DAB").[38/] Plaintiffs seek reversal of this decision on a host of grounds. First, plaintiffs argue that since the ALJ reversed the agency's findings of "immediate jeopardy," the agency's use of fast-track termination constituted an abuse of discretion, and the scope and severity of the remaining deficiencies were not sufficient to sustain a termination decision according to defendants' regulations, policies, procedures and customary practices. (*See* Pls.' Mem. at 103-119.) Second, plaintiffs argue that the termination violated their due process rights and their right to equal protection under the law because plaintiffs did not get fair notice that they would be terminated for non-immediate jeopardy findings; they were treated more harshly than other offenders in violation of defendants' duty to treat "'like cases alike,'" *Williston Basin Interstate Pipeline Co. v. FERC*, 165 F.3d 54, 65 (D.C. Cir. 1999) (citation omitted); and the ALJ committed error by not remanding the case to the agency once the jeopardy findings had been overturned. (*See* Pls.' Mem. at 119-124.) Before one can address these legal arguments, it is necessary to review briefly the relevant regulatory provisions and the procedural history relating to Spring Hill's termination.

A. Regulatory Framework

[38/] The ALJ's opinion appears as Exhibit 2 to the A.R. at 3, and the DAB's opinion appears as Exhibit 3 to the A.R. at 55. The pagination used refers to the page numbers of the administrative record, not the page numbers of the actual opinion.

Using the survey protocol, state surveyors, pursuant to contract with HHS, conduct annual surveys of nursing homes which receive Medicare and Medicaid payments in order to determine whether the home is in substantial compliance with the participation requirements. *See* 42 U.S.C. §§ 1395a, 1395i-3(g), 1396r(g); 42 C.F.R. §§ 431.610(f)(1), 488.26, 488.330. If the surveyors find that a facility is not in compliance, the state agency and HCFA have several available remedies or sanctions from which to select. 42 U.S.C. §§ 1395i-3(h)(1), 1396r(h)(1); 42 C.F.R. §§ 488.404, 488.406, 488.408. These include termination of a provider's ability to participate in the Medicare or Medicaid programs, denial of payments to the provider, placement of a temporary manager or state monitor in the facility, and civil money penalties up to $10,000 per day. 42 U.S.C. §§ 1395i-3(h)(2), 1396r(h)(2).

In order to select the appropriate sanction, surveyors first classify deficiency findings by seriousness. 42 C.F.R. § 488.404(b). Seriousness is assessed by evaluating the severity of the deficiency (*i.e*., the degree of actual and potential harm) in conjunction with the scope of the deficiency (*i.e.*, the degree to which it is pervasive or isolated), *id*., and then by assigning a letter category from A-I. (*See* Pls.' Mem. Ex. 19, SOM § 7400, at 7-39.) The findings are reported on a standard form (called a "2567") which identifies specific deficiencies and assigns "tag" numbers. In order to be found in "substantial compliance," a provider must have no deficiencies that pose a risk to resident health or safety greater than "the potential for causing minimal harm." 42 C.F.R. § 488.301. (*See* Pls.' Mem. Ex. 19, SOM § 7400, at 7-42.) The most serious deficiencies are those designated at the "immediate jeopardy" level (at level "J" or higher), which means that the provider's non-compliance

"has caused, or is likely to cause, serious injury, harm, impairment or death to a resident." 42 C.F.R. § 488.301. (*See* Pls.' Mem. Ex. 19, SOM § 7400, at 7-42.)

If the deficiencies present "immediate jeopardy" to the health and safety of residents, defendants must either appoint a temporary manager or terminate the provider agreement within twenty-three days, or do both. 42 C.F.R. §§ 488.408(e), 488.410. As for other types of deficiencies, HCFA and the state agency have a range of available remedies depending on the level of the deficiency, as well as other relevant factors. *Id*. §§ 488.404, 488.406 and 488.408. Regardless of the remedy imposed, the facility must submit a plan of correction ("POC") unless the deficiencies identified are isolated and present no more than a potential for minimal harm. *Id*. § 488.402(d).

A facility may appeal a survey finding of non-compliance leading to imposition of a remedy (including termination), but not HCFA's selection of a particular remedy to address the non-compliance or HCFA's evaluation of the level of non-compliance. 42 C.F.R. §§ 498.3(d)(11), 488.408(g). *See also* 59 Fed. Reg. at 56,121, 56,159, 56,178.

B. Procedural History

Surveyors from the Florida Agency for Health Care Administration conducted their first standard survey of Spring Hill on May 4-7, 1998, to determine whether Spring Hill was in compliance with the statutory requirements governing long-term facilities. (A.R. at 5.) The surveyors concluded that Spring Hill had numerous deficiencies that warranted sanctions. By letters dated May 11 and 19, 1998, the surveyors informed Spring Hill of its findings and recommendations of termination and imposition of fines of $10,000 per day until substantial compliance was achieved. Surveyors identified sixteen deficiencies, including four deficiencies that were classified at the "immediate jeopardy" level

(or level "J") and the remaining deficiencies which, while not at the "immediate jeopardy" level, were found to "pose the potential for more than minimal harm to residents." (A.R. at 4.) Accordingly, the state surveyors made the decision to terminate Spring Hill from participation in the Medicare and Medicaid programs.

By letter to Spring Hill Administrator Sharon Colbert dated May 19, 1998, HCFA informed plaintiffs that it concurred with the state surveyors' findings that Spring Hill "was not in substantial compliance with the participation requirements and that conditions in [Spring Hill] constituted immediate jeopardy to resident health or safety." (A.R. at 192.85.) HCFA also informed the plaintiffs that it was intending to terminate Spring Hill's Medicare and Medicaid agreements involuntarily on June 2, 1998, and was imposing a civil money penalty of $10,000 per day from May 7, 1998 through June 1, 1998. Finally, plaintiffs were required to submit a POC by May 21, 1998. (*Id*. at 192.85-192.87.)

Thereafter, plaintiffs submitted a POC, which contained two dates by which they indicated that they would be in substantial compliance: plaintiffs proposed that they would comply with all "immediate jeopardy" ("J") tags and all "G" tags by May 21, 1998, and would comply with all other tags by June 22, 1998. On May 27-29, the surveyors revisited Spring Hill to resurvey the "J" and"G" level deficiencies. Again, the surveyors concluded that plaintiffs' facility was in a state of immediate jeopardy. (A.R. at 4-5.) As a result, defendants terminated Spring Hill on June 2, 1998, and imposed a civil money penalty of $10,000 per day. (A.R. at 192.85.)

Spring Hill appealed the termination and the imposition of civil money penalties. (A.R. at 105.) Following a hearing, ALJ Kessel issued his decision on October 27, 1998. Although he upheld

HCFA's decision to terminate Spring Hill because it was not in substantial compliance with the participation requirements, he found that the evidence did not support the agency's finding of immediate jeopardy. (A.R. at 4.) While recognizing that HCFA does not normally terminate providers where deficiencies are less serious than the immediate jeopardy level (A.R. at 51), the ALJ found:

> The evidence in this case show Petitioner's deficiencies to be relatively serious in nature. That is particularly so with the failures of Petitioner to complete the assessments and plans of care for residents mandated by the Act and regulations . . . . Here the evidence shows a relatively widespread dereliction of duty by Petitioner, which put at risk the health and well being of several of its residents.

(A.R. at 52.)[39/] Given Spring Hill's previous record of compliance, the ALJ reduced the civil monetary penalty to $1,000 per day for each day from May 7 to June 1, 1998. (A.R. at 5, 51-52.) Finally, the ALJ concluded that he was without the authority to review the appropriateness of the choice of termination as a remedy since a basis existed to impose such a remedy. (A.R. at 5, 51.)

[39/] The deficiencies found included the failure to: perform comprehensive assessments of sixteen residents in violation of 42 U.S.C. § 1395i-3(b)(3), 42 C.F.R. § 483.20(b); develop comprehensive plans of care for more than 50% of the cases reviewed in violation of 42 C.F.R. § 438.20(d); conduct a resident assessment after a significant change in the resident's physical or mental condition; assure that the wheels of its residents' beds were locked as required by 42 C.F.R. § 483.25(h)(1); provide necessary treatment and services to maintain the ability of residents to perform various activities of daily living as required by 42 C.F.R. § 483.25(a)(2); have a written agreement with an outside dialysis services provider as required by 42 C.F.R. § 483.75(h)(1)-(2); administer the facility properly as required by 42 C.F.R. § 483.75; make reasonable accommodations for residents diagnosed with seizures as required by 42 C.F.R. § 483.15(e)(1); respect the dignity of residents; and provide written notice to residents regarding hospital transfers and/or discharges as required by 42 C.F.R. § 483.12(a)(4)-(6). (*See* A.R. at 45-48.)

Both parties appealed. The DAB upheld the ALJ's decision in its entirety and found that: (1) Spring Hill had adequate notice that its termination was based upon the lack of substantial compliance generally and not just the immediate jeopardy findings (A.R. at 63-68); (2) the ALJ had authority to remand the case to HCFA, but he did not abuse his discretion by not remanding (A.R. at 77-81); and (3) Spring Hill's termination was consistent with the statute, regulations, and procedures and not the result of inequitable treatment. (A.R. at 71, 83-88.)

C. Legal Analysis

As the parties agree, judicial review of the DAB's decision is governed by the APA. Under § 706(2) of the APA, the agency action will be set aside if it is found to be arbitrary, capricious, an abuse of discretion, not in accordance with law or unsupported by substantial evidence. 5 U.S.C. § 706(2)(A), (E). A court is not empowered to "substitute its judgment" for that of the agency, but it is required to give the agency's decision "a thorough, probing, in-depth review." *Citizens to Preserve Overton Park, Inc.*, 401 U.S. at 415-16. Applying this standard, this Court concludes that the termination of Spring Hill must be upheld.

While no one appears to dispute that it is unusual, if not unique, for a termination to be based on non-immediate jeopardy findings (A.R. at 51), for a termination for such deficiencies to occur on short notice (*id*.), or for an ALJ to overturn an agency's findings of immediate jeopardy deficiencies (*see* AARP and NCCHHR *Amici* Br. at 23-24), the novelty of the situation does not mean that the termination is arbitrary and capricious. First, it bears noting that at the time of Spring Hill's termination, the nursing home enforcement regulations were only three years old, so any argument regarding the agency's past practices has limited historical support. Second, as pointed out by the DAB, an agency's

arguably prior lax enforcement policies cannot hamstring its future enforcement efforts. (A.R. at 87-88.)[40/] But perhaps most importantly, as found by the ALJ, "[u]nder both the Act and regulations, HCFA has the authority to terminate immediately the participation of a deficient facility regardless of the level of the deficiencies." (A.R. at 51.) As plaintiffs concede (*see* Pls.' Mem. at 104), the Secretary has the power under the statute to terminate a facility after determining that the provider has failed to comply substantially with the agreement or the applicable law and regulations. *See* 42 U.S.C. §§ 1395cc(b)(2)(A). Similarly, the regulations permit termination where a facility is not in substantial compliance even if there are no immediate jeopardy findings.[41/] HCFA's policies and procedures also permit the use of termination here. As the DAB recognized (A.R. at 71), section 7556 of the SOM states that "termination is always an option that may be imposed for any noncompliance." (*See* Pls.' Mem. Ex. 19 at 7-61.) Additionally, section 7400 of the SOM states: "NOTE: Termination may be imposed by the State or CMS at any time when appropriate." (*Id.* at 7-42.) Further, HCFA clearly

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[40/] As noted by the DAB:

> [T]o conclude otherwise would require the federal government to "throw good money after bad" and to continue indefinitely to fund ineffective, incompetent or non-complying programs because it had once begun to do so. . . . If the termination of a grantee is justified by its failings, it is hardly a defense that someone else should be terminated first.

Id. (citation omitted).

[41/] *See, e.g*., 42 C.F.R. § 488.412(a) ("[i]f a facility's deficiencies do not pose immediate jeopardy to resident's health or safety, and the facility is not in substantial compliance, CMS or the State may terminate the facility's provider agreement or may allow the facility to continue to participate for no longer than 6 months from the last day of the survey"); *id*. § 488.412(a) ("a provider may be terminated if it no longer meets the appropriate conditions of participation or requirements"); and *id*. § 488.456(b)(1) (agency may terminate a facility's provider agreement if a facility "[i]s not in substantial compliance regardless of whether or not immediate jeopardy is present").

contemplated the instant set of facts when a provider is terminated, after immediate jeopardy findings have been overturned, but the provider is still not in substantial compliance:

> [I]n the case of provider agreement terminations, *even if a facility were able to successfully contest a conclusion that immediate jeopardy exists, the agency could still proceed with the termination action since the agency's authority to bring such an action is not limited to immediate jeopardy cases, but may span all noncompliant facility behavior*. As has been agency policy for many years, the determination of what remedy to seek is beyond challenge in light of the government's fundamental necessity to protect the welfare of facility residents as expeditiously as possible. This is especially the case with respect to provider agreement terminations since residents may be at considerable risk even where there is no immediate jeopardy. 59 Fed. Reg. at 56,178 (emphasis added). For this reason, the regulations provide that "HCFA . . . may terminate a facility's provider agreement if a facility . . . [i]s not in substantial compliance regardless of whether or not immediate jeopardy is present."

(A.R. at 76-77) (citing 42 C.F.R. § 48.456(b)(1).)

Thus, there can be no question that the agency did not abuse its discretion by imposing termination, and it is not within this Court's province to substitute its judgment for the agency's decision that termination was appropriate given the scope and severity of the deficiencies found.[42/]

In addition to challenging defendants' use of termination for non-immediate jeopardy findings, plaintiffs also contend that defendants' use of fast-track terminations for level "F" violations violated defendants' policies, as set forth in section 7309 of SOM, to stop "fast-track termination if immediate

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[42/] While the parties engage in a heated debate over how serious Spring Hill's noncompliance was, the Court has not been asked to, nor could it, resolve that issue based on the record before it. Rather, it is sufficient that the deficiencies identified, which have not been challenged here, justify the agency's decision to terminate. Moreover, it is worth noting that both the DAB and the ALJ referred to the deficiencies as constituting a "relative widespread dereliction of duty." (A.R. at 52, 77), which finding would provide further support for the agency's decision to use its ultimate sanction, *i.e.*, termination.

jeopardy is removed prior to the termination date." (*See* A.R. at 70.) As the DAB recognized, the policies relied on by plaintiffs do not in fact support this argument; rather, section 7309 of SOM provides that where the facility has corrected the immediate jeopardy but not achieved substantial compliance, as was the case here, it "*may* be given some additional time (up to 6 months from the last day of the survey) to achieve substantial compliance." (A.R. at 70) (citing SOM § 7309) (emphasis added.) As the DAB held, there is nothing that prevents HCFA from using a 23-day time frame for terminations where there are no immediate jeopardy findings or requires HCFA to reconsider its remedy if the immediate jeopardy conditions are corrected or found not to have existed. (A.R. at 71-72.) Since this conclusion is not erroneous, it will not be disturbed.

For these same reasons, plaintiffs' equal protection argument fares no better. As defendants persuasively argue (*see* Defs.' Mem. at 90), since each noncompliant facility's situation is different, plaintiffs cannot argue that their termination was improper because other facilities where the deficiencies were not classified as immediate jeopardy were not terminated. (*See also* A.R. at 87, DAB Opinion) ("[S]elective enforcement by the agency, including any alleged failure to take equally harsh steps against other similarly noncompliant services providers, may not itself be made to constitute a defense or a bar to future enforcement actions.") Moreover, as previously noted, any prior laxity in enforcement cannot deprive the agency of its ability to sanction a facility that is not in substantial compliance. (*See* A.R. at 87-88.) Finally, as found by the DAB, plaintiffs' evidence was not sufficient to show that facilities similarly situated to Spring Hill had been treated differently. While plaintiffs offered the affidavit of Charles McKeen Cowles, who had reviewed the involuntary terminations by HCFA for the period 1995-1998 (A.R. at 891-895), the DAB properly found this work to be of limited relevance, given its

failure to provide any details relating to the "number or nature of or the interrelationship among deficiencies found in particular instances." (A.R. at 87.) Moreover, as defendants point out, since Cowles only analyzed the records of facilities that had been terminated, plaintiffs provided no evidence of any facility that was similarly situated to Spring Hill that had not been terminated. (*See* Defs.' Mem. at 91 n.68.)

Plaintiffs also argue that they were denied adequate notice that they would be subject to termination based on the non-immediate jeopardy findings, and that because the AHCA agreed to Spring Hill's POC, which proposed May 21 as the date to correct the immediate jeopardy and actual harm level deficiencies and June 22 as the date to correct the remaining deficiencies, they did not have fair warning that it had to correct all deficiencies by June 2, 1998. Both of these arguments were rejected by the DAB. (*See* A.R. at 64-68, 72-74.)

Contrary to plaintiffs' argument regarding the failure to receive notice that termination was based on immediate and non-immediate jeopardy findings, the evidence supports the DAB's finding that defendants provided notice as required by 42 C.F.R. § 488.402(f), and that the notice, *i.e.*, HCFA's letter of May 19, 1998 (A.R. at 192.85), was adequate to inform Spring Hill of the basis and the effective date of the termination remedy. (A.R. at 64.)

Under 42 C.F.R. § 488.402(f), HCFA was required to provide "notice of the remedy," including (i) the nature of the noncompliance; (ii) which remedy is imposed; (iii) the effective date of the remedy; and (iv) the right to appeal the determination leading to its remedy. HCFA's notice to plaintiffs sent on May 19, 1998, established the nature of noncompliance: "On May 7, a survey was conducted at your facility. . . . This survey found that your facility was not in substantial compliance with

participation requirements and that conditions in your facility constituted immediate jeopardy to resident health or safety." (A.R. at 192.85.) The letter also informed plaintiffs of the requirement that: "A facility must meet the pertinent provisions of Sections 1819 and 1919 of the Social Security Act and be in substantial compliance with each of the Requirements for Long Term Care Facilities . . . in order to participate as a skilled nursing facility." (A.R. at 64.) The letter then outlined the remedy and its effective date: "Your Medicare provider will be terminated on June 2, 1998. We will also notify the State Medicaid agency to terminate [your] agreement." (*Id.*) The letter explained that HCFA was imposing a $10,000 a day monetary penalty effective May 7, 1998, but that the amount of the penalty could be decreased if the jeopardy findings were removed. (*Id.*) Lastly, it informed plaintiffs of their appellate rights.

In this letter, HCFA did not justify the termination based on a failure to correct by June 2, 1998; it based it on the actual deficiency findings -- the combination of both immediate jeopardy findings and non-immediate jeopardy findings. As defendants note, "they did not specify whether either would have been enough by itself, and [they were] not obligated to make such a specification." (Defs.' Mem. at 95.) But as found by the DAB, "on the face of th[e May 19, 1998 letter], HCFA made clear that the remedies imposed, including termination, were based on the lack of substantial compliance found by the survey, and not, as Spring Hill now claims, on the finding of immediate jeopardy alone." (A.R. at 65.) Thus, any argument that plaintiffs did not get fair notice of the deficiencies -- including the non-immediate jeopardy findings -- lacks merit.

Similarly, plaintiffs' claim that HCFA was bound by the dates in the POC that had been submitted to the state agency fails for both factual and legal reasons. HCFA never provided a "'date

certain' by which Spring Hill could achieve substantial compliance and avoid termination." (A.R. at 72-73.) As the May 19, 1998 HCFA letter makes clear, Spring Hill was to be terminated on June 2, 1998, regardless of Spring Hill's success in correcting the deficiencies. Moreover, under the regulations, plaintiffs cannot argue that acceptance of a facility's POC creates a binding contract not to terminate, since "regardless of which remedy is applied, each facility that has deficiencies with regard to program requirements must submit a plan of corrections for approval by HCFA or the survey agency." 42 C.F.R. § 488.402.[43/] Thus, as found by the DAB, "the State agency's acceptance of Spring Hill's plan of corrections alone could not convert the termination already imposed into a termination contingent on the results of a revisit." (A.R. at 73.) Additionally, plaintiffs' attempt to bolster their argument with reference to cases involving hospices. (*See* Pls.' Opp. at 52-53.) These cases are, however, inapposite, since the regulations governing hospices provide that the hospice must be given the opportunity to correct deficiencies (*see* 42 C.F.R. § 488.28), whereas nursing home regulations are stricter, for they do not require the granting of a grace period, but give the agency discretion to terminate or to allow the facility to continue to participate for no longer than six months if certain conditions are met. 42 C.F.R. § 488.412(a).

Finally, plaintiffs appear to seek reversal of the termination on the grounds that Spring Hill was denied the opportunity to have the sanction reviewed without consideration of the immediate jeopardy findings that were overturned by the ALJ. (*See* Pls.' Mem. at 120-121.) In this regard, plaintiffs argue that by not addressing the propriety of Spring Hill's termination so as not to interfere with defendants'

[43/] *See also* section 3016 of the SOM which provides that "credible allegations of compliance constitute intervening actions that do not postpone or delay [the] termination – timetable . . . . only compliance can rescind a termination action." (*See* A.R. at 74.)

discretion to select and impose enforcement remedies, the Board effectively "pretermit[ted] any exercise of discretion by defendants and effects the very interference that it claimed that it wished to avoid." (Pls.' Mem. at 113.) At the DAB, plaintiffs couched this argument in different terms by claiming that "the ALJ erred by failing to remand the case to HCFA to redetermine the appropriate remedy, if any." (A.R. at 77.) While plaintiffs no longer speak in terms of a remand, they still appear to be pressing the claim that by not sending the case back to the agency for reconsideration, the DAB committed error.[44/]

When the DAB considered plaintiffs' argument, it agreed with the ALJ that he could not overturn a legal termination, but it concluded that the ALJ had "the authority to remand a case to enable HCFA in the situation where the factual basis of the deficiency findings as resolved at the hearing is so substantively different that the ALJ is uncertain whether HCFA would choose the same remedy under the circumstances as found. However, exercise of that authority by the ALJ is discretionary, and we find no abuse of discretion in what the ALJ did here." (A.R. at 77.) Despite its recognition that the ALJ had the power to remand, the DAB found no abuse of discretion because neither party requested a remand;[45/] the ALJ could reasonably assume that HCFA believed that the termination was

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[44/] In fact, only AARP and the NCCNHR, in their *amici curiae* brief, suggest that given the highly unusual circumstances in this case, a remand to HCFA so that it can "have an opportunity to exercise its discretion to select a remedy appropriate to the deficiencies under the new factual circumstances" would be appropriate. (AARP and NCCNHR *Amici* Br. at 26.) Curiously, plaintiffs do not reference this argument in their reply, which was filed after AARP and NCCNHR filed their brief, nor do they mention the desirability of a remand at this stage.

[45/] As for Spring Hill, the DAB noted that "while . . . [it] plainly sought to have the termination overturned outright, it could also have requested that if the ALJ found a basis to impose a remedy, he remand to HCFA to reconsider the appropriate remedy." (A.R. at 81.)

appropriate since it had "continued to strongly defend the termination remedy" on appeal; and there was a "clear basis in the record to find that HCFA had the authority to terminate Spring Hill." (A.R. at 81.)

DAB's conclusion is flawed insofar as it is clear that the ALJ did not recognize that he had the authority to remand the case once he determined that the immediate jeopardy deficiencies did not exist. It therefore necessarily follows that he could not have exercised discretion that he did not know he had. Nonetheless, the Court is unwilling to follow the recommendation of the *amici curiae*. First, as was the case at the hearing before the ALJ, plaintiffs have not requested a remand here. Second, it is not factually correct to maintain that the agency has not had the opportunity to reconsider the appropriateness of its remedy. On the contrary, following the ALJ's decision but before the DAB issued its opinion, plaintiffs requested HCFA to rescind the termination. The agency declined to do so, citing the agency's belief that "the facility's noncompliance with multiple health and safety requirements posed significant risks to the residents." (Defs.' Mem. A.R. at 631, Letter from Elizabeth Benton, HCFA's counsel, to plaintiffs' counsel, dated November 17, 1998.) The agency has thus remained steadfast in its determination that termination is warranted based on the aggregate deficiency findings, and no useful purpose could possibly be served by remanding this matter to the agency for it to review a June 1998 decision that it has supported and reaffirmed for over four years.[46/]

[46/] While plaintiffs are correct to point out that a court cannot affirm the Secretary's order "on the assumption that the agency might reach the same result on remand" (Pls.' Mem. at 108) (citing *JSG Trading Corp. v. U.S. Dep't of Agric*., 176 F.3d 536, 545 (D.C. Cir. 1999)), this rule, referred to as the "Chenery doctrine" after the case of *SEC v. Chenery Corp*., 318 U.S. 80, 87 (1943), has been "softened in its application." 3 K. Davis, Administrative Law Treatise § 14.29, at 130 (2d ed. 1980). Thus, "reversal and remand are [not] required each and every time an administrative agency assigns a wrong reason for its action; rather, it requires reversal and remand *only* where there is a significant

CONCLUSION

Based on the foregoing, the Court concludes that Spring Hill's termination should not be reversed and HHS' survey protocol will not be enjoined. Accordingly, defendants' motion for summary judgment is granted, and plaintiffs' motion for summary judgment is denied. A separate Order accompanies this Memorandum Opinion.

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ELLEN SEGAL HUVELLE
United States District Judge

Dated:

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chance that but for the error, the agency might have reached a different result." *N.L.R.B. v. American Geri-Care, Inc.*, 697 F.2d 56, 64 (2d Cir. 1982), *cert. denied*, 461 U.S. 906 (1983) (emphasis added). *See also Envirocare of Utah, Inc. v. Nuclear Regulatory Comm.*, 194 F.3d 72, 79 (D.C. Cir. 1999) ("In the absence of such a possibility, affirmance entails neither an improper judicial invasion of the administrative province nor a dispensation of the agency from normal responsibility.'") (quoting Henry J. Friendly, *Chenery Revisited: Reflecting on Reversal and Remand of Administrative Orders*, 1969 Duke L.J. 199, 211).

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BEVERLY HEALTH & REHABILITATION SERVICES, Inc., *et al*.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 99-02367 (ESH)**
TOMMY G. THOMPSON, Secretary of Health and Human Services, *et al*.,	)	
Defendants.	)	

ORDER

Upon consideration of the entire record and the pleadings, it is hereby

ORDERED that defendants' motion for summary judgment [50-1; 54-1] is **GRANTED**; it is

FURTHER ORDERED that plaintiffs' motion for summary judgment [43-1] is **DENIED**; and it is

FURTHER ORDERED that plaintiffs' complaint is **DISMISSED WITH PREJUDICE**.

This is a final appealable order.

ELLEN SEGAL HUVELLE
United States District Judge

Dated: