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Long-Term Care Survey, Certification, and Enforcement Issues:
CMS and Provider Perspectives¹

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I. Background

In 1965, when Congress enacted the Medicare and Medicaid programs, it authorized the Department of Health, Education and Welfare (HHS, formerly HEW) to establish standards for nursing homes participating in those programs. Those standards have continued to evolve since the inception of the Medicare and Medicaid programs.

During the 1970s and 1980s, Congress held hearings regarding its concern over the quality of care being rendered in nursing homes. While this was occurring, in 1975 a class action suit was filed on behalf of a number of Medicaid recipients who were residents of Colorado nursing homes. *Smith v. O'Halloran*, 557 F. Supp. 289 (1983). Those plaintiffs alleged that, "Medicaid recipients in nursing homes in Colorado are not receiving adequate care because the Secretary has failed to force the state of Colorado to use an appropriate patient care management system to insure the delivery of adequate care." *Id.* On appeal, the Tenth Circuit Court of Appeals reversed and remanded the case holding that, "The Secretary has a duty 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." *Smith v. Heckler*, 747 F.2d 583 at 591 (10th Cir. 1984).²

¹ The views expressed herein are those of the authors and do not necessarily reflect the official position or the policy of the U.S. Department of Health and Human Services or the Office of the General Counsel.

² In response to the Court's Order on Remand, the Secretary filed a plan of compliance that addressed revisions to the survey process and promulgated regulatory changes. *HHS Plan of Compliance with Court Order in Smith v. Heckler*, 1985 WL 56558 (D. Colo.).

In 1983, the Centers for Medicare and Medicaid Services (CMS, formerly known as HCFA) requested that the Institute of Medicine (IOM) to conduct a study regarding the regulations governing certification of nursing homes participating in Medicare and Medicaid. In response, after three years, the IOM's Committee on Nursing Home Regulation published its report, "Improving the Quality of Care in Nursing Homes."³ That report strongly recommended significant revision of Federal and State regulation of nursing facilities.⁴

At the same time that *Smith v. O'Halloran* was winding its way through the courts and the IOM was conducting its study, the General Accounting Office (GAO) published a report recommending that the Department of Health and Human Services (HHS) strengthen its existing regulatory authority.⁵ The GAO report concluded that more than one third of the nursing homes had dropped below minimum federal standards as determined on three consecutive inspections.⁶

³ Committee on Nursing Home Regulation of the Inst. of Med., *Improving the Quality of Care in Nursing Homes*. (1986).

⁴ The IOM Report recommended changes in all three major components of the regulatory system: conditions of participation in Medicaid; the survey and certification process; and sanctions. H.R. Rep. 100-391(I) at 452, 1987 U.S.C.C.A.N. 2313-1-272, *See*, 59 Fed Reg 56116 at 56193.

⁵ Medicare and Medicaid: Stronger Enforcement of Nursing Home Requirements Needs (July 1987), GAO/HRD-87-113 at 5.

⁶ Sen. Charles Grassley, Essay, *The Resurrection of Nursing Home Reform: A Historical Account of the Recent Revival of the Quality of Care Standards for Long-Term Care Facilities Established in the Omnibus Reconciliation Act of 1987*, 7 *Elder L. J.*, 267 (1999).

As a result of both the IOM and the GAO reports, Congress enacted sweeping reforms in the Nursing Home Reform Act 1987 as part of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87).⁷

⁷ Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 42 U.S.C. §1320a *et seq.* and 42 U.S.C. §1396 *et seq.*

Many of the IOM recommendations were adopted by OBRA 87.⁸ This was the beginning of a concerted and continuing effort by Congress to enhance the quality of care in long term care facilities. Significant improvements have been made in the context of long-term care. However, the GAO has reported serious and repeated problems in the area of skilled nursing facilities.⁹ Providers and regulators (*i.e.*, Federal and State agencies) as well as other stakeholders share the same goal: to ensure that quality of care is rendered to our nation’s elderly and most frail segment of the population.

II. Surveys

A. Surveys as Evidence of Compliance

In order to participate in the Medicare or Medicaid programs as a provider of skilled nursing services, a facility must meet all of the provisions of Section 1819 (b) (c) and (d) of the Social Security Act (Act).¹⁰ Additionally, a skilled nursing facility (SNF) must meet all of the Requirements for Long Term Care Facilities established by the Secretary of Health and Human Services (the Secretary) and be free of hazards to the health and safety of residents. 42 C.F.R. Part 483.

Section 1864(a) of the Act requires the Secretary to enter into an agreement with any State that is able and willing to do so, under which appropriate State or local survey agencies will determine whether providers or prospective providers meet the Medicare conditions of participation or requirements (for SNFs and NFs).

⁸ The Committee noted that, “The Committee is deeply troubled that the Federal Government, through the Medicaid program, continues to pay nursing facilities for providing poor quality care to vulnerable elderly and disabled beneficiaries.” H.R. Rep. 100-391(I) at 452, 1987 U.S.C.C.A.N. 2313-272. The Committee seemed troubled by the IOM’s conclusion that “the poor-quality homes outnumber the very good homes.” *Id.*

⁹ *See e.g.*, General Accountability Office, Federal Monitoring Surveys Demonstrate Continued Understatement of Serious Care Problems and CMS Oversight Weaknesses GAO-08-517 (2008); Efforts to Strengthen Federal Enforcement Have Not Deterred Some Homes from Repeatedly Harming Residents, GAO 07-241 (March 2007); Nursing Home Quality: Prevalence of Serious Problems, While Declining, Reinforces Importance of Enhanced Oversight, GAO-03-561, (2003); Nursing Homes: Many Shortcomings Exist in Efforts to Protect Residents from Abuse, GAO-02-44ST (2002); Nursing Homes: Sustained Efforts Are Essential to Realize Potential of the Quality Initiatives, GAO/HEHS-00-197 (2000); Nursing Homes: Additional Steps Needed to Strengthen Enforcement of Federal Quality Standards, GAO/HEHS-99-46 (1999);

¹⁰ Social Security Act, ch. 531, 49 Stat. 620 (1935) (codified as amended in various sections of 42 U.S.C.).

In an effort to assure the quality of care of residents in SNFs, the Secretary has promulgated regulations dealing with the Requirements for Long Term Care Facilities. 42 C.F.R. Part 483. State survey agencies (SSA) act as CMS' agent in monitoring compliance with the requirements for participation in Medicare by conducting onsite inspections (*i.e.*, surveys). 42 C.F.R. §§ 488.11, 488.330(a). Any facility that is determined not to be in substantial compliance with the Part 483 requirements is subject to those remedies set forth in Section 1819(h)(2) of the Act and 42 C.F.R. Part 488, Subpart F. *See*, 42 C.F.R. § 488.330(b).¹¹

Following a survey, a Statement of Deficiencies (CMS Form 2567) is issued to a SNF which articulates the survey findings specifically identifying both the scope and severity of any deficient finding. State Operations Manual (SOM) § 7316. If the survey findings demonstrate that the facility is not in substantial compliance with the requirements for participation, the facility must submit an *acceptable* plan of correction (POC) to the State survey agency (SSA). 42 C.F.R. §§ 488.402(d), 488.408 (f)(2), SOM §2728(b). Additionally, the survey findings serve as the legal basis for remedies imposed by CMS and/or the SSA. The enforcement framework is articulated in Section 1395i-3(h) of the Act.

Note: a facility may continue to be deemed not in substantial compliance until a revisit survey or credible allegation of compliance verifies that the facility has regained substantial compliance. 42 C.F.R. § 488.440(h), SOM § 7316. Alternatively, surveys demonstrate that facilities are in substantial compliance and they serve as a basis for certification and recertification in the Medicare and Medicaid programs.

B. Types of Surveys

1. The types of surveys are authorized by the Act and the implementing regulations. *See e.g.* 42 U.S.C. § 1395i-3(g), 42 C.F.R. § 488 Subpart E.
2. Standard Survey 42 C.F.R. § 488.301
 - a. a periodic, resident-centered inspection which gathers information about the quality of service furnished in a facility to determine compliance with the requirements for participation
 - b. initial survey, recertification (annual) survey

¹¹ A certification of noncompliance requires denial of participation for prospective providers and enforcement action for current providers in accordance with 42 C.F.R. subpart F. 42 C.F.R. § 488.330(b)(2).

3. Extended Survey 42 C.F.R. § 488.301
 - a. evaluates additional participation requirements subsequent to finding substandard quality of care (SQC) during a standard survey
 - b. the purpose of an extended survey is to identify the policies and procedures that caused the facility to furnish substandard quality of care. 42 C.F.R. § 488.310
 - c. reviews larger sample of resident assessments than used in standard survey
 - d. reviews staffing and inservice training
 - e. examines contracts with outside consultants, if appropriate
 - f. reviews policies and procedures related to the deficiencies
 - g. investigation of any participation requirement at the discretion of the survey agency
 - h. timing: the SSA conducts an extended survey within 14 calendar days following the standard survey that determined SQC.

4. Abbreviated Standard Survey 42 C.F.R. § 488.301
 - a. a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation.
 - b. An abbreviated standard survey may be premised on complaints received; a change in ownership, or a director of nursing; or other indicators of specific concern.

5. Partial Extended Survey 42 C.F.R. § 488.301
 - a. a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during an abbreviated standard survey.

6. Expanded Survey
 - a. when the SSA or Regional Office (RO) suspects SQC based on a standard or abbreviated standard survey but lacks sufficient data to either confirm or refute the SQC, it may expand the survey. SOM §§ 7001, 7210 and Appendix P. (This expansion does not necessarily constitute an extended survey.)
 - b. if SQC is determined during an expanded survey, the SSA or RO conducts an extended survey or a partial extended survey.

7. Life Safety Survey 42 C.F.R. § 483.70
 - a. certifications by the State survey agency that a SNF is in compliance with Federal requirement represent *recommendations* to CMS. 42 C.F.R. § 488.12
 - b. SSA's failure to conduct a Life Safety Code survey is not a basis to grant an earlier effective date for a provider agreement. *See Forest Glen Skilled Nursing & Rehabilitation Center v CMS*, DAB No. 1887 (July 9, 2003).
8. Initial Certification
 - a. The determination of whether a provider or supplier is eligible to participate in or be covered under the Medicare program lies with CMS. *See e.g., Forest Glen, supra.*
 - b. Failure by a SSA to follow survey procedures "does not relieve a [facility] of its obligations to meet all requirements for program participation or invalidate adequately documented deficiencies." 42 C.F.R. § 488.318(b), *See, Golden State Manor and Rehabilitation Center*, DAB No. 1597 (1996).
9. Quality Indicator Survey (QIS)
 - a. The Quality Indicator Survey (QIS) is a computer assisted survey process used by State survey agencies and CMS to determine if facilities are in substantial compliance with Federal requirement for participation in the Medicare program.
 - b. National implementation of the QIS survey is progressing State by State.
 - c. CMS published a memo to State survey agency directors regarding the QIS along with a brochure describing the QIS training process on May 16, 2008. *See CMS S & C Memo 08-21* (May 16, 2008).
10. Survey nomenclature
 - h. comparative survey, monitoring survey or validation survey: what's in a name?
 - b. an ALJ held, and the DAB affirmed, that a petitioner's characterization of a survey by CMS as a "comparative" survey, a

“monitoring” survey, or a “validation” survey was irrelevant. In *Big Bend Hospital Corporation d/b/a Big Bend Medical Center v. CMS*, CR804 (2001), *aff’d*, DAB 1814 (2002), CMS did not accept the recommendation of a state survey agency to certify the petitioner (a hospital) to participate in the Medicare program. Instead, CMS conducted its own initial survey for purposes of determining whether the facility complied with the Medicare participation requirements.

- c. the ALJ noted, “What CMS called the survey is irrelevant to establish its authority to perform it. The fact that the survey is not described specifically by regulations or the SOM does not derogate from CMS’s authority to conduct it.” *Id.*

C. Use of Interpretive Guidelines By Surveyors

1. Surveyors determine whether a facility is in substantial compliance with the requirements for participation in Medicare consistent with Sections 1819 and 1919 of the Act (42 U.S.C. §§ 1395(i)-3 and 1396r, respectively) and the regulations at 42 CFR Part 483.
2. CMS has published its authoritative interpretation of the regulatory requirements in the State Operations Manual (SOM) (available online only). The SOM’s Interpretive Guidelines and Appendices are intended to serve as and provide surveyors with specific survey protocols, such as investigative protocols in order to determine compliance with the regulations.¹²
3. On January 8, 2008, CMS published a memo to State survey agency directors in which it emphasized that any deficiency citation must be written to explain how the facility failed to comply with the regulatory requirements, not the SOM, which provides “guidance” for the interpretation of those requirements.¹³ (S & C Memo 08-10).

D. Inadequate survey performance

1. Inadequate survey performance does not relieve a SNF or NF of its

¹² The State Operations Manual is available at CMS’ website at: <http://www.cms.hhs.gov/manuals/downloads/som107c07.pdf>.

¹³ CMS S& C-08-10 can be accessed at: <http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter08-10.pdf>

obligations to meet all requirements for program participation.

2. Inadequate survey performance does not invalidate adequately documented deficiencies. 42 C.F.R. § 488.318(b)

E. Survey Frequency

1. State survey agencies must conduct standard surveys not later than 15 months after the date of the last standard survey.
2. Statewide average times between standard surveys must be 12 months or less.
3. State survey agencies may conduct surveys as frequently as necessary to ensure compliance with Federal participation requirements.
4. State survey agencies must review all complaint allegations and conduct surveys (standard survey or abbreviated standard survey) in response to complaints.

F. Key Terms

1. Substandard Quality of Care (SQC):
 - a. Substandard Quality of Care (SQC) means one or more deficiencies related to participation requirements under 42 C.F.R. § 483.13, Resident behavior and facility practices; 42 C.F.R. § 483.15, Quality of Life; or 42 C.F.R. § 483.25, Quality of care, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm. 42 C.F.R. § 488.301, *See also*, SOM §7002.
 - b. SQC: deficiencies must constitute immediate jeopardy (IJ) at any level (J, K, L); actual harm at either pattern or widespread level (H, I), or, no actual harm but potential for more than minimal harm that is widespread (F). 42 C.F.R. § 488.301.
 - c. a determination of SQC will trigger an extended survey (or partial extended survey)
 - d. if SQC is determined during a standard survey, the SSA conducts an extended survey within two weeks. *See*, 42 C.F.R. § 488.310.
2. Substantial compliance

a. A level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm. 42 C.F.R. § 488.301.

3. Noncompliance

a. Any deficiency which causes a facility to not be in substantial compliance. 42 C.F.R. § 488.301

4. Immediate Jeopardy

a. 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; *see also, Liberty Commons Nursing and Rehab Center*, DAB No. 2031 (June 12, 2006), *aff'd, Liberty Commons v. Leavitt*, (4th Cir. July 20, 2007) 2007 WL 2088703.

b. components

i. harm

note: harm may be psychological and/or physical

ii. immediacy

high potential for serious harm in the near future constitutes immediate jeopardy (IJ),
See SOM 3010(B)(6)

iii. culpability

key concerns:

did the facility know or *should* the facility have known about the situation, was there a thorough investigation into the relevant circumstances?

were corrective measures implemented?

did the facility perform an evaluation of the situation following implementation of corrective measures? *See Appendix Q: Guidelines for Determining Immediate Jeopardy (SOM)*

c. removal vs. correction

- i. removal
 - ii. correction
- See Guidance on the Removal, Correction, and Documentation of Immediate Jeopardy, Electronic Regional Program Letter No. 2002-3, CMS (October 25, 2003).*

III. Scope and Severity Determinations

A. The Scope and Severity Grid

Required: Category 3 J	Required: Category 3 K	Required: Category 3 L
Required: Category 2 G	Required: Category 2 H	Required: Category 2 I
Required: Category 1 D	Required: Category 1 E	Required: Category 1 F
No POC A	POC B	POC C

B. Remedies

- 1. Category 1:
Directed POC; State Monitor; and/or Directed Inservice

2. Category 2:
DPNA, CMP: \$50 -\$3,000 per day
3. Category 3:
Temporary Management
Termination
4. Optional:
CMP: \$3,050- \$10,000 per day

59 *Fed Reg* 56183 (November 10, 1994).

C. The Scope and Severity grid is used in all regions

1. X axis delineates the three levels of “scope” (*i.e.*, isolated, pattern, widespread)
2. Y axis delineates the four levels of “severity” (*i.e.*, no actual harm with a potential for minimal harm, no actual harm with potential for more than minimal harm that is not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy).
See 42 C.F.R. § 488.404(b) for measurement of seriousness of deficiency.

D. Determining severity

1. did the deficiency cause “actual harm”?
 - a. if actual harm, did it create an immediate threat to resident health and safety?
 - a. if actual harm, how significant was the harm?
2. was the deficiency likely to cause serious injury, harm, impairment, or death to a resident? *See* 42 C.F.R. § 488.301

E. Determining scope

1. “Isolated” represents one (or few) residents involved
2. “Widespread” represents a systemic problem involving many residents or frequent deficiencies
3. “Pattern” represents more than isolated but less than widespread. *See*

SOM

F. Challenging Scope and Severity

1. The level of noncompliance may be challenged only if a successful challenge would affect the range of CMPs that CMS could collect, or where a finding of SQC exists that results in loss of a nurse aide training program. 42 C.F.R. § 498.3(b)(14)(i),(ii). “As a general rule, a facility may not challenge the level of a deficiency determination. However, an exception to that rule is where a determination of substandard care is made which results in loss of a nurse aide training authorization.” *Josephine Sunset Home*, DAB CR 1038 (2003), *citing* 42 C.F.R. § 498.3(b)(14)(ii).
2. Providers may challenge the scope and severity levels of noncompliance where those findings served as the basis for an IJ determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000).
3. In CMP cases, “CMS’ determination of the level of noncompliance must be upheld unless it is clearly erroneous.” 42 C.F.R. § 498.60 (c)(2), *See Laurelwood Care Center*, CR1796 (May 30, 2008); *Franklin Care Center*, DAB No. 1900 (December 4, 2003), *Woodstock Care Center*, DAB No. 1726 at 9, 38 (2000), *aff’d*, No. 01-3889 (6th Cir. Nov. 17, 2003).

IV. Federal Enforcement Actions

- A. The Social Security Act (Act) and the implementing regulations authorize and in some cases mandate that CMS impose various remedies for a facility’s noncompliance with Federal requirements for participation in the Medicare program. *See generally*, Sections 1819(h) and 1919(h) of the Act, 42 U.S.C § 1395i-3(b),(c),(d), and (e), *see also* 42 C.F.R. § 488.400 - 488.456.

B. Remedies

The selection of a remedy is based on a regulatory system “built on the assumption that all requirements must be met and enforced and that requirements take on greater or lesser significance as a function of the circumstances and resident outcomes in the facility at the time of a survey.” 64 Fed. Reg. 13,354, at 13,355 (March 18, 1999).

1. Termination
 - a. If a facility is not in substantial compliance for 180 days, CMS

must terminate that facility from the Medicare program.

- b. If a facility has conditions that pose immediate jeopardy for 23 days, CMS must terminate that facility.
 - c. CMS has the discretion to terminate a facility that is not in substantial compliance
2. Imposition of a temporary manager
 3. Denial of payment for all Medicare and Medicaid admissions (DPNA)
 - a. DPNA is mandatory where the facility fails to achieve substantial compliance within 90 days of determination of noncompliance
 - b. DPNAs may be imposed by CMS at its discretion prior to 90 days where there the facility is not in substantial compliance.
 4. Denial of payment for all new admissions
 5. Civil money penalties (CMP)
 - a. CMS may impose a CMP for either the number of days that a facility is not in substantial compliance with one or more requirements for participation in Medicare or for each instance that the facility is not in substantial compliance.
 - b. A \$50 to \$3,000 per day may be imposed where there is no immediate jeopardy but deficiencies either: 1) caused actual harm, or, 2) caused no actual harm, but have the potential for more than minimal harm.
 - c. A \$3,050 to \$10,000 per day CMP may be imposed for a finding of immediate jeopardy or if a \$50 to \$3,000 penalty was previously imposed and the deficiencies in the same regulatory grouping are repeated.
 - d. A \$1,000 to \$10,000 per instance CMP may be imposed for noncompliance that constitutes actual harm or for noncompliance that has the potential for more than minimal harm.
 - e. A per day CMP may be imposed when a facility is not in substantial compliance even absent a finding of immediate

jeopardy. It may also be imposed for the number of days of past noncompliance since the last standard survey.

- f. CMS considers the following factors before imposing a CMP:
 - i. The facility's history of noncompliance;
 - ii. The facility's financial condition;
 - iii. The seriousness and scope of the deficiencies and the relationship of one deficiency to another;
 - iv. The facility's culpability.
 - g. CMS may not collect a CMP until after an administrative appeal, if any.
 - h. CMS provides a 35% discount if a facility waives its right to an administrative appeal in writing within 60 days from the date of notice of imposition of the CMP. 42 C.F.R. § 488.436.
- 6. Directed plan of correction
 - 7. Directed in-service training
 - 8. Transfer of residents
 - 9. Loss of Nurse Aide Training and Competency Evaluation Program
 - a. Approval of a nurse aide and competency evaluation program is prohibited if a facility has been assessed, within the two previous years, a CMP of not less than \$5,000 or had a finding of substandard quality of care.
 - b. CMS may waive the mandatory loss of a facility's NATCEP program if the CMP was not related to quality of care issues.

V. Relationship between CMS and State survey agencies

A. Statutory Basis

- 1. Section 1864(a) of the Act authorizes the Secretary to enter into agreements with State health agencies (usually the State's Department of

Health, acting as the SSA) to ensure that SNFs meet the Federal requirements for participation in Medicare and Medicaid. This is known as “provider certification.” SOM § 1002.

B. Informal Dispute Resolution

1. State survey agencies conduct Informal Dispute Resolution (IDR).
2. Facilities may challenge the State surveys agency’s findings of noncompliance through the IDR process.
3. Filing an IDR with the State does not toll the imposition of remedies or the time within which providers must file an appeal with an ALJ.
4. CMS generally accepts the State’s IDR findings. However, it may, after review, decide that it does not agree with the IDR findings and impose a remedy even if the IDR finding did not support the noncompliance.

C. Precedence of SSA and CMS Determinations

1. Section 1819(h)(1) and (2) of the Act and 42 C.F.R. § 488.11(a) note that the State survey agency “makes recommendations” to CMS.
2. Disagreement over compliance with program requirements
 - a. The regulations address disagreements between the SSA and CMS regarding findings of noncompliance when non-State operated NFs and dually participating facilities are at issue (in the absence of a finding of IJ) *See* 42 C.F.R. § 488.452.
 - i the SSA’s findings of noncompliance take precedence when the SSA finds noncompliance and CMS finds that a NF or dually participating facility has achieved substantial compliance.
 - ii CMS’s findings of noncompliance take precedence when CMS finds that a NF or dually participating facility has not achieved substantial compliance and the SSA finds that a NF or dually participating facility has achieved substantial compliance.
3. Disagreement regarding termination
 - a. CMS’ determination takes precedence when

- both CMS and SSA find facility has not achieved substantial compliance; and, CMS, not the SSA finds that the facility's participation should be terminated
- b. the SSA's determination takes precedence when the SSA, not CMS finds that the NF's participation should be terminated *See* 42 C.F.R. § 488.452(b)(2).
4. Disagreement regarding the effective date of certification as a provider:
- a. CMS' determination is dispositive. The SSA "recommends" certification but, the determination is made by CMS.
 - b. Even if a State survey agency fails to or delays conducting a Life Safety Code survey and issues a license to a provider, it is not binding on CMS. *Forest Glen Skilled Nursing & Rehabilitation Center*, CR943 (August 20, 2002), *aff'd*. DAB No. 1887 (July 9, 2003).

VI. Federal Appeals

A. Timing

Appeals must be filed within 60 days from the CMS letter giving notice of intent to impose enforcement remedy. 42 C.F.R. § 498.40. *See, Horizon Specialty Hospital v. CMS*, Docket No. C-96-354, Dec. No. CR-514 (March 19, 1998), dismissing request for hearing as untimely where provider did not file a written appeal 60 days from receipt of notice of intent to terminate its participation from Medicare. The ALJ rejected the hospital's argument that 60 days should run from receipt of notice that determination has become effective, relying in part on clear specification of time requirement for filing request for hearing contained in CMS notice letter to provider. *Note*: 60 day appeal period may be extended for "good cause." 42 C.F.R. § 498.40(c)(2).

B. Jurisdiction

Appeals of CMS enforcement actions must be filed with an Administrative Law Judge of the Departmental Appeals Board (Board). Appeals are governed by the regulations at 42 C.F.R. § 498.40 et. seq.

C. Waiver

If facility waives its right to an appeal and hearing in writing, it will receive a 35% reduction in its CMP. The waiver of appeal letter must be filed within 60 days.

D. Content of Hearing Request

1. The appeal (hearing request) must identify the specific issues, findings of fact, and conclusions of law with which the party disagrees and it must state the basis upon which it disagrees. 42 C.F.R. § 498.40(b)
2. Where a facility fails to adequately challenge a deficiency on appeal, CMS will move to have the ALJ rule that the facility has conceded the deficiency. CMS will therefore request dismissal of the case where the appeal was legally insufficient. *See e.g.*, the *Jewish Home of Eastern Pennsylvania*, CRD Decision No. CR1863 at 3. (November 13, 2008).
3. Note: A facility may not appeal the choice of remedies, including the factors considered by CMS in selecting the remedy.
42 C.F.R. § 488.408(g)(2)

E. Reduction of amount (or duration) of CMP

1. If there is some basis for a CMP, the ALJ and DAB cannot reduce the CMP to zero. The minimum of \$50 per day must be imposed. 42 C.F.R. § 488.438(e) *CarePlex of Silver Spring v. CMS*, Docket No. CR 536 (1998) 1998 WL 354971 (HHS) (June 11, 1998).
2. An ALJ (or the Board) may reduce the amount of the CMP if it is shown that the amount is not reasonable. Additionally, an ALJ (or the Board) may determine that a facility regained substantial compliance prior to the date CMS determined, thereby shortening the length of time for a per day CMP.

F. Legal Burdens

1. At the hearing, CMS has the burden of establishing its *prima facie* case that the facility failed to be in substantial compliance with Federal requirements for participation in the Medicare program.
2. Once CMS establishes its *prima facie* case, the burden shifts to the provider to overcome CMS' case by a preponderance of the evidence. *Bradford County Manor*, DAB No, 2181 at 3 (June 23, 2008).
3. CMS typically establishes its *prima facie* case by presenting the testimony of the surveyors who were involved with the survey(s) at issue as well as

an expert witnesses that may be necessary.

G. HHS clarifies the term “employee” for purposes of providing testimony and/or documents.

1. Federal/state employees may not testify or produce documents in cases where the U.S. Government is not a party. 45 C.F.R. § 2.3.
2. On September 15, 2008, the U.S. Department of Health (HHS) published a final rule in which it clarified and amended the definition of “employee” regarding 45 C.F.R. § 2.1(a). That final rule explicitly notes that state survey agency personnel may not provide testimony or produce documents in any litigation relating to information acquired in the course of their official duties where the U.S. is not a party. Such testimony may be permitted only if the Administrator of CMS or his/her designee and the Office of the General Counsel determine that it promotes the objectives of the Department. 73 Fed. Reg. 53148 (September 15, 2008).

H. Either party may appeal an adverse ALJ decision to the Board.

1. Any party that is dissatisfied with the ALJ’s decision may appeal to the Board in writing within 60 days.
2. The Board may review an appeal of an ALJ decision based solely on the party’s appellate briefs and the record or it may permit (or request) oral argument. Oral arguments are conducted either at the Board’s courtroom in Washington, D.C. or by telephone.
3. The Board’s standard of review on the law is whether the ALJ’s decision is erroneous and its standard of review on a disputed issue of fact is whether the ALJ’s decision is supported by substantial evidence in the record as a whole. *Bradford County Manor*, DAB No. 2181 (June 23, 2008). *Guidelines - Appellate Review of Decisions of Administrative Law Judges Affecting a Provider’s Participation in the Medicare and Medicaid Programs* (at <http://www.hhs.gov/dab/guidelines/prov.html>)
4. There are no interlocutory appeals of an ALJ Ruling.
5. The Board is not empowered to remove a case from the ALJ for the limited purpose of issuing an interlocutory order and then remanding the case to the ALJ. See *Lakewood Plaza Nursing Center v. HCFA*, DAB No. 1767 (2001). A provider may appeal an adverse decision from the Board but CMS may not.

6. The Board may either issue its own decision or remand the case back to the ALJ.

I. Appeals of Board Decisions.

1. Decisions of the Board are considered the Secretary's final determination. Therefore, only the provider may appeal the Board's decisions.
2. Appeals of CMPs are made to the Circuit Court, not the U. S. District Court. *See* Section 1395i-3(h)(2)(B)(ii)
3. Appeals of all other remedies are made to the District Court where the facility is located. 42 U.S.C. § 405(g).
4. On December 28, 2007, the Secretary of HHS published a proposed rule that would permit the Secretary to review Board decisions and ALJ decisions (where the Board denies review). 72 Fed. Reg. 73708.

J. Federal Court Jurisdiction.

1. The Medicare Act contains a jurisdictional bar. Judicial review of a claim "arising under" the Medicare Act is precluded prior to exhaustion of administrative remedies (*i.e.*, appeals to both an ALJ and the Board) *See* 42 U.S.C. § 405(h), *See also, Shalala v. Illinois Counsel on Long Term Care, Inc.*, 529 U.S. 1 (2000), *Weinberger v. Salfi*, 422 U.S. 749 (1975), *Heckler v. Ringer*, 466 U.S. 602 (1984), holding that constitutional and APA claims "inextricably intertwined" with Medicare claims must be channeled through the administrative process.

2. Injunctive Actions.

The United States District Court for the Western District of Pennsylvania held that it lacked subject jurisdiction over a SNF's claim for termination from Medicare prior to exhaustion of the administrative appeal process. The plaintiff, Trade Around the World of PA d/b/a Highland Hall, alleged that HCFA, DOH and the Department of Health and Human Services violated its due process right because they exceeded their authority under the Social Security Act when they terminated Highland Hall prior to a hearing without a finding of immediate jeopardy. In addition to the due process argument, Highland Hall alleged it would suffer irreparable harm if its provider agreements were terminated before the court decided the due process issues. The court denied the injunction because "Plaintiff is required by Illinois Counsel to pursue this matter through the

administrative appeals process before consideration by this court.” *Trade Around the World of PA v. Shalala*, 145 F.Supp.2d 653 (W.D. Pa. 2/8/2001).