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Final Survey, Certification, and Enforcement Rules for Nursing Facilities

Final Survey, Certification, and Enforcement Rules for Nursing Facilities

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The Health Care Financing Administration (HCFA) has published the long-awaited final rules governing survey, certification, and enforcement of Requirements of Participation for Medicare skilled nursing facilities and Medicaid nursing facilities. /1/ The rules, which become effective July 1, 1995, make significant changes in the survey and certification process and describe the intermediate sanctions that states and the federal government have available and must use in responding to facilities that do not meet federal standards. This article describes the background of the rules, their major provisions, and HCFA's plans for implementation of its new enforcement system. /2/

I. Introduction

The federal nursing home reform law, enacted by Congress in 1987, comprehensively revised all aspects of federal nursing home law, including the standards for survey and certification activities and the enforcement options that are available to, or, in certain circumstances, mandatory for, HCFA and state survey agencies. /3/

In the area of enforcement, the most controversial part of the reform law and the area in which the consumer and provider communities never reached agreement during negotiations over the legislation, the reform law made major changes from existing practices. First, the law gives states a broad range of intermediate sanctions for use under Medicaid. /4/ A range of sanctions enables states to choose remedies that are appropriate to the specific types of noncompliance and to avoid overreliance on termination, the sole federal remedy ever used. /5/ Second, the reform law requires states to impose sanctions quickly after they identify deficiencies. The law provides for the prompt imposition of intermediate sanctions and expressly permits states to hold administrative hearings for all sanctions other than civil money penalties after the sanctions are imposed.

To implement the new method of enforcement, the reform law required the Secretary of the Department of Health and Human Services to publish regulatory guidance on enforcement of federal standards by October 1, 1988. /6/ It also established a state implementation date of October 1, 1989. By that date, the law required states to develop enforcement systems and to have in place the statutorily mandated range of intermediate sanctions, whether or not the Secretary gave guidance and published enforcement rules. /7/ States could develop alternative remedies if they demonstrated to the satisfaction of the Secretary that their alternative remedies were as effective as the specified remedies in deterring noncompliance and correcting deficiencies. /8/

HCFA published proposed rules on August 28, 1992. /9/ The agency received more than 27,900 comments, primarily from facility owners, operators, administrators, staff, and attorneys. /10/ Many of the industry comments were form letters generated by the American Health Care Association (AHCA), the for-profit trade association. In anticipation of the proposed rules, AHCA had produced its first videotape for its members, in which it urged all facilities to send at least four letters to HCFA supporting enactment of conflict resolution and use of scope and severity scales both to identify deficiencies and to impose sanctions.

II. Overview of the Final Rules

The final rules include several major changes from the proposed rules and a number of significant provisions. Among the major changes from the proposed rules are the addition of an informal dispute resolution process; the creation of a new standard of compliance called "substantial compliance" for all providers; a requirement that a survey agency consider facility culpability when it receives a complaint about resident neglect or abuse or misappropriation of resident property; the deletion of denial of payment for certain diagnostic categories as an available remedy; and a prohibition (in most situations) against retroactive payment when a ban on admissions is lifted.

Other major provisions of the final rules include elimination of the Level A/Level B system for classifying Requirements of Participation; regulatory language prohibiting facilities from using as a defense against regulatory action and enforcement a state agency's failure to comply fully with the federal survey protocol; reaffirmation that postsanction hearings are sufficient; and an explicit statement that survey agencies may impose civil money penalties retroactively against facilities whose noncompliance with statutory and regulatory standards occurred prior to the survey.

The rules reflect a close adherence to the language of the reform law and a general unwillingness to go beyond explicit statutory requirements. As a result, HCFA rejects many public comments with the observation that the Act does not require the interpretation offered by the commenter. The only two exceptions to this pattern are major: HCFA creates the concept of "substantial compliance" as the standard for participation in the Medicare and Medicaid programs and it says that it will apply a state's additional or alternative remedies, instead of the remedies specified in the statute, in facilities that participate in both Medicare and Medicaid (i.e., in dually participating facilities).

Several themes also emerge in the final rules. The key theme is state flexibility. HCFA repeats throughout the preamble that it intends to give states flexibility in designing and implementing their survey and enforcement systems. As a result, it leaves many critical areas for state decision making: whether and how to establish an incentive program for providers; how to develop and present educational programs for facility staff and residents; how to implement programs to assure accuracy and consistency in survey results and enforcement activities; composition of survey teams; specific procedural requirements for the informal dispute resolution process (e.g., how the request is made, the method for conducting the process, who participates); procedures for investigating allegations of resident neglect and abuse and misappropriation of resident property; decisions about when to impose single or multiple sanctions for deficiencies; how to evaluate plans of correction; content of orientation program for temporary managers; decisions about transfer,

including case-by-case methods to use in transferring residents and selection of the state agency to be responsible for conducting transfers; and procedures for using civil money penalties collected by states.

A second theme, which is related to HCFA's refusal to exercise its general rule-making authority, is its plan to provide additional, more detailed guidance in the State Operations Manual on issues that are not specifically mandated by the Act. Among the significant issues identified for treatment in this manner are: requirements for standard surveys; guidelines for educational programs for facility staff and residents; the process that HCFA will use in determining whether a state's alternative remedies may be substituted for the statutory sanctions; explanations of when deficiencies are treated individually or consolidated, for purposes of imposing sanctions; description of the role and responsibilities of monitors; examples of deficiencies and plans of correction that are appropriate in content and identification of responsible staff person; and guidelines describing when HCFA approves corrective actions requested by states, under the provision permitting continuation of payments pending remediation.

A third theme is HCFA's balancing and mediating differences between the provider and consumer communities. HCFA sees itself as finding a middle ground between the two factions and justifies some of its most controversial decisions, such as substantial compliance and informal dispute resolution, with this rationale. In many of its responses to public comments on the proposed rules, HCFA couples a decision that would be considered favorable to providers with a decision favorable to residents, and vice versa. The results are often inconsistency and confusion about the meaning of the rules.

A. *Survey and Certification*

While survey and certification are generally among the least controversial parts of the reform law, the final rules make several important points.

1. Deficiency

HCFA defines "deficiency" broadly as any failure to meet a federal requirement. /11/ Although HCFA rejects use of scope and severity scales to determine whether deficiencies exist, as providers had urged, it achieves a similar purpose by creating a new term, "substantial compliance," to establish a standard of compliance that "tolerates a reasonable degree of imperfection." /12/ Thus, facilities that fail to meet federal requirements may be found in "substantial compliance" with requirements of participation if the deficiencies "constitute no actual harm with a potential for minimal harm." Facilities that meet this standard are eligible for Medicare and/or Medicaid reimbursement and are not subject to formal enforcement actions, although these lesser deficiencies are officially recorded and are disclosable to the public. /13/

Unfortunately, the preamble gives inconsistent and ambiguous direction on how much imperfection may be tolerated. /14/ On the one hand, HCFA says that substantial compliance may not be found if deficiencies cause any harm to any resident or more than the potential of minimal harm to

residents. This definition in the regulatory language is strict and appears to tolerate only very minor problems. On the other hand, HCFA says in the regulatory impact analysis at the end of the preamble that the majority of facilities that were cited with Level B deficiencies in 1992 would meet the substantial-compliance standard. /15/ These statements are not compatible or easily reconciled.

2. Failure to Follow Procedures

HCFA retains language from the proposed rule stating that "failure to follow the procedures" governing survey and certification "will not invalidate otherwise legitimate determinations that a facility's deficiencies exist." /16/ HCFA's lengthy discussion of this issue reflects the strong provider opposition to this approach. HCFA stresses facilities' statutory obligation to comply with the reform law and rules, not with the survey protocol, and directly counters providers' claims that surveys are unreasonable searches and seizures that violate the Fourth Amendment. It concludes this discussion with a strong statement about the importance of facilities' complying with federal standards:

Protocols and guidelines are necessary to promote consistent survey practice. However, whether 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. /17/

3. Informal Dispute Resolution

A third important issue in the survey and certification portion of the final rules is the introduction of an informal dispute resolution process, which the industry had urged HCFA to adopt and which consumers were unanimous and adamant in opposing. /18/ In the familiar pattern in these rules, HCFA attempts to accommodate both provider and consumer interests. For providers, the rules require HCFA and states to offer a facility "an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies." /19/ For consumers, the rules provide that the failure to complete the informal dispute resolution process in a timely way "cannot delay the effective date of any enforcement action against the facility" and that a facility "may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action." /20/ Of even greater importance to consumers is HCFA's statement in the preamble that the dispute resolution process simply formalizes a process that already exists: "This dispute resolution system does not introduce additional requirements into the survey process; rather, it reinforces instructions that already exist but which have been applied inconsistently up to this point." /21/ Thus, the new requirement for informal dispute resolution does not require states to establish any additional procedures or opportunities for providers to contest survey findings.

HCFA sets out the core elements of the informal dispute resolution process in the rules but otherwise refuses to be prescriptive and allows states to implement their own specific procedural

requirements. /22/ State procedures may involve residents and their advocates as formal participants in the informal resolution of disputes, if states choose. /23/ HCFA refuses to require states to establish a process to notify residents and their families when surveyors need additional information to cite deficiencies (in essence, a parallel dispute resolution piece, which advocates had urged, for residents). Instead, HCFA says that residents and their families who are concerned about deficiencies or "inappropriate practices" should "contact the state ombudsman, request a complaint investigation, or both." /24/ HCFA's identification of states and providers as the sole parties to provider agreements leads HCFA to deny residents a role in certification disputes.

4. Resident Neglect and Misappropriation of Resident Property

Another area that underwent significant change from the proposed rules involves actions on complaints of resident neglect and abuse and misappropriation of resident property. New language recognizes the need to investigate the possibility of facility responsibility for neglect, abuse, and misappropriation. Thus the final rules require states to review the results of all complaint investigations in order to determine whether the facility violated a federal requirement and then, as appropriate, to initiate actions against the facility. /25/ The rules also prohibit a state from finding that an individual neglected a resident "if the resident demonstrates that such neglect was caused by factors beyond the control of the individual." /26/ While states must have a written process for timely review and investigation of allegations of neglect or abuse or misappropriation, most details of the process related to time frames, and the hearing process remain matters of state discretion. /27/

5. Remaining Issues

The remainder of the final rules for the survey and certification process generally quotes or paraphrases statutory requirements and, with few exceptions, adds little new substantive content. Standard surveys must be unannounced. /28/ Surveys must be conducted no later than 15 months after the last previous standard survey, with a 12-month statewide interval between standard surveys. /29/ In extended surveys, the resident sample is expanded and surveyors review policies and procedures, staffing, and in-service training. /30/ HCFA and states must implement programs "to measure accuracy and improve consistency in the application of survey results and enforcement remedies." /31/ Surveys must be conducted by multidisciplinary teams that must include a registered nurse and may include other professionals, as determined by states. /32/ States may also use specialized survey teams, including an attorney, auditor, and appropriate health professionals. /33/

HCFA deletes all provisions from the proposed rules that addressed federal validation surveys. /34/ HCFA defines "inadequate survey performance" as (1) "a pattern of failure" to cite deficiencies, to cite only valid deficiencies, to conduct surveys as required by the federal rules, or to use the federal standards, procedures, and forms, and (2) failure to identify an immediate jeopardy situation. /35/ Despite inadequate performance by a state agency, facilities are not relieved of their obligation to comply with federal requirements, and adequately documented deficiencies are not invalidated. /36/

HCFA has authority to impose sanctions under both Medicare and Medicaid for inadequate survey performance by state agencies. /37/

On request, states and HCFA must make public information about surveys, including statements of deficiencies and providers' comments; the separate list of isolated deficiencies that constitute no actual harm, with the potential for only minimal harm; approved plans of correction; statements that a facility did not submit an acceptable plan of correction or failed to comply with conditions of remedies; final appeal results; Medicare and Medicaid cost reports; and names of individuals with direct and indirect ownership interests in facilities. /38/ States may charge members of the public, including the ombudsman program, for copies of documents, using their own fee schedules; HCFA will use Medicare payment rules, which include provisions for waiving and reducing fees. /39/

A certification of compliance means that a facility is in "substantial compliance" with federal requirements and is eligible to participate in Medicare and/or Medicaid. /40/ The final rules on certification are similar to the proposed rules; they require states to impose remedies "promptly" after notifying the facility of deficiencies and remedies and, except for civil money penalties, "during the pendency of any hearing that may be requested by the provider of services," "notwithstanding any provision of State law." /41/ HCFA provides a lengthy discussion supporting postsanction hearings for providers, citing constitutional law on due process, case law on nursing home enforcement, the explicit language of the reform law, and the government's responsibility -- which supersedes the private interest of facilities in continuing their participation in Medicare and Medicaid -- to protect the health and safety of residents /42/ However, the final rules omit a provision from the proposed rules that would have required states to impose penalties "at the time the State identifies violations of Federal requirements." /43/ The significance of this omission becomes clearer in the enforcement provisions that follow.

New language about complaint investigations requires states to take "appropriate precautions to protect a complainant's anonymity and privacy, if possible." /44/ HCFA requires states to "properly evaluate and investigate all complaints that may affect a facility's certification" and says that it would seriously consider imposing a civil money penalty if a complaint was resolved before the surveyors arrived. /45/ States must also provide periodic educational programs for staff and residents about rules, procedures, and policies concerning survey, certification, and enforcement. /46/ The details of the education programs are left to the states. /47/

B. Enforcement

The final enforcement rules do not encourage use of intermediate sanctions, rather than termination, and they fail to require prompt imposition of sanctions when survey agencies cite deficiencies. They also give limited guidance on the specific intermediate sanctions.

1. Intermediate Sanctions

While the preamble to the final rule recognizes the importance of using intermediate sanctions to achieve correction of deficiencies and compliance with standards, the final rules and preamble

encourage use of termination in virtually all cases. /48/ HCFA rejects public comments to impose termination only as a last resort and contends that the reform law gives states and the Secretary authority to impose any remedy, including termination, for any deficiency. /49/ While this statement about the reform law is literally true, it does not reflect the reform law's new focus on using intermediate sanctions, and it ignores the strong legislative history of the law promoting alternatives to termination. /50/

HCFA interprets the statute to require states to submit to the regional office a plan and timetable for corrective action and to agree to repay federal Medicaid funds if a facility fails to take corrective action according to the HCFA-approved plan and timetable. /51/ This sequence and these requirements are necessary, HCFA writes, in all situations when a state wants to use intermediate sanctions alone. Only if a state combines use of intermediate sanctions with termination will the requirements for regional office approval and for payback of federal funds not apply. HCFA anticipates that termination would rarely occur in any of these cases. /52/ HCFA's interpretation of the statute plainly promotes pro forma use of termination in virtually all cases. This interpretation not only creates unnecessary paperwork and wastes increasingly limited state enforcement resources but also perpetuates the historical problem of the enforcement system's overreliance on termination.

The final rules also create substantial delays in the imposition of intermediate sanctions by establishing new regulatory requirements not required by the statute: lengthy advance notice of sanctions and correction periods.

The rules require states to give facilities prior notice before they impose any sanction other than state monitoring in immediate jeopardy situations. /53/ (Civil money penalties are separately addressed in the rules.) In cases of immediate jeopardy, at least two calendar days' notice must be given before the effective date of any sanction; in cases of nonimmediate jeopardy, at least 15 calendar days' notice is required. While the notice periods begin when the facility receives the notice, the effective date of an enforcement action may not be later than 20 calendar days after the notice is sent. /54/ HCFA rejects provider comments to lengthen the advance notice as well as consumer comments to reduce the advance notice and therefore believes that it "struck a fair balance between giving facilities fair notice and a reasonable chance to correct deficiencies and fulfilling our responsibility to safeguard the health or safety of residents." While HCFA acknowledges that the reform law does not require advance notice of sanctions, it cites "constitutional principles of due process" as generally requiring advance notice of adverse agency action. /55/

HCFA also creates "correction periods," although it again acknowledges that "neither the Act nor the Constitution require[s] that providers have the opportunity to correct deficiencies before sanctions are imposed." /56/

The enforcement portion of the final rules describes a single purpose of enforcement: "ensur[ing] prompt compliance with program requirements." /57/ This purpose does not include protection of residents and deterrence of noncompliance, which the preamble to the proposed rules defined as additional purposes of enforcement. /58/

HCFA and states impose remedies "on the basis of noncompliance found during surveys." /59/ They may impose one or more remedies for each deficiency or for a group of related deficiencies. /60/ The final rule gives flexibility to HCFA and states to choose the numbers of remedies and to decide when and how to impose them. HCFA's explicit intention to provide "maximum flexibility" is inconsistent with the Institute of Medicine's observation that "guidelines on when to initiate sanctions are necessary for effective state enforcement." /61/

The rules set out the factors that HCFA and states consider in selecting remedies. These factors reflect ranges in scope (whether deficiencies are isolated, a pattern, or widespread) and harm (whether there is no actual harm with a potential for no more than minimal harm; no actual harm with a potential for more than minimal harm; actual harm; and immediate jeopardy). /62/ These scope and harm scales replace the scope and severity scales in the proposed rules.

The rules then group remedies into three categories and correlate the remedy categories with deficiencies "according to how serious the noncompliance is." /63/ Unless there is substantial compliance, one or more Category 1 remedies -- directed plan of correction, monitoring, and directed in-service training -- must be imposed when there

(i) are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy. /64/

One or more Category 2 remedies -- denial of payment for new admissions, denial of payment for all individuals (a HCFA-only remedy), and civil money penalties of \$50 to \$3,000 per day -- must be imposed, in the absence of substantial compliance, when there are

(i) widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy;

(ii) one or more deficiencies that constitute actual harm that is not immediate jeopardy. /65/

Category 3 remedies include temporary management, immediate termination, and civil money penalties of \$3,050 to \$10,000 per day. /66/ If there is immediate jeopardy, HCFA and states must impose temporary management or terminate the provider agreement, and they may also impose civil money penalties. /67/ If there are widespread deficiencies constituting harm but not immediate jeopardy, HCFA and states may impose temporary management and Category 2 remedies. /68/

HCFA declines to give further guidance on the rules and says that the system gives HCFA and states "discretion to design their own schemes." /69/ Many commenters had sought additional federal guidance.

While providers may appeal a certification of noncompliance that leads to an enforcement action, the rules do not permit them to appeal the level of noncompliance, the choice of remedy, or the factors considered by HCFA or a state in selecting a remedy. /70/ In its lengthy explanation of its

rationale, HCFA argues that selection of a remedy is a "prosecutorial prerogative of the government," not a decision of a provider; that the sanction of termination may not be challenged; and that states have complete discretion to choose among most remedies in categories 1 and 2. /71/

Two other important enforcement issues are addressed in only cursory fashion in the final rules. HCFA requires facilities to submit plans of correction for all deficiencies other than isolated ones that have a potential for only minimal harm. /72/ However, it declines to give guidance on plans of correction. While agreeing with one commenter's observation that some plans of correction "do nothing more than complain about the law, the surveyor, or the circumstances, without ever describing how the violation will be corrected," HCFA offers no regulatory response:

We agree and would only add that it is highly probable that facilities submitting these plans considered them to be "reasonable," and extremely improbable that these plans would be acceptable to HCFA or the State. /73/

HCFA also agrees that plans of correction should be clear and specific, but it refuses to state these principles as regulatory requirements. /74/

HCFA's refusal to set out specific guidelines for plans of correction, including standards for approval and rejection, is one of the most serious lapses in the final rules. The Institute of Medicine's 1986 report on nursing homes was highly critical of the postsurvey phase of nursing home certification and highlighted the lack of specific federal standards for evaluating plans of correction and for determining the elements that are necessary for an acceptable plan. /75/ Since many deficiencies in the past have had plans of correction as their only consequence, HCFA's failure to provide regulatory guidance is especially disturbing.

As noted, states may use alternative or additional remedies, instead of remedies specified in the reform law, if they demonstrate to the satisfaction of the Secretary that these remedies are equally effective in deterring noncompliance and correcting deficiencies. /76/ The final rules add nothing to the statutory language and provide no explanation of the standards that the Secretary intends to use in considering a state's request to use alternative remedies. While agreeing with commenters that uniformity is needed in the process used to approve alternative remedies, HCFA says that it will prepare manual instructions, rather than regulations, on this point. /77/

Since states that choose to use the specified remedies must use them exactly as they appear in the Federal Register, it is likely that many states will prefer to use their own alternative remedies rather than the specified remedies. In addition, states that want to use alternative remedies following publication of the final rules must submit a state plan amendment to HCFA, even if they sought and received permission from HCFA at an earlier time to use alternative remedies. These factors make this provision in federal law particularly important, and the lack of federal rules particularly troublesome.

2. Remaining Enforcement Rules

The remainder of the final enforcement rules provides limited guidance on each of the specific remedies.

a. Temporary Management

Temporary management is the administrative appointment of a manager or administrator "with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in the facility's operation." /78/ Despite this language, HCFA is ambivalent about the scope of a temporary manager's authority. While the preamble says that a temporary manager must have "authority to completely manage the entire facility with enough autonomy to remove any immediate jeopardy and/or correct deficiencies," HCFA also prohibits temporary managers from refusing to honor excessive preexisting leases, mortgages, and contracts and instead requires them to honor "any limitations under which the facility operates." /79/

The potential usefulness of the sanction is also limited by HCFA's repeated statements in the preamble that facilities have the right to reject the sanction entirely, either by refusing to relinquish control to a temporary manager or by refusing to continue with the remedy after it is imposed. Although HCFA insists elsewhere in the rules and preamble that facilities may not choose or challenge the remedy selected by a state agency, the final rules allow facilities to reject appointment of a temporary manager. HCFA also invites facilities "to monitor the performance of the temporary manager," and says that "if they have any apprehension about his or her performance, they may have the remedy discontinued." HCFA's rationale is that it cannot force a facility to relinquish control to a temporary manager because participation in the Medicare and Medicaid programs is voluntary. /80/ If a facility refuses to relinquish authority to a temporary manager, the rules require HCFA or a state to terminate a provider agreement. /81/

b. Denial of Payment for All New Admissions

Denial of payment for all new admissions may be imposed by HCFA and states for deficiencies and is mandatory under two sets of circumstances: when a facility is not in substantial compliance three months after the last day of a survey that identified noncompliance and when a state has cited a facility for substandard quality of care on the last three consecutive standard surveys. /82/ Agreeing with public comments to prohibit retroactive payments once the sanction is lifted, /83/ HCFA adds regulatory language to permit "prospective resumption" of payments under Medicare and Medicaid. /84/ In response to public comments, HCFA, having been persuaded that the denial of payment would violate the Rehabilitation Act of 1973 and the Americans with Disabilities Act, also deletes such a remedy for certain diagnostic groups. /85/

A new optional remedy, which did not appear in the proposed rules, is Secretarial authority to deny all payments. /86/ Under this remedy, the Secretary may deny further payment for all Medicare residents as well as payment to a state for all Medicaid residents. Federal payments resume prospectively.

c. State Monitoring

State monitoring is a remedy for which HCFA finds "implicit" statutory authority. /87/ A monitor is an employee or contractor of the survey agency whose job is "oversee[ing] correction of deficiencies . . . and protect[ing] the facility's residents from harm." /88/ Monitors are mandatory and must be imposed when a survey agency finds substandard quality of care on three consecutive standard surveys. /89/ The sanction is discontinued when the facility demonstrates that it is in substantial compliance and will remain in substantial compliance or when the facility is terminated. /90/

Preamble language stating that monitors may be appointed immediately in immediate jeopardy situations, without prior notice to the facility, is not reflected in the rules. /91/ Nor do the rules reflect the preamble's statement that states may impose a monitor if a facility refuses to relinquish control to a temporary manager. /92/

d. Directed Plan of Correction

A directed plan of correction is an optional remedy in which HCFA, a state survey agency, or a temporary manager "require[s] a facility to take action within specified timeframes." /93/ The remedy is different from a facility-initiated plan of correction, which is the definition of a traditional plan of correction. HCFA refuses to explain in rules the types of situations in which a directed plan of correction would be appropriate, and it says it will provide guidance in the manual. It also rejects the consumer recommendation that directed plans of correction be used to require correction of deficiencies or violation of rights for specific residents whose care was deficient or whose rights were violated, as determined by the state survey agency. /94/

e. Directed In-Service Training

The final rules create a new optional remedy, directed in-service training, which requires facility staff to attend in-service training if "the facility has a pattern of deficiencies" and "education is likely to correct the deficiencies." /95/ The impetus for this sanction is HCFA's experience with the reform law and its view that some compliance problems are the result of "imperfect knowledge on the part of the health services staff relative to state-of-art practices and resident outcome expectations." /96/ Although the rules require facilities to pay for in-service training, the preamble does not expressly say that directed in-service education is not an allowable cost under Medicaid. /97/

f. Closure of a Facility or Transfer of Residents

Closure of a facility or transfer of residents, or both, may be used in emergencies and when the state terminates a facility in either immediate-jeopardy or nonimmediate-jeopardy situations. /98/ HCFA recognizes that closures of facilities and transfers of residents are rare; however, since HCFA believes that most states have experience with closure, it refuses to mandate specific

procedures. /99/ The rules permit residents to use the transfer/discharge appeals process to challenge the "appropriateness of transfer plans," but residents may not appeal the termination of the facility's provider agreement. /100/

g. Civil Money Penalties

Civil money penalties are extensively discussed in both the rules and the preamble. In contrast to other sanctions, civil money penalties may not be imposed until the provider has first been given the opportunity for an administrative hearing. While HCFA claims to have adopted the Institute of Medicine's recommendations related to civil money penalties, the rules actually contradict the Institute's recommendations concerning size and versatility of penalties. /101/

The final rules clarify that civil money penalties may be imposed for past noncompliance that occurred and was fully corrected prior to a survey. /102/ Penalties for civil money penalties accrue daily, but they are not collected until a facility achieves substantial compliance or is terminated. /103/ Correction of deficiencies is relevant only for determining the number of days that a civil money penalty accrues.

If a facility waives the right to a hearing, in writing, within 60 days of the notice of intent to impose a penalty, HCFA or the state must reduce the penalty amount by 35 percent. /104/ HCFA contends that the intent of this waiver provision, which was strongly opposed by public commenters, is to encourage settlements. Another regulatory provision addressing settlements permits HCFA to settle cases at any time prior to a final administrative decision; states have authority to settle cases prior to the evidentiary hearing decision. /105/ Despite public criticism, the rules contain no guidelines or limitations of any kind on these settlements. /106/

In determining the amount of a penalty, states consider a facility's history of noncompliance, /107/ financial condition, /108/ the factors specified in section 488.404, /109/ and the facility's "degree of culpability." /110/ HCFA says that, "as a matter of policy, [it] will limit the use of civil money penalties to more serious deficiencies." /111/ This policy decision is inconsistent with the Institute of Medicine, which said, "Fines are a valuable enforcement tool because they can be applied to minor violations early and often, thus deterring facilities from making more serious transgressions." /112/

New regulatory language added to the final rules prevents administrative law judges, state hearing officers, and higher review authorities from reducing a penalty to zero, "review[ing] the exercise of discretion . . . to impose a civil money penalty," and considering factors other than those specified in the rules when they find that the basis for imposing a penalty exists. /113/

The final rules also eliminate the proposed rules' "grace period" for correcting deficiencies and permit, although they do not require, penalties to begin accruing as soon as noncompliance is identified. /114/

III. Implementation of the Final Rules

By the spring of 1995, HCFA intended to have revised the survey protocol and the interpretive guidelines in the State Operations Manual and to have drafted a new enforcement manual. HCFA circulated drafts of these three documents to a small number of states, provider, consumer, and professional organizations in January 1995 and conducted a few pilot tests of the proposed changes in the survey process. HCFA intended to conduct four training courses for trainers, supervisors, surveyors, and state attorneys on April 3 -- 7, April 24 -- 28, May 1 -- 5, and May 8 -- 12, 1995. The new manuals and training are planned to meet the July 1, 1995, implementation date for the final rules. HCFA does not intend to publish the changes in the Federal Register for notice and public comment. In the final rules, it rejects the public comment that the survey materials are subject to the Administrative Procedure Act.

As a result of OBRA '87, the Medicare and Medicaid law and regulations now contain comprehensive, detailed criteria for assessing the quality of care provided to Medicare and Medicaid residents, as well as the standards and methodology for determining deficiencies. The survey forms, procedures and guidelines merely enable surveyors to certify whether facilities are, in fact, complying with these binding statutory and regulatory requirements. These materials do not, in any way, add to or change these requirements and thus cannot be characterized as "substantive" rules; rather, they are a mixture of "interpretive rules," "general statements of policy," and "rules of agency procedure" within the meaning of 5 U.S.C. Sec. 553(b)(A), which excludes such rules from the notice and comment requirements. /115/

HCFA's decision not to publish the survey forms, procedures, and guidelines has been challenged. The state of Colorado, plaintiff in intervention in *Smith v. Shalala*, filed a supplemental memorandum in the 20-year-old litigation on December 14, 1994, in support of its pending motion to require HCFA to publish any new survey process in the Federal Register for notice and public comment. /116/ Colorado quotes the language above from the November 10, 1994, final rules.

More than a decade ago, in 1984, the Tenth Circuit reversed a lower court decision in *Smith* and held 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." /117/ On remand, the district court ordered the Secretary to publish rules. /118/ Following enactment of the nursing home reform law, the federal defendants, in January 1988, sought to be relieved of the court order requiring publication of the survey process. The motion to vacate judgment and orders in light of new legislation was denied by the court in February 1988. /119/ The federal defendants published the survey process as rules on June 17, 1988, following the district court's third order requiring publication. /120/

In August 1990, the federal defendants filed a new motion for relief from court's orders, requesting that the court relieve the Secretary from its previous order to publish the federal survey protocol in regulations. The Secretary argued that the published protocol would be obsolete when the reform law went into effect on October 1, 1990, and that the Department had sought and received comments from a large number of people and groups over a long period of time in drafting the new protocol, Transmittal 232. The court granted the Secretary's motion "on an interim basis" on September 27, 1990, and allowed the new protocol (and thus the nursing home reform law) to go

into effect on October 1, 1990. The Secretary never sought permission from the court to use the April 1992 version of the survey protocol, Transmittal 250, which is now in effect.

Two enforcement actions against nursing facilities have been overturned by administrative law judges who found that the survey team failed to use the survey protocol that was published in the Federal Register in June 1988 (and that still appears in the Code of Federal Regulations). /121/

On January 21, 1993, citing the earlier of the two cases and other factors, the Secretary filed a memorandum renewing efforts to be relieved of the obligation to publish the survey protocol in the Federal Register for notice and comment under the Administrative Procedure Act. The Secretary's request is still pending. Colorado's December 1994 memorandum seeking publication of the survey protocol also cites Devon Gables and Heritage Manor of Marrero.

IV. Conclusion

In the preamble to final rules, an agency reports the public comments it received about proposed rules and explains how it resolved disputed and controversial issues. As a responsive document, the preamble is not a focused statement of agency policy. Nevertheless, despite limitations inherent in the form, the preamble to these final rules is repetitive and inconsistent. Different articulations of a single point have different nuances and sometimes entirely different interpretations. This confusion is most apparent in HCFA's numerous discussions of "substantial compliance," which is variously described as "virtual compliance" and, the opposite, as the level of compliance already met by most facilities.

While recognizing that a preamble is a limited document, residents' advocates nevertheless have a number of concerns about the final rules, many of which are similar to concerns they expressed about the proposed rules. One significant issue is the failure of the rules to focus on using intermediate sanctions, rather than termination, as the primary and preferable method of responding to deficiencies in facilities. While the preamble recognizes the change in enforcement orientation, the regulations themselves do not follow through fully on this change. Instead, the rules place so many regulatory obstacles in the way of a state's using intermediate sanctions that states are likely to continue using their old methods of enforcement -- that is, relying on termination as the remedy they impose, even if they also impose alternative remedies.

Second, as in the proposed rules, there is insufficient focus on residents' rights and quality of life -- new statutory requirements enacted in the 1987 reform law. HCFA's focus on violations related to "harm" continues the agency's long-standing bias toward health and safety concerns and minimizes consideration of issues related to residents' rights, welfare, and quality of life. The agency's concentration on harm also gives insufficient attention to statutory and regulatory language requiring positive outcomes -- that each resident achieve his or her highest possible functioning. While the survey and enforcement processes need to determine compliance with all statutory and regulatory requirements, the final rules are dominated, as before, by issues involving losses in health and safety.

A third concern is that the extensive flexibility and discretion given to states to resolve survey and enforcement issues have negative consequences that undermine strong enforcement. Flexibility is granted at the expense of consistency and predictability. When states are permitted to establish their own procedures and rules, the consistency required by the reform law is more difficult to achieve. Second, and perhaps more significant, flexibility exposes states to pressure from providers not to enforce standards. Federally mandated enforcement practices would reduce states' discretion and protect states from providers' efforts to weaken enforcement activities.

On the positive side, advocates are pleased that HCFA resisted efforts to require use of scope and severity scales to determine whether deficiencies exist and instead defined deficiency as failure to meet any federal Requirement of Participation. Other positive features are HCFA's strong endorsement of the adequacy of postsanction hearings for providers; a new requirement that survey agencies consider facility culpability whenever they receive complaints related to abuse or neglect of residents or misappropriation of resident property; the refusal to allow providers to appeal the level of noncompliance or the enforcement sanction chosen by HCFA or a state; and recognition in the preamble of the importance and need for enforcement agencies to use intermediate sanctions aggressively to protect residents.

Footnotes

/1/ 59 Fed. Reg. 56116 (Nov. 10, 1994).

/2/ A 102-page, more detailed version of this article, published in *The Nursing Home Law Letter of the National Senior Citizens Law Center (NSCLC)*, can be obtained from Gloria Crawford, NSCLC, 1815 H St. NW, Suite 700, Washington, D.C. 20006, for \$10.

/3/ Pub. L. No. 95-142, 42 U.S.C. Secs. 1395i-3(a) -- (h), 1396r(a) -- (h), Medicare and Medicaid, respectively.

/4/ 42 U.S.C. Sec. 1396r(h)(2)(A)(i) -- (iv).

/5/ In 1981, Congress enacted an intermediate sanction -- denial of payment for admissions of new Medicare beneficiaries -- but the Health Care Financing Administration (HCFA) did not publish proposed rules until February 21, 1985, 50 Fed. Reg. 7191. Both the statute and the proposed rules required an administrative hearing before the sanction could go into effect. The intermediate sanction was expressly repealed by the 1987 reform law. Pub. L. No. 100-203, Sec. 4213(b), 42 U.S.C. Sec. 1396(a).

/6/ 42 U.S.C. Sec. 1396r(h)(2)(B)(i).

/7/ *Id.*

/8/ *Id.* Sec. 1396r(h)(2)(B)(ii).

/9/ 57 Fed. Reg. 39278 (Aug. 28, 1992).

/10/ 59 Fed. Reg. 56116, 56127 (Nov. 10, 1994).

/11/ 42 C.F.R. Sec. 488.301; 59 Fed. Reg. 56182 (Nov. 10, 1994).

/12/ 59 Fed. Reg. 56226 (Nov. 10, 1994).

/13/ These deficiencies are recorded on a separate form, not the official HCFA 2567. 42 C.F.R. Sec. 488.325(a)(2).

/14/ See 59 Fed. Reg. 56153 (Nov. 10, 1994).

/15/ Id. at 56230 -- 31.

/16/ 42 C.F.R. Sec. 488.305(b).

/17/ 59 Fed. Reg. 56134 (Nov. 10, 1994).

/18/ Id. at 56223 -- 25.

/19/ 42 C.F.R. Sec. 488.331(a)(2).

/20/ Id. Sec. 488.331(b)(1), (2).

/21/ 59 Fed. Reg. 56224 (Nov. 10, 1994).

/22/ The process must include one opportunity for a facility to refute survey findings when it receives the official HCFA 2567; an opportunity to present disagreements to the survey agency or HCFA regional office officials, or both; a prohibition against delay in the effective date of any enforcement action; and a written copy of the dispute resolution process. 59 Fed. Reg. 56224 (Nov. 10, 1994).

/23/ At the November 10, 1994, press conference announcing the new rules, NSCLC asked if residents could participate in the informal dispute resolution. HCFA said that nothing in the rules prohibited states from allowing such participation.

/24/ 59 Fed. Reg. 56225 (Nov. 10, 1994).

/25/ 42 C.F.R. Sec. 488.334(h)(1), (2); 59 Fed. Reg. 56163 -- 64. HCFA is somewhat ambiguous in its discussion of facility culpability. While it recognizes that it may be appropriate to impose sanctions against facilities, it also suggests that firing the employee who neglects a resident "could immediately correct that deficiency." 59 Fed. Reg. 56164 (Nov. 10, 1994).

/26/ 42 C.F.R. Sec. 488.334(d).

/27/ Id. Sec. 488.334(a)(3). If the state makes a preliminary determination that abuse, neglect, or misappropriation occurred, it must provide written notification of the determination to both the

individual and the current administrator of the facility where the incident occurred. Id. Sec. 488.334(c). The written notice must include the nature of the allegations and the date and time of the occurrence and the right to a hearing; it must also advise the individual of the consequences of failing to request a hearing or waiving a hearing. Id. Sec. 488.334(c)(3)(i) -- (vii). Findings of neglect, abuse, or misappropriation are reported to the individual, the current administrator of the facility where the incident occurred, the administrator of the facility where the individual currently works, and the nurse aide registry. Id. Sec. 488.334(f)(1) -- (5).

/28/ Id. Sec. 488.307; 59 Fed. Reg. 56135 -- 36 (Nov. 10, 1994). This is a change from the proposed rules, which required that all surveys be unannounced. However, HCFA agrees that as many surveys as possible should be unannounced and that survey schedules should be unpredictable. Preamble language prohibiting advance notice to ombudsman programs has been superseded by a policy decision to give advance notice to ombudsman programs.

/29/ 42 C.F.R. Sec. 488.308; 59 Fed. Reg. 56136 -- 38 (Nov. 10, 1994). The preamble includes a lengthy discussion of a 1986 report of the Institute of Medicine, which stressed the importance of flexible survey cycles. Committee on Nursing Home Regulation, Institute of Medicine, Improving the Quality of Care in Nursing Homes 155 (1986).

/30/ 42 C.F.R. Sec. 488.310; 59 Fed. Reg. 56139 -- 40 (Nov. 10, 1994). HCFA explains its policy decision not to conduct "extended surveys" within the meaning of the rules unless it finds substandard quality of care during a standard survey. The reason for this policy is that a facility automatically loses its approval to conduct nurse-aide training and competency evaluation whenever it has an extended survey. HCFA says that it and states can lengthen a survey, if necessary, without calling the survey an extended one.

/31/ 42 C.F.R. Sec. 488.312; 59 Fed. Reg. 56140 -- 41 (Nov. 10, 1994). HCFA changes the language from the proposed rules by adding "accuracy." HCFA declines to be prescriptive about what state agencies must do.

/32/ 42 C.F.R. Sec. 488.314(a)(1), (2). HCFA refuses to "dictate" to states the composition of survey teams. 59 Fed. Reg. 56142 (Nov. 10, 1994). It rejects comments that surveyors must have professional training in clinical areas before being allowed to survey facilities. Id. at 56143. It allows states to decide whether to rotate surveyors onto different teams or to keep them on the same teams. Id. at 56142.

/33/ 42 C.F.R. Sec. 488.332(c).

/34/ Proposed 42 C.F.R. Sec. 488.166, which addressed sample validations, focused review, and appeals, is deleted in its entirety. HCFA says that the statutory provisions are self-implementing. 59 Fed. Reg. 56144 (Nov. 10, 1994). Nevertheless, HCFA responds to public comments on the proposed rules.

/35/ 42 C.F.R. Sec. 488.318(a)(1)(i) -- (iv), (2). In an addition to the proposed rules, "systematically citing unfounded deficiencies" will be considered "inadequate survey performance." 59 Fed. Reg.

56147 (Nov. 10, 1994). However, because of the language of the Act, federal financial participation is reduced only for failure to cite deficiencies, not for citing unfounded deficiencies.

/36/ 42 C.F.R. Sec. 488.318(b)(1), (2).

/37/ Id. Sec. 488.320. For Medicaid, the rules authorize reduction in federal financial participation through a specified formula and training of surveyors if the state agency fails to identify deficiencies; other state agency failures (such as deficiencies in survey scheduling or team composition) are sanctioned only through surveyor training. For all survey inadequacies under Medicare, the rules require the state agency to submit a plan of correction; provide surveyor training, technical assistance on scheduling and procedural policies and HCFA-directed scheduling; and require HCFA to initiate action to terminate the Sec. 1864 agreement with the state.

/38/ 42 C.F.R. Sec. 488.325(a)(1) -- (9). Information from complaint surveys must be publicly disclosed.

/39/ Id. Sec. 488.325(b).

/40/ States certify the compliance of nonstate-operated nursing facilities (NFs), id. Sec. 488.330(a)(1)(i)(A); of dually participating skilled nursing facilities (SNFs)/NFs, id. Sec. 488.330(a)(1)(i)(D); and, subject to HCFA approval, of nonstate operated SNFs, id. Sec. 488.330(a)(1)(i)(C). HCFA certifies the compliance of all state-operated facilities, id. Sec. 488.330(a)(1)(i)(B). HCFA's determination of noncompliance is binding and overrules a state's finding of compliance, however, id. Sec. 488.330(a)(1)(ii).

/41/ Id. Sec. 488.330(e)(1)(i), (ii).

/42/ 59 Fed. Reg. 56155 -- 58 (Nov. 10, 1994).

/43/ Proposed 42 C.F.R. Sec. 488.180(e)(1)(i).

/44/ 42 C.F.R. Sec. 488.332(a)(2).

/45/ 59 Fed. Reg. 56159 -- 61 (Nov. 10, 1994).

/46/ 42 C.F.R. Sec. 488.334.

/47/ 59 Fed. Reg. 56162 (Nov. 10, 1994).

/48/ Id. at 56168.

/49/ Id. at 56167 -- 68.

/50/ In 1986, the Institute of Medicine recognized that federal sanctions were inadequate because they essentially permitted only termination, a sanction that was rarely used because it puts providers out of business. Committee on Nursing Home Regulation, *supra* note 32, at 155. The

institute recommended that federal law be amended to require states to develop and to use a uniform set of intermediate sanctions. *Id.* at 164.

/51/ 42 C.F.R. Sec. 488.450(a)(1)(i), (iii); 59 Fed. Reg. 56211 -- 13 (Nov. 10, 1994).

/52/ 59 Fed. Reg. 56212 (Nov. 10, 1994).

/53/ The notice of remedies must include the "nature of the noncompliance," identification of the remedy and its effective date, and the right to appeal. 42 C.F.R. Sec. 488.402(f)(1) (all facilities other than nonstate-operated NFs), *id.* Sec. 488.402(f)(2) (non state-operated NFs).

/54/ *Id.* Sec. 488.402(f)(3), (4), (5).

/55/ 59 Fed. Reg. 56171 (Nov. 10, 1994).

/56/ *Id.*

/57/ 42 C.F.R. Sec. 488.402(a).

/58/ 57 Fed. Reg. 39390, 39279 (Aug. 28, 1992).

/59/ 42 C.F.R. Sec. 488.402(b); 59 Fed. Reg. 56243 (Nov. 10, 1994).

/60/ 42 C.F.R. Sec. 488.402(c).

/61/ Committee on Nursing Home Regulation, *supra* note 32, at 154.

/62/ 42 C.F.R. Sec. 488.402(b)(1), (2); 59 Fed. Reg. 56171 -- 73 (Nov. 10, 1994).

/63/ 42 C.F.R. Sec. 488.408(a).

/64/ *Id.* Sec. 488.408(c)(2).

/65/ *Id.* Sec. 488.408(d)(2).

/66/ *Id.* Sec. 488.408(e)(1).

/67/ *Id.* Sec. 488.408(e)(2)(i)(A), (B), and Sec. 488.408(e)(2)(ii), respectively. Immediate jeopardy is further discussed at *id.* Sec. 488.410; 59 Fed. Reg. 56180 -- 81 (Nov. 10, 1994).

/68/ 42 C.F.R. Sec. 488.408(e)(3). Nonimmediate jeopardy is also discussed at *id.* Sec. 488.412.

/69/ 59 Fed. Reg. 56178 (Nov. 10, 1994).

/70/ 42 C.F.R. Sec. 488.408(g).

/71/ 59 Fed. Reg. 56178 (Nov. 10, 1994).

/72/ 42 C.F.R. Sec. 488.402(d)(1), (2).

/73/ 59 Fed. Reg. 56169 (Nov. 10, 1994).

/74/ *Id.*

/75/ Committee on Nursing Home Regulation, *supra* note 32, at 153 -- 55.

/76/ 42 U.S.C. Sec. 1396r(h)(2)(B)(ii); 42 C.F.R. Secs. 488.303(f), 488.406(c).

/77/ 59 Fed. Reg. 56176 (Nov. 10, 1994).

/78/ 42 C.F.R. Sec. 488.415(a).

/79/ 59 Fed. Reg. 56189 (Nov. 10, 1994).

/80/ *Id.* at 56188 -- 90.

/81/ 42 C.F.R. Sec. 488.415(d).

/82/ *Id.* Sec. 488.417(a), (b).

/83/ 59 Fed. Reg. 56192 (Nov. 10, 1994).

/84/ 42 C.F.R. Sec. 488.417(d), (e).

/85/ 59 Fed. Reg. 56191 -- 92 (Nov. 10, 1994).

/86/ 42 C.F.R. Sec. 488.418.

/87/ 59 Fed. Reg. 56194 (Nov. 10, 1994).

/88/ 42 C.F.R. Sec. 488.422(a)(1), (2).

/89/ *Id.* Sec. 488.422(b).

/90/ *Id.* Sec. 488.422(c)(1), (2).

/91/ 59 Fed. Reg. 56171 (Nov. 10, 1994).

/92/ *Id.* at 56188.

/93/ 42 C.F.R. Sec. 488.424.

/94/ 59 Fed. Reg. 56194 -- 95 (Nov. 10, 1994).

/95/ 42 C.F.R. Sec. 488.425(a)(1), (2).

/96/ 59 Fed. Reg. 56198 (Nov. 10, 1994). HCFA cites two articles about reducing the use of chemical restraints through staff training: Jerry Avorn et al., A Randomized Trial of a Program to Reduce the Use of Psychoactive Drugs in Nursing Homes, 327 New Eng. J. Med. 168 (1992); Wayne Ray et al., Reducing Antipsychotic Drug Use in Nursing Homes: A Controlled Trial of Provider Education, 153 Archives Internal Med. 713 (Mar. 22, 1993).

/97/ 42 C.F.R. Sec. 488.425(c).

/98/ Id. Sec. 488.426(a)(1), (2), (b), (c).

/99/ 59 Fed. Reg. 56196, 56221 (Nov. 10, 1994).

/100/ Id. at 56196. HCFA says that nothing in the reform law suggests that Congress intended to overturn the Supreme Court decision in *O'Bannon v. Town Court Nursing Ctr.*, 447 U.S. 773 (1980).

/101/ HCFA cites with approval a comment that criticized the proposed rule for failing to reflect all the points raised by the Institute of Medicine. HCFA paraphrases the comment as "The Institute of Medicine envisioned civil money penalties as a valuable enforcement tool which could be applied in amounts appropriate to the seriousness, duration and repeat occurrence of the violation. It recommended prompt, short hearings on the imposition of the remedy, that fines be large enough to be more costly than the violation, and that fines be versatile enough to be used to correct minor violations, as well as to immediately punish life threatening violations." 59 Fed. Reg. 56198 (Nov. 10, 1994). HCFA contends that the final rule encompasses these points. Id.

/102/ 42 C.F.R. Sec. 488.430(b).

/103/ Id. Sec. 488.432. The effective date and duration of penalties as well as the method of collecting civil money penalties are discussed at id. Sec. 488.440. Due dates for payment of penalties are addressed at id. Sec. 488.442.

/104/ Id. Sec. 488.436(a), (b).

/105/ Id. Sec. 488.444(a), (b).

/106/ 59 Fed. Reg. 56210 (Nov. 10, 1994).

/107/ 42 C.F.R. Sec. 488.438(f)(1). A facility's history of noncompliance means the survey reports from the four most recent surveys, which are maintained in the Online Survey and Certification Reporting System. HCFA rejects comments that a facility's compliance history "only include that of the current owners." 59 Fed. Reg. 56204 (Nov. 10, 1994). HCFA notes that Medicare penalties

and sanctions are "automatically assigned to the new owner or owners," except for the two-year restriction on nurse-aide training and competency evaluation. Id.

/108/ 42 C.F.R. Sec. 488.438(f)(2). Despite criticism of this provision in the proposed rules, HCFA retains it in the final rules. HCFA contends that the Medicare program requires consideration of financial factors. 59 Fed. Reg. 56204 (Nov. 10, 1994). However, HCFA refuses to specify what financial information will be examined "because these factors are unique for each facility." Id. Instead, HCFA says that each facility has the responsibility "to furnish the information it believes appropriately represents its financial status." Id.

/109/ 42 C.F.R. Sec. 488.438(f)(3). These factors relate to scope and harm.

/110/ Id. Sec. 488.438(f)(4). Culpability means "neglect, indifference, or disregard for resident care, comfort or safety." Id. The absence of culpability does not reduce the amount of the penalty. Id. This factor, which is added to the final rules, was "inadvertently omitted from the proposed regulatory text." 59 Fed. Reg. 56204 (Nov. 10, 1994).

/111/ 59 Fed. Reg. 56205 (Nov. 10, 1994).

/112/ Committee on Nursing Home Regulation, *supra* note 32, at 165.

/113/ 42 C.F.R. Sec. 488.438(e)(1) -- (3).

/114/ 59 Fed. Reg. 56206 (Nov. 10, 1994) ("We expect that in virtually all cases, the civil money penalty would start accruing from the date of the noncompliance. The only exception could be those cases in which the survey identifies the noncompliance but there is undue delay before HCFA or the State notifies the provider of the imposition of the penalty.").

/115/ 59 Fed. Reg. 56227 (Nov. 10, 1994).

/116/ *Smith v. Secretary of HHS*, No. 75-M-539 (D. Colo. 1975).

/117/ *Smith v. Heckler*, 747 F.2d 583 (10th Cir. 1984).

/118/ *Smith v. Heckler*, No. 75-M-539 (D. Colo. Aug. 9, 1985), [1986-1] Medicare & Medicaid Guide (CCH) Para. 34,883, at 9372.

/119/ *Smith v. Bowen*, No. 75-M-539 (D. Colo. 1988), [1988-2] Medicare & Medicaid Guide (CCH) Para. 37,018.

/120/ 53 Fed. Reg. 22849 (June 17, 1988).

/121/ *Heritage Manor of Marrero v. HCFA*, HIP 000-61-7069 (SSA Office of Hearings and Appeals Jan. 21, 1994); *Devon Gables Health Care Ctr. v. HCFA*, HIP 000-91-7050 (SSA Office of Hearings and Appeals Aug. 21, 1992). *Devon Gables* has since been reversed.