National Senior Citizens Law Center

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November 6, 1998

Judith Feder
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462 6962

Dear Judy:

Enclosed are the *Nursing Home Law Letter* that includes the first (overview) and seventh (recommendations) chapter from the second Commonwealth Report as well as the Executive Summary. If you want the five individual chapters for the states, let me know and I'll be happy to send them. They're probably more than any sane person would want to read.

Life is incredibly hectic in the nursing home enforcement world. The American Health Care Association is reaching out to us on enforcement in ways it hasn't ever before and Senator Grassley is keeping immense pressure on HCFA to move forward with the President's Initiative. It's fun.

Talk to you soon.

Sincerely,

Toby

Toby S. Edelman

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WHAT HAPPENED TO ENFORCEMENT?
EXECUTIVE SUMMARY

A Study of Enforcement under the Nursing Home Reform Law
Funded by the Commonwealth Fund

The Federal Government's implementation of the enforcement provisions of the nursing home reform law fails to achieve the mandate of the law. Since the federal enforcement provisions became effective on July 1, 1995, nearly seven years after the statutory deadline for their implementation, the Health Care Financing Administration (HCFA) has made a series of changes that continue to weaken the regulatory system. In the post-regulatory phase, HCFA reinstated principles and concepts in the State Operations Manual that Congress had explicitly rejected in the reform legislation. And since implementing the new enforcement system on July 1, 1995, it has continued to revise its informal guidance in a variety of ways that undermine state and federal governments' ability to sanction facilities that provide deficient quality of care or quality of life to residents. The federal enforcement system now in place looks remarkably like the system that Congress repudiated nearly 10 years ago, in December 1987, when it enacted the nursing home reform law. Now, as then, facilities are nearly always given an opportunity to correct deficiencies before they can be sanctioned for providing poor care to residents. The failure to correct deficiencies, rather than the existence of deficiencies, is the basis of enforcement. Deficiencies in the new statutory areas of residents' rights and quality of life are virtually ignored by the enforcement system. And, in practice, few federal enforcement actions are actually taken so that compliance with the 1987 nursing home reform law remains largely a voluntary matter.

Nursing home enforcement has come to resemble the system that Congress criticized – and redesigned -- in 1987 for three principal reasons. First, efforts to reduce the federal budget deficit have reduced federal spending on discretionary programs, resulting in a lack of sufficient resources to enforce public standards at the federal and state levels. Second, HCFA, like the rest of the Executive Branch, has philosophically moved away from a regulatory orientation and towards a collaborative, nonregulatory, corporate model of quality improvement. As a consequence, state and federal agencies see their role as *encouraging* facilities to improve the care they provide, rather than as *sanctioning* facilities that fail to meet statutory quality standards. And finally, HCFA has succumbed to the pressure and demands of the nursing facility industry to reduce regulatory oversight and public accountability.

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Principles of enforcement in the law

The reform law, enacted by Congress in December 1987, fundamentally changed the principles for enforcement of federal standards of care. The law required that all states enact a specified list of intermediate remedies and not rely exclusively on termination. It required that remedies be imposed for violations of residents' welfare and rights, as well as residents' health and safety. It mandated that certain mandatory remedies be imposed for repeated or uncorrected deficiencies. It required that states have enforcement systems to "minimize the time between the identification of violations and final imposition of the remedies." And it disapproved a consultant role for surveyors.

These provisions were not reached by consensus, as were most quality provisions in the statute. They represented a compromise, a combination of the different approaches set out in the House and Senate bills.

Since the reform law was enacted, the nursing home industry has battled enforcement and sought to weaken the strong enforcement orientation of the legislation. Although HCFA added the industry's two main points to the final regulations which had not appeared in the proposed rules -- it created a new regulatory term, "substantial compliance," that would tolerate some level of deviation from full compliance with Requirements of Participation and it required states to have some type of informal dispute resolution process -- the industry has been most successful in the post-regulatory phase of implementation of the reform law.

State Operations Manual (June 1995)

In the State Operations Manual (SOM) issued in June 1995 to implement the final regulations that were published in November 1994, HCFA created a new term -- date certain -- that allows most facilities (other than those subjecting residents to immediate and serious jeopardy or those identified as "poor performing provider" [another new SOM term]) time to correct deficiencies after the survey agency identifies and cites deficiencies. If deficiencies still exist at the time of the revisit, then the state agency may recommend that remedies be imposed by the Regional Office. In practice, most facilities are given an opportunity to correct their deficiencies.

Informal Changes since July 1995

Since issuing the State Operations Manual in June 1995, HCFA has informally made a number of changes to the survey and enforcement processes.

> On June 29, 1995, HCFA imposed a moratorium on the collection of certain lower level civil money penalties (CMPs). The moratorium was subsequently revised. HCFA now claims to have lifted the moratorium, effective January 1997, in a companion memorandum to its revision of its new guidance on civil money penalties, discussed below. However, since the new guidance encourages

states to reevaluate the CMPs that were subject to the moratorium since July 1995 using the new criteria, HCFA's actions in fact have the effect of making the moratorium permanent.

On September 12, 1995, HCFA issued a memorandum "clarifying" the definition of "widespread" scope to limit use of the term to deficiencies that affect all residents in an entire facility. Deficiencies affecting all residents on a particular wing or all residents with a particular problem cannot be cited as widespread.

On November 27, 1995, HCFA created new terms to define facilities that are not in substantial compliance: "correction required" and "significant correction required." HCFA created these new terms specifically in order to avoid labeling facilities with the stigma of an official statement of noncompliance.

On December 6, 1995, HCFA issued an Interim Revisit Policy that permits states to avoid revisits in facilities that have deficiencies cited at lower levels on the federal enforcement grid. Since the enforcement system in the SOM relies on revisits to impose remedies, the lack of revisits means that enforcement is not even theoretically possible for these deficiencies. Most deficiencies in quality of life and residents' rights are cited, if at all, at the lowest levels of the enforcement grid. Consequently, the Interim Revisit Policy means that states are unlikely to impose remedies for deficiencies they identify in quality of life and residents' rights.

In December 1996, HCFA issued another revision to the SOM that encourages states, effective January 24, 1997, not to impose CMPs when they cite deficiencies at the two lower levels on the four-level enforcement grid. CMPs are to be limited to situations of immediate jeopardy or to nursing facilities that are "poor performers" or have "serious deficiencies" that are not corrected at the time of a revisit.

A June 1997 revision to the SOM modified the informal dispute resolution process, giving new authority to facilities to challenge the scope and severity of certain deficiencies, contrary to the survey process introduced in July 1995, which prohibited facilities from challenging scope and severity determinations under all circumstances. The revision also encouraged states to offer facilities telephone or face-to-face meetings and to include as a decision-maker at least one person who was not involved in the original survey.

Data

When HCFA published the final enforcement rules in November 1994, it anticipated that the new enforcement system would lead to considerably more enforcement activity than the prior system. That expectation has not been realized. Instead, while deficiencies are cited, very few federal enforcement actions are actually imposed. In

the second full year of the survey process, the number of remedies imposed, with the exception of civil money penalties, actually declined.

In addition, between 1991 and 1996, the average number of deficiencies per survey declined and the percentage of facilities with no deficiencies cited at all increased. These patterns continued when the new survey and enforcement processes went into effect.

Conclusion

The first two and a half years of the enforcement system have seen HCFA respond to providers' concerns and ignore residents' concerns. HCFA redefined terms of noncompliance to please providers, redefined "widespread," dealt quickly with states that cited more deficiencies than the norm, limited CMPs to serious deficiencies, and gave facilities additional opportunities to challenge survey findings in the informal dispute resolution process. The agency has not taken comparable action to respond to residents' concerns about states that cite few or no deficiencies nor has it issued any guidance to correct states' practice of citing deficiencies at too low a level on the grid.

As implemented by HCFA, the federal enforcement system has not achieved the promise or the mandate of the nursing home reform law.

Feb. 23, 1998

National Senior Citizens LAW CENTER

Nursing Home Law Letter

1998 Issue Nos. 1-2 February 13, 1998

WHAT HAPPENED TO ENFORCEMENT?

I. INTRODUCTION

The Federal Government has failed to implement the enforcement provisions of the 1987 nursing home reform law as mandated by Congress. The Health Care Financing Administration (HCFA) delayed implementation of enforcement for many years. Seven years after rules were due, HCFA issued final regulations that began to weaken statutory requirements. In the post-regulatory phase, HCFA reinstated principles and concepts in the State Operations Manual that Congress had explicitly rejected in the reform legislation. And since implementing the new enforcement system on July 1, 1995, it has continued to revise its informal guidance in a variety of ways that undermine state and federal governments' ability to sanction facilities that provide deficient quality of care or quality of life to residents. The federal enforcement system now in place looks remarkably like the system that Congress repudiated 10 years ago, in December 1987, when it enacted the nursing home reform law. Now, as then, facilities are nearly always given an opportunity to correct deficiencies before they can be sanctioned for providing poor care to residents. The failure to correct deficiencies, rather than the existence of deficiencies, is the basis of enforcement. Deficiencies in the new statutory areas of residents' rights and quality of life are virtually ignored by the enforcement system. And, in practice, few enforcement actions are actually taken so that compliance with the 1987 nursing home reform law remains largely a voluntary matter.

Nursing home enforcement has come to resemble the system that Congress criticized – and redesigned — in 1987 for three principal reasons. First, efforts to reduce the federal budget deficit have reduced federal spending on discretionary programs, resulting in a lack of sufficient resources to enforce public standards at the federal and state levels. Second, HCFA, like the rest of the Executive Branch, has philosophically moved away from a regulatory orientation and towards a collaborative, nonregulatory, corporate model of quality improvement. As a consequence, state and federal agencies see their role as *encouraging* facilities to improve the care they provide, rather than as *sanctioning* facilities that fail to meet statutory quality standards. And finally, HCFA has succumbed to the pressure and demands of the nursing facility industry to reduce regulatory oversight and public accountability.

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II. BACKGROUND

At the time the reform law was enacted, the failure of public enforcement systems to impose timely and effective sanctions against facilities had been repeatedly documented at both the state and federal levels. Two primary shortcomings in public enforcement systems were the limited number of sanctions available for governments' use and the cumbersome and time-consuming procedures that state and federal agencies were required to use before imposing remedies. Providers' demands for "due process," often pursued in lengthy litigation, were given greater deference by administrative agencies and courts than residents' right to receive high quality care.

A. State Reports

Nearly two decades ago, citing earlier reports from Michigan, New York, Illinois, Texas, Arkansas, and Connecticut, the Ohio Nursing Home Commission reported that the "ineffectiveness of regulatory agencies . . . has been acknowledged and reported . . . with depressing regularity."[1] The 1979 report quoted the head of the Long-Term Care Section of the Illinois Department of Health as saying that in seven years, the state had never been able to assess a single fine.[2]

The Commission reported that Ohio surveyors saw themselves as consultants, rather than as inspectors and enforcers.[3] The consultant role led to

> . . . acceptance of substandard care and an apparent belief on the part of departmental personnel that inadequate and non-compliant facilities can be upgraded to meet licensure standards if the facilities are given sufficient time and encouragement.[4]

The Department of Health, the state survey agency, failed to use available sanctions and generally postponed or dismissed license revocation actions, even though it limited its enforcement activities to the most serious cases of facility noncompliance with standards.[5] Fragmentation of regulatory responsibility among state agencies and lack of accountability for facility performance were other systemic problems identified by the Commission.[6]

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[1] Ohio Nursing Home Commission, *A Program in Crisis: Blueprint for Action* 46 (Nov. 1979).
[2] *Id.* 47.
[3] *Id.* 56.
[4] *Id.*
[5] *Id.* 66-67.
[6] *Id.* 68-69.

Many of the Commission's recommendations, including establishment of new statutory enforcement mechanisms,[7] were enacted in the nursing home reform law 18 years later.

Five years after the Ohio Nursing Home Commission issued its report, the Commission on California State Government Organization and Economy found similar inadequacies in California's nursing home enforcement system. In *The Bureaucracy of Care*, the Little Hoover Commission reported that the state health department inadequately assured compliance with federal standards of care.[8] In most situations, public "enforcement is limited to approval and monitoring of a correction plan."[9]

California's civil money penalty system came under particular criticism. The Commission described the appeals system for civil money penalties as filled with "reductions, reversals, inequities, and delays."[10] State law permitted facilities: (1) to appeal every aspect of a citation at an informal administrative review conference, (2) to bypass the administrative forum and go directly to court or, (3) to appeal to court after losing in an administrative hearing.[11] Since fines were not collected if deficiencies were corrected at any time during the lengthy appeals process, "the cycle of citation-correction-no fine could be repeated endlessly."[12]

In the late 1970s and early 1980s, legal scholars had identified similar systemic problems in their critiques of the public enforcement system.[13]

B. Federal Reports

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[7] *Id.* 94-103. The Commission called for statutory authority for health care receivership, injunction authority to prevent admission of new residents, revocation of professional licenses, private enforcement (liability in tort and contract), mandatory reporting of resident abuse, expanded remedies in licensure law, "constant observation teams" (similar to monitors), and fining authority.

[8] Commission on California State Government Organization and Economy and the Nursing Home Study Advisory Committee, *The Bureaucracy of Care: Continuing Policy Issues for Nursing Home Services and Regulation* (Aug. 1983).

[9] *Id.* 111.

[10] *Id.* 134.

[11] *Id.*

[12] *Id.* 115.

[13] *See, e.g.*, Patricia A. Butler, "Nursing Home Quality of Care Enforcement, Part II -- State Agency Enforcement Remedies," 14 *Clearinghouse Rev.* 665 (Oct. 1980) (Special Issue); Patricia A. Butler, "Assuring the Quality of Care and Life in Nursing Homes: The Dilemma of Enforcement," 57 *North Carolina Law Rev.* 1317 (Aug. 1979); Ruchlin, "A New Strategy for Regulating Long-Term Care Facilities," 2 *Journal of Health Politics, Policy, and Law* 190 (1977); John Regan, "Quality Assurance Systems in Nursing Homes," 53 *Univ. of Detroit Journal of Urban Law* 153 (1975); Robert Brown, "An Appraisal of the Nursing Home Enforcement Process," 17 *Albany Law Rev.* 304 (1975); Elias Cohen, "Long-Term Care: A Challenge to Concerted Legal Techniques," 2 *Ohio Univ. Law Rev.* 642 (1975).

The most thorough analysis of recurring problems in public systems to enforce nursing home standards appeared in the March 1986 report *Improving the Quality of Care in Nursing Homes* written by the Institute of Medicine's Committee on Nursing Home Regulation.

In the early 1980s, the Reagan Administration had published proposed regulations on the survey, certification, and enforcement systems for nursing homes.[14] These regulations called for less-than-annual surveys of nursing homes, self-surveys, and deemed status for what was then known as the Joint Commission on the Accreditation of Hospitals, among other proposals. Congress opposed what it perceived to be deregulation of the nursing home industry and promptly enacted two legislative moratoria prohibiting the rules from going into effect.[15] As the second moratorium was about to expire and a third was about to be enacted, Congress reached a compromise with HCFA: HCFA would contract with the Institute of Medicine (IoM) of the National Academy of Sciences to study nursing home issues and it would not make any substantive changes in federal nursing home law until IoM issued its report; in return, Congress would not impose additional moratoria. Thus, the IoM Committee was established.

After an exhaustive 29-month study, IoM issued its report *Improving the Quality of Care in Nursing Homes* in March 1986. The comprehensive report analyzed the public regulatory system and recommended changes in all aspects of federal nursing home law: the standards of care that facilities must meet, the survey process by which facilities' compliance is determined, and the enforcement process that state and federal agencies may, and in some instances, must use to sanction facilities that do not meet federal standards.

IoM began its chapter on enforcement with a strong affirmation of the importance of enforcement to achieving high quality of care for residents:

> Even with improved regulatory standards and a more effective survey process, it is unlikely that quality of care and quality of life for residents in marginal or substandard nursing homes will improve unless compliance with the standards is effectively enforced.[16]

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[14] 47 Fed. Reg. 23,403 (May 27, 1982).

[15] Tax Equity and Fiscal Responsibility Act of 1982, Pub.L. No. 97-248, §235 (signed Sept. 3, 1982); House Conf. Rep. No. 97-760, 441 (Aug. 17, 1982) (describing nursing home deregulation moratorium in the continuing budget resolution), reprinted in 2 U.S.C.C.A.N. 1221, 97th Cong. 2d Sess. (1982).

[16] Committee on Nursing Home Regulation, Institute of Medicine, *Improving the Quality of Care in Nursing Homes 146* (Mar. 1986) [hereafter IoM, *Improving the Quality of Care*].

IoM identified four categories of problems with existing federal and state enforcement activities:

> (1) federal and state orientation and attitudes toward enforcement; (2) the federal rules and procedures; (3) state variations in enforcement authority, policies, and procedures; and (4) inadequate federal and state resources committed to enforcement.[17]

Like many prior state reports, IoM noted that the general enforcement attitude of states is "helping facilities to improve rather than enforcing the certification standards."[18] States consult with facilities and attempt to "coerce" them into compliance.[19] Survey agencies typically give facilities an opportunity to correct deficiencies and consider imposing sanctions only when facilities fail to correct the deficiencies by the deadlines set for compliance. Consequently, facilities are not "punished for violations directly, but rather for failing to carry out an administrative order to correct violations by a certain date."[20] States do not require facilities to comply with public standards of care and sanction them when they fail or refuse to comply. IoM criticized federal rules and procedures that encourage consultation rather than enforcement.[21]

IoM also found that federal guidelines for survey follow-up are "inadequate because they do not specify how plans of correction should be evaluated, how correction actions should be measured, or when more stringent enforcement actions should be initiated."[22] Federal criteria for acceptable plans of correction are general; "[a]lthough the procedures for obtaining a plan of correction are specific, the directions concerning the actual content of the plan are quite vague."[23]

A "major finding" of IoM was that "state survey agencies lack formal enforcement procedures and guidelines."[24] States do not have "written guidelines for when and how to take formal enforcement actions"[25] or guidelines on when to initiate sanctions.[26] IoM suggested that specific guidelines would "encourage states to be less tolerant of substandard providers, and . . . more consistent in initiating enforcement activity and in setting precedents for future activities."[27]

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[17] *Id.* 147.
[18] *Id.*
[19] *Id.* 148.
[20] *Id.*
[21] *Id.* 150.
[22] *Id.*
[23] *Id.* 152.
[24] *Id.* 153.
[25] *Id.*
[26] *Id.* 154.
[27] *Id.*

IoM recognized that federal law created only limited and "inadequate" authority for sanctions. Termination was the primary sanction available,[28] but its harsh consequences for residents and facilities meant that the sanction was rarely imposed. Consequently, IoM reported, the sanction is of limited value and a broader range of intermediate sanctions employed by all states is necessary.[29]

IoM called for more stringent procedures for providers' hearings and appeals, recommending that federal regulations allow states to "implement sanctions prior to hearings and appeals,"[30] rather than after, and that "the appeals process of sanctions . . . be made less permissive."[31] "Frivolous appeals" would be discouraged by statutory changes

> (1) clarifying the lack of a facility's right to a stay, pending judicial review of decertification decisions; (2) not making states prove that the violation is still outstanding at the time of the hearing in order to continue applying the sanction; and (3) not reimbursing provider legal fees for unsuccessful appeals of survey-related cases.[32]

IoM recognized that without a strong and effective enforcement system, improvements in standards of care and in survey activities would be insufficient to bring about the changes that were needed to assure high quality of care and life for residents.

III. THE ENFORCEMENT PROVISIONS OF THE NURSING HOME REFORM LAW

In enacting the enforcement provisions of the nursing home reform law in December 1987, Congress closely followed the recommendations of the Institute of Medicine and

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[28] Section 916(b) of the Omnibus Budget Reconciliation Act of 1980, Pub.L. 99-499, authorized denial of Medicare or Medicaid payments for new admissions to providers that were found to be out of compliance with federal requirements but whose deficiencies did not immediately jeopardize resident health or safety. However, the so-called intermediate sanction could not be imposed until the facility had "a reasonable opportunity . . . to correct its deficiencies, and following this period, [had] been given reasonable notice and opportunity for hearing." 42 U.S.C. §1396a(i)(2).

HHS did not publish proposed rules until February 1985, 50 Fed. Reg. 7191 (Feb. 21, 1995); it published final rules in 1986, 51 Fed. Reg. 24,484 (July 3, 1986).

The Institute of Medicine was critical of the intermediate sanction's statutory requirement of a formal hearing before imposition of the intermediate sanction. IoM said that the requirement for a pre-termination hearing makes the sanction "more difficult and slower to implement than decertification." IoM, *Improving the Quality of Care, supra* note 16, 159.

Congress repealed the intermediate sanction when it enacted the nursing home reform law in 1987. Pub.L. 100-203, §4213(b).

[29] IoM, *Improving the Quality of Care, supra* note 16, 155, 159.

[30] *Id.* 159.

[31] *Id.*

[32] *Id.*

fundamentally changed the principles for enforcement of federal standards of care.[33] The primary legislative history, written by the House Energy and Commerce Committee's Subcommittee on Health, made clear that Congress was no longer willing to tolerate the lack of enforcement that characterized so many state enforcement systems.[34]

The 1987 reform law, for the first time, sets out the Secretary's "duty and responsibility" to assure adequate federal and state enforcement of requirements related to health, safety, welfare, and rights of residents.[35] As IoM recommended, the reform law requires that all states enact a specified list of intermediate remedies and not rely exclusively on termination;[36] that remedies be imposed for violations of residents' welfare and rights, as well as residents' health and safety;[37] that certain mandatory remedies be imposed for repeated or uncorrected deficiencies;[38] and that states have enforcement systems that "minimize the time between the identification of violations and final imposition of the remedies."[39] Except for civil money penalties, the law explicitly authorizes states to impose remedies *before* administrative appeals are decided.[40] And it disapproves a consultant role for surveyors.

Even though these provisions are found in the IoM's and the GAO's recommendations on which Congress expressly relied, they were not reached by consensus in Congress, as were most quality of care provisions in the reform law.

The final House and Senate bills were quite different from each other with respect to enforcement, in contrast to the virtually identical requirements related to standards of care and survey procedures.[41] The House legislation called for each state to enact a

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[33] House Report No. 100-391(I), 448, 470-477, 100th Cong., 1st Sess. (1987) U.S.C.C.A.N. 2313-268, at 2313-291.

[34] The House Committee also quoted and relied on the July 1987 report by the General Accounting Office, *Medicare and Medicaid: Stronger Enforcement of Nursing Home Requirements Needed*, GAO/HRD-87-113 (July 1987).

[35] 42 U.S.C. §1396r(f)(1). Prior to the enactment of the reform law, case law and federal statutory language limited the Secretary's role to enforcement of requirements related to residents' health and safety. *Estate of Smith v. Heckler*, 747 F.2d 583, 589-590 (10th Cir. 1984), 42 U.S.C. §1396b (added by the Deficit Reduction Act of 1984, Pub.L. 98-369, §2363(b)), respectively.

[36] *Id.* §1396r(h)(2)(A)(i)-(iv).

[37] *Id.* §§1395i-3(h)(1), 1396r(h)(1) (failure to meet *any* statutory requirement subjects a facility to the possibility of an enforcement action).

[38] *Id.* §§1395i-3(*h*)(2)(D), (E), 1396r(h)(2)(C), (D).

[39] *Id.* §1396r(h)(2).

[40] *Id.* §1396r(h)(8).

[41] Toby Edelman, "Enforcement of the Nursing Home Reform Law: We're Not There Yet," *Bifocal*, 3, ABA Commission on Legal Problems of the Elderly, Vol. 13, No. 2 (Summer 1992) [hereafter Edelman, "Enforcement of the Nursing Home Reform Law"].

specified list of intermediate sanctions;[42] the Senate bill required states to develop a process to determine enforcement decisions.[43] These different approaches to enforcement were reconciled only at the end of the legislative process, in conference committee, when the House and Senate methods were combined and both were placed in the final legislative language.[44]

The different strategies for enforcement in the House and Senate bills reflected the lack of consensus about enforcement among outside groups that were supporting nursing home reform legislation. The National Citizens' Coalition for Nursing Home Reform, the national resident advocacy organization, had formed an *ad hoc* coalition of more than 50 national consumer, provider, and professional organizations shortly after the IoM report was issued in an effort to develop and mobilize support for federal legislation encompassing the IoM's recommendations. This *ad hoc* coalition, the Campaign for Quality Care (CQC), met weekly and developed a list of legislative priority topics on which member groups reached consensus.

The recommendation for enforcement, endorsed by consumers, health care professionals, and health care provider organizations, remained general. It called for a range of state remedies, federal leadership and support for state actions, look-behind authority for the Secretary, and Secretarial responsibility for state-owned facilities and for monitoring state performance.[45] A more detailed supplemental recommendation endorsing a specific set of state enforcement sanctions, a less permissive provider appeals process, mandatory remedies for repeat violators, and a private right of action for residents, among other points, was not endorsed by provider members of the Campaign for Quality Care.[46]

The reform law required the Secretary to give guidance on enforcement to the states by October 1, 1988 and required states to have their Medicaid enforcement systems in place by October 1, 1989.[47]

IV. POST-LAW, PRE-REGULATION ACTIVITY

Even before HCFA published proposed rules, the American Health Care Association (AHCA), the trade association of for-profit facilities, prepared its membership for the

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[42] H.R. 2270, §4114 (House Energy and Commerce Committee, amending the Medicaid statute); H.R. 2770, § 9213 (House Ways and Means Committee, amending the Medicare statute).

[43] S. 1108, §4051 (Senate Finance Committee, amending the Medicare and Medicaid statutes).

[44] Edelman, "Enforcement of the Nursing Home Reform Law," *supra* note 41, 3.

[45] Campaign for Quality Care in Nursing Homes 52-55 (Consensus Position on Enforcement of Laws and Regulations) (Apr. 24, 1987).

[46] *Id.* 56-57.

[47] 42 U.S.C. §1396r(h)(2)(B)(i).

issues it considered most important for the enforcement rules. Producing its first videotape for its membership, AHCA urged its members to send comments to HCFA on two points, once the proposed rules were published: requiring use of scope and severity scales to determine the existence of deficiencies (so that less than full compliance with standards would be accepted) and requiring states to offer providers what was then called an alternative dispute resolution process, in addition to the formal appeals process, that they could use to contest deficiencies in an informal forum.[48]

HCFA was fully aware that the enforcement process was controversial. In its own attempt to achieve consensus, or at least to narrow the issues of dispute, before issuing proposed rules, HCFA convened a work group on enforcement in early 1989 to develop draft rules. With representatives from the industry, states, provider associations, and one consumer, HCFA held three sets of meetings in January, March, and April 1989. In the end, however, the three sessions considered survey issues (i.e., how to identify a deficiency), rather than what actions states should take after they cited deficiencies (i.e., enforcement).[49]

HCFA continued to work on its controversial enforcement draft after it disbanded the workgroup in 1989. Leaked drafts of the proposed rules reflected changes that strengthened the work group's document. Most significant was deletion of a requirement that surveyors use "scope and severity" scales to determine whether deficiencies exist.[50] This change, urged by HHS' Office of General Counsel, was later effectively reversed in the final rules.[51] After completing its work, HCFA sent the proposed rules to the Office of Management and Budget (OMB), where they were reviewed for more than a year. Under pressure from consumer groups and Congressional leadership, OMB finally released the proposed rules and allowed them to be published in the Federal Register for public comment.[52]

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[48] "AHCA Video Promotes Campaign to Change Enforcement Rules," NCCNHR, *Quality Care Advocate* 1 (Mar./Apr. 1992).

[49] Edelman, "Enforcement of the Nursing Home Reform Law," *supra* note 41, 3-4.

[50] *Id.* 4.

[51] *See* notes 68-74, *infra*, and accompanying text.

[52] *See, e.g.*, the August 6, 1992 letter to Richard G. Darman, Director, Office of Management and Budget, from Senators George J. Mitchell and David H. Pryor and Representatives John D. Dingell, Henry A. Waxman, Dan Rostenkowski, and Pete Stark, which begins:

> As the authors of the 1987 Medicaid/Medicare nursing home reform law ("OBRA '87"), we are writing to urge your immediate release of the Department of Health and Human Services' proposed regulations to implement the enforcement provisions of this statute. In our view, the prolonged delay – of over three and one-half years – in the publication of the proposed rule has been extended far beyond what is reasonable and any additional postponement simply cannot be justified.

(Letter is included in NCCNHR, *Enforcement, Background Materials* 25-26 (Oct. 1992). "Consumer Victory: Enforcement Rules Published," NCCNHR, *Quality Care Advocate* (Jul./Aug. 1992)).

HCFA made changes to the draft rules at the request of OMB that reflected industry views. For

V. FEDERAL REGULATIONS

The public rulemaking process was lengthy and controversial.

A. Proposed rules

HCFA published proposed rules on August 28, 1992.[53] The preamble projected a strong and aggressive enforcement orientation. HCFA stated that the reform law requires facilities to comply fully with all Requirements of Participation and that facilities' interests are secondary to the interests and needs of residents. The agency correctly implemented the statutory directive that sanctions other than civil money penalties be imposed during the pendency of a facility's administrative appeal. It prohibited facilities from challenging the enforcement agency's choice of an intermediate sanction and refused to allow facilities to challenge surveys that have technical problems if the survey teams' findings are substantively valid.

Although pleased with the generally strong enforcement tone of the preamble, many residents' advocates felt that HCFA did not adequately carry out this orientation in the proposed regulatory language.[54] The proposed rules placed regulatory obstacles in the way of using intermediate sanctions, which, residents' advocates feared, would perpetuate states' over-reliance on termination. Advocates wanted HCFA to strengthen the rules so that they would more clearly direct states to use intermediate sanctions, rather than termination, as the primary and preferable way of responding to deficiencies.

Advocates also expressed concern that the proposed rules' discussion of resident outcomes appeared to require the actual occurrence of a bad outcome before enforcement would occur.

The Association of Health Facility Survey Agencies (AHFSA) recommended that the rules designate states as the primary enforcement entity, rather than the Secretary, and that HCFA provide additional regulatory guidance on temporary management, monitors, and civil money penalties. AHFSA supported scope and severity scales for determining deficiencies and for imposing remedies, but was critical of using them rigidly when they

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example, at OMB's direction, HCFA added language to the preamble requesting public comment on how to apply scope and severity scales to the determination of deficiencies. *Id.* 6.

[53] 57 Fed. Reg. 39,278 (Aug. 28, 1992).

[54] *See* comments to HCFA on the proposed rules by the Coalition of Institutionalized Aged and Disabled, 2 (Oct. 27, 1992); National Citizens' Coalition for Nursing Home Reform; Citizens for Better Care (Michigan). *See also* Toby Edelman, memorandum to advocates (Sept. 15, 1992).

were "arbitrary, not supported by field testing, not quantitatively precise."[55]

Four members of the IoM Committee on Nursing Home Regulation submitted comments on four points. They (1) supported the preamble language stating that providers' interests are secondary to the needs of program beneficiaries; (2) opposed use of scope and severity scales for determining the existence of deficiencies; (3) opposed alternative dispute resolution; and (4) proposed that the definition of substandard quality of care and use of scope and severity scales for remedies "rest on a broad and meaningful concept of 'resident-focused' and 'outcome-oriented.'"[56]

The American Health Care Association identified as "key issues" in the proposed rules the need for revisions that would: (1) incorporate scope and severity scales and a determination of a facility's "level of responsibility" before deficiencies would be cited; (2) add an informal dispute resolution process allowing for "timely resolution of survey and enforcement disputes short of litigation;" and (3) "allow pre-sanction hearings where there were no findings of immediate and serious threat to residents."[57]

The American Association of Homes for the Aging (AAHA), the trade association of non-profit facilities, issued a News Release on September 1, 1992 that criticized the proposed rules for not allowing facilities to appeal surveyor decisions, for not establishing "an objective way of determining whether a deficiency exists," and for not including a dispute resolution process. AAHA noted that it would be recommending significant changes to the proposed rules.[58]

B. Final rules

HCFA published final rules on survey, certification, and enforcement on November 10, 1994, with a delayed effective date of July 1, 1995.[59] In the lengthy preamble, HCFA described the nearly 28,000 public comments it received, the majority of which were form letters submitted at AHCA's direction. HCFA's responses to the comments provide insight into the agency's analysis and authoritative interpretation of the law.

In the relatively noncontroversial area of survey practices, HCFA adhered closely to the

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[55] AHFSA, Position Paper on Proposed Rule (undated).

[56] Letter of Catherine Hawes on behalf of herself, Iris C. Freeman, Rosalie A. Kane, and Charlene Harrington, to Acting Deputy Administrator William Toby (Oct. 26, 1992).

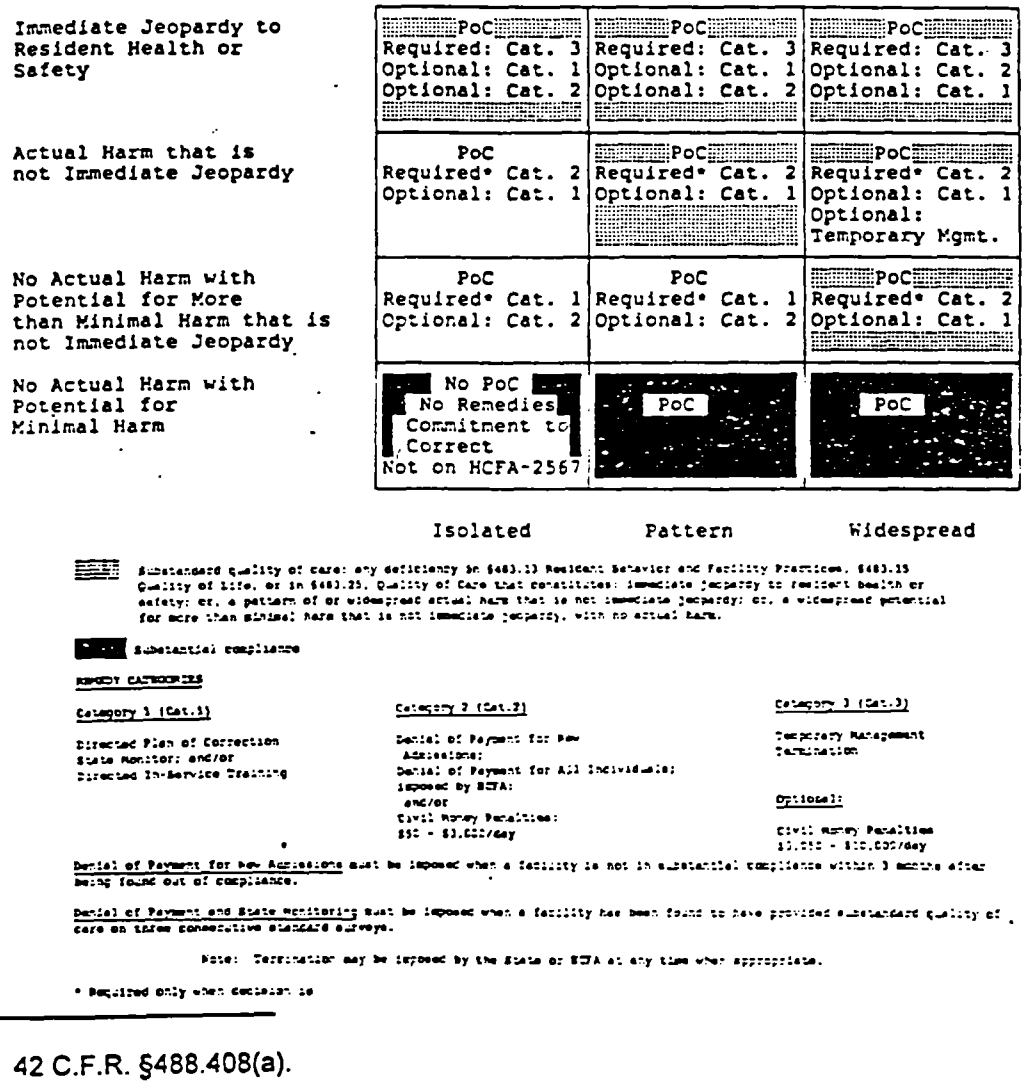
[57] AHCA, "Survey, Certification, and Enforcement Regulations" (included in NCCNHR, *Enforcement, Background Materials* 12-14 (Oct. 1992)).

[58] American Association of Homes for the Aging, "Statement by Sheldon L. Goldberg, President, AAHA, on Nursing Home Enforcement Regulations" (News Release, Sept. 1, 1992).

[59] 59 Fed. Reg. 56,116 (Nov. 10, 1994). The final rules were discussed in *The Nursing Home Law Letter*, 1994 Issue Nos. 2-4 (Jan. 12, 1995), "Final Survey, Certification, and Enforcement Rules for Nursing Facilities."

language of the statute, as it had with other rules implementing the nursing home reform law. The rules paraphrased the statutory language and reflected HCFA's general unwillingness to go beyond explicit statutory requirements in rulemaking, with a major exception. HCFA created a new regulatory term, "substantial compliance," as the standard for participation in the Medicare and Medicaid programs.

In the enforcement provisions, HCFA again did not stray far from the statutory language. HCFA set out limited detail for each of the federally-mandated remedies. In guiding states on how to select the appropriate remedy(ies) in particular cases, the rules grouped the mandated remedies into three categories and directed states to select remedies from the categories according to the scope and severity of the facility's noncompliance."[60] To illustrate this system, the final rules included an enforcement "grid," reflecting three levels of scope along the horizontal axis and four categories of severity along the vertical axis.



[60] 42 C.F.R. §488.408(a).

HCFA intended that states would use the grid to classify deficiencies, to determine appropriate remedies, and to identify deficiencies that reflect substandard quality of care.[61]

The grid gives the appearance of creating a structured method for approaching decision-making. However, since the same remedies are available along each horizontal axis, the grid does not alter the broad discretion given to states to choose among available remedies in particular situations.

In the final rules, HCFA added one remedy, directed plan of correction, and deleted another remedy that it had proposed in 1992 – denial of payment by diagnostic categories. HCFA was persuaded by public comments that the latter remedy would violate the Rehabilitation Act of 1974 and the Americans with Disabilities Act of 1991.[62]

Several themes emerge in the final rules. The first theme was state flexibility. The rules gave states considerable discretion to design and implement their survey and enforcement systems. While some state flexibility may be necessary to accommodate legitimate variations among states, flexibility also reduces consistency among states. According to the Institute of Medicine, one express purpose of the federal enforcement system was to create uniform enforcement practices among the states.[63] The rules granted states flexibility at the expense of national consistency. In addition, state flexibility exposes states to political pressure from providers. When practices are mandated by federal law, states' discretion is reduced and states are more protected from providers' efforts to weaken enforcement.

Related to HCFA's refusal to exercise its rulemaking authority to expand upon statutory directives was HCFA's stated intention to provide additional, more detailed guidance in the manuals on issues that are not specifically mandated by the Act.[64] One consequence of HCFA's plan to use the manuals, rather than the regulations, to clarify the law was that HCFA shielded itself from the need to explain its rationale in its manuals, as it must do in rulemaking conducted under the Administrative Procedures Act. HCFA itself is more subject to political pressure and less accountable to the public when it gives informal guidance than when it engages in the public rulemaking process.

A third theme was HCFA's consciously balancing and mediating differences between consumers and providers, to the extent possible. For example, HCFA claimed that its

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[61] 59 Fed. Reg. 56,116, 56,183 (Nov. 10, 1994).

[62] *Id.*, 56,191-56,192.

[63] IoM, *Improving the Quality of Nursing Home Care, supra* note 16, 155.

[64] HCFA did not follow through on this intention. Many issues identified for further discussion, such as when to consolidate deficiencies and when to address them individually, for purposes of imposing remedies, were not further clarified in the manuals.

definition of substantial compliance "strikes the appropriate balance that best implements the statute, the IoM study, and accommodates both facility and resident concerns."[65] In many of its responses to public comments on the proposed rules, HCFA coupled a decision that would be considered favorable to providers with a decision favorable to residents, and vice versa. When the conflicting positions were too contentious to accommodate, HCFA either relied on the specific mandates of the law[66] or promised to address the issue in greater detail in the State Operations Manual.[67] HCFA did not view its role as implementing the law to benefit residents; it saw its role as mediator.

Despite its generally narrow view of its role in drafting rules, HCFA added AHCA's two main points to the final regulations. It created a new regulatory term, "substantial compliance," reflecting the agency's willingness to tolerate some amount of deviation from full compliance with Requirements of Participation, and it required states to have some type of informal dispute resolution process. But even on these two issues, HCFA gave conflicting messages.

HCFA's discussion of substantial compliance was ambiguous at best. At several points in the preamble to the final rules, HCFA offered different and highly inconsistent definitions of the term. First, it said that the new term means "virtual" compliance "because the type of deficiency tolerated under a substantial compliance standard is very limited."[68] Later, acknowledging that the term substantial compliance "will accomplish much of what the advocates of scope and severity scales [i.e., providers] claimed that the scales would accomplish,"[69] HCFA defined the term as "tolerat[ing] a reasonable degree of imperfection."[70] Here HCFA said that the term means deficiencies of "negligible seriousness," which would "insulate providers from the uneven enforcement that may result from inconsistent surveyor behavior."[71] Finally, virtually reversing itself from its initial definition, HCFA said in the Regulatory Impact

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[65] 59 Fed. Reg. 56,116, 56,153 (Nov. 10, 1994) (preamble to final regulations).

[65] For example, in the proposed rules, HCFA required all surveys to be unannounced. In the final rules, HCFA limited the requirements of unannounced surveys to *standard* surveys, noting that the reform law does not mandate that all surveys be unannounced. 59 Fed. Reg., 56,135.

[67] Among the most significant issues that HCFA undertook to address in manuals were: requirements for standard surveys; guidelines for educational programs for facility staff and residents; the process that HCFA would use to determine whether a state's alternative remedies could be substituted for the statutory 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 would approve correction actions requested by states, under the provision permitting continuation of payments pending remediation.

[68] 59 Fed. Reg., 56,116, 56,198 (Nov. 10, 1994).

[69] *Id.* 56,226.

[70] *Id.*

[71] *Id.*

Analysis portion of the preamble, "the majority of the 86 percent of facilities cited in 1992 with at least one Level B deficiency would fall within this range [of substantial compliance]."[72]

The ambiguous and inconsistent explanations of the term have created problems as HCFA has attempted to implement the new enforcement system and its final rules. Advocates for residents believe that all but the most trivial deficiencies should be cited and sanctioned with appropriate enforcement actions; providers contend that enforcement should be limited to the most egregious situations. Advocates and providers alike can point to HCFA language in the preamble supporting their view.

With respect to informal dispute resolution, HCFA required states to have a process, as AHCA urged, but then said all states already have a process.[73] It also refused to mandate any specific features for informal dispute resolution, saying, "[W]e have no evidence that suggests that any particular State's process is more successful or effective than that of another state."[74]

Residents' advocates found some reason to be pleased with parts of the rules, particularly the language of the preamble, which affirmed the reform law's strong orientation to enforcement:

> We believe that the Act's alternative remedies offer States and the Secretary a valuable opportunity to redress a wide variety of facility shortcomings through means that will promote quick correction without having to exclude the facility from program participation, and **it is our expectation not only that serious consideration will be given for such opportunities when there is facility non-compliance, but that they will be used far more frequently than they have in the past.**[75] [emphasis supplied]

HCFA also firmly recognized that Congress had created an entirely new enforcement

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[72] *Id.* 56,230-56,231.

[73] *Id.* 56,224.

[74] *Id.*

[75] *Id.* 56,167-56,168. Similar comments appear throughout the preamble to the final enforcement rules. For example, in accepting consumer recommendations to apply remedies once deficiencies are identified, prior to provider appeals, HCFA says, "We . . . are adopting procedures that allow for *the swift imposition of remedies* prior to a hearing. We believe that the intent of the Act was that remedies be imposed as soon as possible in order to protect the residents." 56 Fed. Reg., 56,155.

system when it enacted the reform law:

> [W]e do not accept the notion that the use of more severe remedies for more severe deficiencies is excessive. There can be little question that the Congress was concerned about what it concluded was an unsatisfactory enforcement scheme prior to nursing home reform. As a result, it wrote into the law a series of remedies that it expected to be used should circumstances at individual facilities warrant. The driving force behind the legislation in this context was to provide the Secretary and the States with the authority to aggressively enforce the Act's new requirements in a way that would discourage facility noncompliance that the Congress believed to be widely evident between surveys, and thereby, to encourage lasting compliance. The design of these enforcement rules provides for incrementally more severe remedies as cited noncompliance is more egregious. We do not believe that an enforcement approach styled this way is harsh or excessive.[76]

Advocates supported the regulations' definition of deficiency as failure to meet a Requirement of Participation; post-sanction hearings for providers; and the new requirement that survey agencies consider facility culpability whenever they receive complaints related to abuse or neglect of residents or misappropriation of residents' property.

At the same time, advocates were concerned that the rules did not focus on intermediate sanctions, rather than termination, as the primary and preferable response to deficiencies. The rules failed to focus on residents' rights and quality of life, continuing, instead, the long-standing bias towards health and safety. Advocates also felt that the regulatory language failed to follow through on promises made in the preamble to impose remedies frequently and forcefully and that HCFA had avoided its responsibility to make difficult decisions about enforcement that would benefit residents. A new regulatory definition of the purpose of remedies also gave advocates cause for concern. In the preamble to the proposed enforcement rules, HCFA had identified remedies' comprehensive purpose: "encourag[ing] prompt, rapid compliance with program requirements so as to protect residents from actual or potential harmful

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[76] *Id.* 56,175.

outcomes resulting from deficiencies.[77] In the final rules, HCFA identified a more limited goal: "to ensure prompt compliance with program requirements."[78]

Advocates were concerned about the final regulations and hoped that HCFA would be more direct, more consistent, and more forceful in the post-rulemaking, manual-writing phase of implementation.

VI. POST-REGULATORY ACTIVITY

A. Writing the State Operations Manual

HCFA's weakening of the mandates of the reform law continued and intensified, however, when the agency prepared additional, informal guidance to states in the State Operations Manual (SOM) that it issued in June 1995, just before the final enforcement rules were to go into effect.[79]

In December 1994, shortly after the final enforcement regulations were published, residents' advocates offered to meet with staff of HCFA's Office of Survey and Certification to help develop and draft manual provisions. Although advocates and providers had worked collaboratively with HCFA on survey issues, they were rebuffed in the area of enforcement. It later became apparent, however, that industry officials were speaking directly to officials at higher levels in the Administration.

In late January 1995, HCFA circulated a draft enforcement manual. Residents' advocates and survey agencies expressed concern about the direction in which HCFA

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[77] Proposed §488.202(a), in 57 Fed. Reg. 39,278, at (Aug. 28, 1992). In the preamble to the proposed rules, HCFA had identified.a "dual purpose" for enforcement: "(1) to protect residents against inadequate care; and (2) to motivate providers to comply with the requirements of participation so that they may continue to provide quality services to residents." 57 Fed. Reg. 39,278, at 39,290. Elsewhere in the preamble, HCFA had identified the "deterrent" value of remedies. *Id.* 39,279.

[78] Section 488.202(a).

[79] Although the SOM is considered "informal" policy, because it is not published in compliance with notice and comment rulemaking under the Administration Procedures Act, it is official HCFA policy and binding on states to the extent that it is consistent with the law and regulations it is intended to implement. *See, e.g., State of New Jersey v. Department of Health and Human Services*, 670 F.2d 1262, 1282-283 (3rd Cir. 1981).

was moving and called on the agency to withdraw the draft and begin again.[80] The primary objection was the SOM's failure to implement the statutory and regulatory mandate to impose remedies quickly after deficiencies are identified. Criticism was focused on the manual's new term "date certain," which allowed facilities an opportunity to correct cited deficiencies before the state would consider imposing remedies. Advocates and states saw the new term, and the principle it reflected, as a direct contradiction of the statutory mandate requiring states to impose remedies swiftly when they cite deficiencies.[81] The draft SOM created other new delays. In addition to informal dispute resolution, the SOM directed survey agencies to conduct revisits before sanctions became effective, giving facilities still another chance to demonstrate substantial compliance and to avoid sanctions.

The March draft made few corrections and met with similar objections from the advocacy community.[82]

B. The State Operations Manual

The enforcement provisions of the State Operations Manual that went into effect on July 1, 1995 addressed few of these concerns. Like the final rules, the manual began with a strong Introduction that announced three new expectations for enforcement: (1) facilities must have "continued, rather than cyclical, compliance;" (2) "all deficiencies will be addressed promptly;" and (3) "residents will receive the care and services they need

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[80] In a February 13, 1995 letter to HCFA, the National Citizens' Coalition for Nursing Home Reform wrote that the enforcement manual "creates loopholes for providers to avoid enforcement and obstacles for survey agencies to overcome." The same day, the Association of Health Facility Survey Agencies commented on the draft SOM expressing similar concern. The first point was, "The SOM as presently drafted will impede the effectiveness of the enforcement regulation by requiring a corrective period and revisit before imposition of remedies." The National Senior Citizens Law Center sent letters on February 9 and 12 urging the agency to withdraw the seriously-flawed draft, as did the American Association of Retired Persons in its February 13 letter.

[81] "Advocates Decry HCFA Enforcement Instructions," NCCNHR, *Quality Care Advocate* 1 (Jan./Feb. 1995).

[82] "Hopes, Doubts as Enforcement Nears," NCCNHR, *Quality Care Advocate* 10 (Mar./Apr. 1995) (reporting on description of enforcement at state ombudsprograms' annual training conference, Seattle, Washington, April 1995). Letter of Toby Edelman to Anthony Tirone, Director, Office of Survey and Certification, HCFA (Mar. 22, 1995).

to meet their highest practicable level of functioning."[83] However, the text of the manual did not follow through on these new enforcement principles. Instead, while the survey portions of the enforcement manual summarized SOM 274 (the survey provisions of the State Operations Manual) and focused primarily on procedures, timetables, and interactions between states and Regional Offices, the enforcement portions whittled away enforcement authority.

The most significant provision in the enforcement Manual was HCFA's creation of a new term, "date certain," to reflect a category of facilities that are given an opportunity to correct deficiencies before sanctions may be imposed. The term does appear in either the law or regulations.

HCFA defined the term date certain as "a specific date on which remedies will be imposed if a facility does not achieve substantial compliance with Requirements of Participation."[84] The date is based on the "relative seriousness of deficiencies . . . and whether the facility has a history of going in and out of compliance."[85] Only a facility whose deficiencies pose immediate jeopardy to residents' health or safety or a facility that is defined as a "poor performer"[86] is not given an opportunity to correct deficiencies before remedies are imposed.

HCFA directed states not to impose remedies in date certain facilities that are found to be in substantial compliance at the time of a revisit.[87] This direction authorizes the imposition of sanctions for failure to *correct* deficiencies, rather than for the *existence* of deficiencies.

The Manual also discouraged states from using enforcement remedies. HCFA suggested that denial of payment for all new admissions be used "only when the facility makes little or no effort to come into compliance, e.g, when it fails to adhere to its PoC

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[83] HCFA, Transmittal 273, §7000, page 7-5 (July 1, 1995). *See The Nursing Home Law Letter*, 1995, Issue No. 3 (July 31, 1995), "New Survey Guidelines," and 1995, Issue No. 4 (Dec. 14, 1995), "The New Enforcement System."

[84] HCFA, Transmittal 273, §7304, page 7-25 (July 1, 1995).

[85] *Id.*

[86] A "poor performer" is defined as a facility "with a history of going in and out of compliance and/or a facility that has no system in place to monitor its own compliance." HCFA, Transmittal 273, §7304.B, page 7-26 (July 1, 1995).

[87] *Id.* §7313.B, page 7-33.

[plan of correction.]"[88] It also suggested that states not impose a retroactive civil money penalty if a facility has a quality assurance program in place and has corrected the deficiency, unless the deficiency reflects "egregious past noncompliance."[89] While HCFA offered no rationale for these new policy directions in the manual, they appear to reflect HCFA's view, offered in the Introduction, that the new enforcement process distinguishes "those facilities that have an active and effective quality assurance process in place that in fact lead to enhanced quality of care and life of residents and those facilities that do not."[90] This language contains the first suggestion that HCFA intended to place more attention on facilities' quality assurance *processes* than on residents' actual *outcomes*.

Finally, the Manual minimized the federal oversight role in enforcement. Although HCFA required states to refer all survey data and recommendations for remedies for Medicare-only or dually-certified facilities to Regional Offices, which have sole authority to impose remedies for these facilities, it said that Regional Offices would accept state agency decisions "except in the most extraordinary circumstances."[91]

Advocates were concerned about how much noncompliance would be tolerated under the definition of substantial compliance and about how informal dispute resolution would affect survey, certification, and enforcement activities. Rubber-stamp review of state enforcement recommendations by federal officials would do little more than waste time, consume limited federal and state survey resources, and delay enforcement.

In the view of many advocates, the enforcement system set out in the State Operations Manual reinstated terms and concepts that IoM had explicitly criticized in its 1986 report. The IoM had written:

> The current survey policies and procedures encourage states to consult and coerce facilities into compliance, not to punish them. The state agency does not have authority under federal regulations to punish a violation immediately. The survey agency must issue a notice to the operator of a substandard nursing home, giving the facility a period of time (usually 30 to 60 days) in which to correct deficiencies. The survey agency is instructed to try to resolve cases

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[88] *Id.* §7506.B, page 7-48.
[89] *Id.* §7510, page 7-51.
[90] *Id.* §7000, page 7-5.
[91] *Id.* §7313.B, page 7-33.

> before referring them to the formal administrative or law enforcement system. The agency may apply formal sanctions only if the facility remains in violation beyond the deadline set for compliance. Consequently, the facility is not punished for violations directly, but rather for failing to carry out an administrative order to correct violations by a certain date. Resort to formal sanctions by a compliance-oriented agency therefore becomes the last step in a long series of follow-up visits and plans of correction designed to induce conformity on the part of substandard facilities.[92]

Under the SOM, as before the reform law was passed, consultation would be called for; states would impose remedies, if at all, for facilities' failure to correct deficiencies rather than for the existence of deficiencies; facilities would be given notice and an opportunity to correct deficiencies before remedies could be imposed; and states would try to induce compliance, not sanction noncompliance.

C. Monitoring after July 1, 1995

Knowing that the enforcement provisions and their implementation remained extraordinarily controversial, HCFA took two steps to demonstrate its commitment to closely overseeing implementation of the final rules.

First, it established two outside monitoring groups in the summer of 1995 to help evaluate the new system. The Impact Assessment Advisors (IAA) met with HCFA Administrator Bruce Vladeck; the Enforcement Procedures Group (EPG) met with officials from HCFA's Office of Survey and Certification who had drafted the new enforcement rules and manuals. Both groups were composed of providers, consumers, long-term care ombudsmen, state survey agencies, and Regional Offices. The IAA also included a single nursing home resident.

Although the two groups were originally designed with different missions (IAA was to consider whether the new enforcement system reflects appropriate policy; EPG, whether the enforcement system created by HCFA was working as the agency intended), in practice, the two groups considered the same issues.

Consumer representatives on both groups were frustrated by the process, which appeared to be far more responsive to providers' concerns than to residents' concerns.

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[92] IoM, *supra* note 16, 148.

HCFA acknowledged residents' concern that some states cited very few deficiencies, or none at all, but focused its attention on states that cited more deficiencies than the norm. On the other hand, the two monitoring groups spent considerable time discussing two issues of greatest concern to providers, the definitions of substandard quality of care and poor performing provider. Residents' representatives also felt that HCFA made decisions about policies in advance and used their meetings simply to announce what had already been decided.

After several meetings and conference calls, both the IAA and EPG were disbanded in the Fall of 1996.

In a second unusual step, HCFA established a process to receive and evaluate state survey reports (HCFA 2567's) in its Central Office in Baltimore. The "Situation Room" spent more than a year evaluating and analyzing the survey reports that states sent in electronically each week. This process was biased and flawed from the outset. By focusing solely on deficiencies that states *cited* on survey reports, HCFA avoided the broader issues of enforcement and ignored the problem of states' underciting deficiencies and imposing too few remedies.[93]

HCFA staff prepared data and analyses of the reports and used the findings in surveyor training during the Summer of 1996. HCFA also appeared to use the findings to identify states that cited more deficiencies than the norm, notably Michigan, and to advise these outliers to revise their enforcement practices.

Early on, AHCA prepared a study of "harm" that indicated that 82% of facilities would not be found in substantial compliance under the new enforcement system.[94] The trade association tried to use this study to argue that the draft manual did not correctly implement the rules. This effort met with little immediate success. Residents' advocates agreed with AHCA's predictions of extensive facility noncompliance with federal standards of care and argued that the industry's expected poor showing underscored the need for prompt and full implementation of the enforcement rules.

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[93] *See* Report of the State Auditor, State of Colorado, *Health Facilities Division, Department of Public Health and Environment, Follow-Up Performance Audit* (June 1995) (criticizing state's use of a deficiency review tool that led to a dramatic decrease in the number of deficiencies cited and an increase in the number of deficiency-free surveys). This report was brought to HCFA's attention as the agency began its evaluation of the new survey and enforcement systems. *See* July 20, 1995 letter of Toby Edelman to Debbie Schoenemann, HCFA.

[94] American Health Care Association, *Harm Study* (Apr. 1995).

The industry, however, had far greater success in its private meetings with HCFA officials and with the Secretary of the Department of Health and Human Services. While correspondence between HCFA and AHCA officials suggests that the meetings were often heated and that HCFA defended both the need for enforcement and the enforcement system it had created, the changes made by HCFA to the system after July 1, 1995 reflect agreements that appear to have been reached or promised in these private meetings.

In the post-regulatory phase of implementation of the enforcement provisions of the reform law and regulations, the industry has had its greatest success in weakening the strong enforcement orientation of the federal legislation.

D. Informal changes since July 1995

After issuing the State Operations Manual in June 1995, HCFA continued to make a number of changes to the survey and enforcement processes, particularly in the first year. The repeated changes have been disruptive and confusing to states, residents, and providers alike, who were frequently unsure of which procedures were in place. Most important, the substance of the changes further weakened the principles of the reform law and regulations.

HCFA's revisions are discussed here in chronological order.

1. *Moratorium on the collection of civil money penalties*

Two days before the July 1 effective date of the enforcement rules, HCFA imposed a moratorium on the collection of certain lower level civil money penalties. In a June 29 memorandum to states, HCFA told states to propose, but not to impose, civil money penalties during the first 90-day period of the new enforcement system except for the limited situations where harm is considered immediate or serious or where a facility is a poor performer.[95] Three days earlier, the American Health Care Association publicly claimed credit for the delayed implementation of the enforcement rules, accurately

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[95] "HCFA Holds Firm on July 1 Enforcement, But Halts Collection of Fines for 90 Days," NCCNHR, *Quality Care Advocate* 1 (May/June 1995).

describing the moratorium that HCFA would impose.[96] The Administration denied that it had yielded to industry pressure.[97] Nevertheless, the agency imposed this moratorium in June 1995 on an enforcement system that Congress had directed to be in place by October 1, 1989.

In November 1995, HCFA said it would continue to suspend collection of civil money penalties until it conducted a "proportionality study" evaluating the penalties that states proposed.[98] The study, completed in February 1996, is discussed below.[99]

2. *Definition of "widespread" scope*

On September 12, 1995, HCFA issued a memorandum to state survey agency directors and others "clarifying" the definition of "widespread" scope to limit use of the term to deficiencies that affect all residents of an entire facility.[100] Deficiencies affecting all residents on a particular wing or all residents with a particular care need may not be cited as widespread under the clarification. Deficiencies must be "pervasive" in the facility to be called widespread.

HCFA illustrated the new definition with an example. If all the residents in a facility with Alzheimer's disease, including all residents on the facility's special care Alzheimer's unit, do not have appropriate activities, but if most other residents are alert and participate in appropriate activities, the deficiency is not widespread because the

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[96] Memorandum from Paul R. Willging, Ph.D., Executive Vice President, AHCA, to Board of directors, State Executives, "HCFA Accepts AHCA Plan for Phased-In Implementation of Enforcement" (June 26, 1995):

> After weeks of intense lobbying by the American Health Care Association at the administrative and Congressional levels, the Health Care Financing Administration has agreed to adopt a phased-in implementation of the enforcement provisions of the final survey, certification and enforcement rule, slated for implementation on July 1, 1995. My thanks to all of you who worked so hard with your congressional delegation to achieve this result.

[97] Peter Eisler, "Nursing home reforms at risk," *USA Today* 2A (June 28, 1995).

[98] Memorandum from Deputy Bureau Director for Survey and Certification, HSQB, to Associate Regional Administrators and State Agency Directors, "Implementation Status of the Long Term Care Enforcement Process" 2 (Nov. 27, 1995); "More Delay: HCFA Prolongs Impasse on Fines," NCCNHR, *Quality Care Advocate* 1 (July-Nov. 1995).

[99] The study is discussed, *infra*, at notes 115-122 and accompanying text.

[100] Memorandum from Director of Office of Survey and Certification, HSQB, to Associate Regional Administrators and State Survey Agencies, "Clarification of Definition of 'Widespread' Scope," Sept. 12, 1995.

practice is not pervasive in the facility. A deficiency would be pervasive, and therefore appropriately cited as widespread, only if *most* residents *throughout the facility* had dementia and did not receive appropriate activities.

The definition of widespread is primarily important because of its connection to the statutory term, substandard quality of care. Under the enforcement system, deficiencies that are called widespread are also considered substandard quality of care if they fall in boxes F, I, or L on the enforcement grid and if they are identified in one of three regulatory groupings (quality of care, quality of life, and resident behavior and facility practices [the rules related to restraints]).[101] Providers want to avoid the designation of substandard quality of care because of the enforcement consequences that automatically flow. Facilities lose their ability to conduct nurse aide training for two calendar years and the state survey agency must notify both the attending physicians of all residents affected by the substandard care and the nursing home administrator licensing board that the facility has been found to provide substandard quality of care.[102] Since these consequences occur by operation of law and are not appealable issues,[103] providers want to avoid the designation.

The policy revision was controversial from the outset. Residents' advocates and many state surveyors believe that a deficiency affecting all residents on a wing or all residents with a particular need (such as Alzheimer's Disease) should be called widespread. They believe that providers' concerns about the consequences of the designation substandard quality of care should not be allowed to influence the classification of deficiencies.

3. *New terms for facilities not in substantial compliance*

On November 27, 1995, HCFA created new terms to define facilities that are not in substantial compliance with Requirements of Participation: "correction required" and "significant correction required."[104] When HCFA created the new terms, 74% of facilities surveyed under the new process in the previous six months had been found to

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[101] 42 C.F.R. §488.301.

[102] 42 U.S.C. §§1395i-3(g)(5)(C)(i), (ii), 1396r(g)(5)(C)(i), (ii), 42 C.F.R. §488.325(g), (h).

[103] HCFA does not consider these results to be "remedies," within the meaning of the reform law. Consequently, it does not view them as proper subjects of provider appeals.

[104] Memorandum from Deputy Bureau Director for Survey and Certification, HSQB, to Associate Regional Administrators and State Agency Directors, "Implementation Status of the Long Term Care Enforcement Process" (Nov. 27, 1995).

be out of substantial compliance. HCFA explained its rationale for the new terminology as helping to distinguish among these non-complying facilities:

> This high [74%] level [of noncompliance] may not only produce a negative reaction to the industry as a whole, but also makes it more difficult for consumers to differentiate between facilities on the basis of the survey findings.[105]

Despite HCFA's claim that consumers would benefit from the new terminology, the language was changed solely to benefit providers.[106] From the consumer perspective, the new terminology is obscure, if not intentionally misleading, and it minimizes the consequences of facilities' noncompliance.

4. Interim Revisit Policy

On December 6, 1995, HCFA issued an Interim Revisit Policy that permits states to avoid revisits in facilities where deficiencies are cited at the D-E-F level (level two) of the enforcement grid.[107] HCFA acknowledged that the sole motivation for this interim policy was the lack of sufficient resources to conduct revisits in all cases.[108]

Since the enforcement system established by the SOM relies on revisits in order to impose remedies in most situations, the lack of revisits means that enforcement is not even theoretically possible for the vast majority of deficiencies. HCFA reported to the Impact Assessment Advisors at their March 19, 1996 meeting that states cited 84.7% of all deficiencies at the A-B-C-D-E-F levels, the lower two levels of the enforcement grid. Consequently, only 15% of the deficiencies cited by state survey agencies would be

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[105] *Id.*

[106] In an earlier letter to members of the Impact Assessment Advisors, HCFA Administrator Bruce Vladeck had offered a different rationale for the proposed change in terminology. Noting that all but five to seven percent of the facilities given an opportunity to correct are found in substantial compliance at the time of their revisit, he wrote, "the high percentage of facilities found out of compliance initially may be producing adverse public perceptions of some facilities and of the industry as a whole." Letter of Bruce Vladeck to Impact Assessment Advisors, Nov. 8, 1995, page 2.

[107] Memorandum from Deputy Bureau Director for Survey and Certification, HSQB, to Regional Administrators and State Agency Directors, "Interim Revisit Policy" (Dec. 6, 1995).

[108] The memorandum setting out the interim revisit policy acknowledged the financial motivation behind the new policy: "It is recognized that resource limitations may not allow revisits in every instance that noncompliance is identified. Thus, it is necessary that we issue an interim policy at this time on when to conduct revisits." The financial motivation was confirmed by Anthony Tirone, Director, Office of Survey and Certification, at the March 5, 1996 meeting of the Enforcement Procedures Group.

subject to revisits and enforcement in states implementing the Interim Revisit Policy.

Moreover, most deficiencies in quality of life and residents' rights are cited, if at all, at the lowest two levels of the enforcement grid. HCFA reported to the Impact Assessment Advisors at the March 1996 meeting that over 90% of deficiencies in quality of life were cited at the lowest two levels of the enforcement grid. Nearly 50% (48.2%) were cited at the lowest severity level; another 43.3% were cited at level two; 8.5% at level three; and 0% at level four. These data indicated that only 8.5% of the quality of life deficiencies (those cited at levels three and four) would have a required revisit and would be subject to the possibility of any enforcement action. Consequently, states using the Interim Revisit Policy would be unlikely to impose any remedies for deficiencies they identify in quality of life. A similar lack of enforcement would occur for deficiencies in residents' rights, which are also placed at the lowest levels of the enforcement grid.

5. Limitation on state use of civil money penalties

In December 1996, HCFA issued another revision to the SOM that encourages states, effective January 24, 1997, to limit the imposition of civil money penalties (CMPs) to situations of immediate jeopardy or to a nursing facility that either is a "poor performer" or has "serious deficiencies" that are not corrected at the time of a revisit.[109] CMPs are not to be used for deficiencies that are cited at lower levels of the enforcement grid. A HCFA memorandum dated December 16, 1996 also advised states to use these same criteria in reviewing CMPs that had been held in abeyance under the moratorium since July 1, 1995.[110]

The changed policy flatly contradicts the regulations and HCFA's explanation of the final rules in its 1994 preamble and demonstrates the power of the nursing home industry in the post-regulatory phase of implementation of enforcement.

In July 1996, HCFA circulated draft changes to its CMP policy, which were virtually identical to those that HCFA issued five months later. Residents' advocates uniformly

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[109] HCFA, Transmittal No. 279 (Jan. 1997).

[110] Memorandum from Deputy Bureau Director for Survey and Certification to Associate Regional Administrators, Health Standards and Quality, Regions I-X, and to State Survey Agency Directors, "Treatment of Civil Money Penalties Held in Abeyance Due to Moratorium" (Dec. 16, 1996).

opposed the changes.[111]

Advocates objected to the new policy's limiting CMPs to the most serious deficiencies. They pointed to the final rules' preamble, where HCFA had cited with approval a public comment that criticized the proposed rules' failure to reflect all the points raised by IoM about the value of CMPs. HCFA paraphrased the public comment as follows:

> 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.[112]

HCFA's analysis of the public comment expressed its endorsement of the comment, stating "the regulatory provisions for civil money penalties encompass the above referenced points from the Institute of Medicine." The single exception implemented the statutory requirement that states offer hearings before imposing penalties.[113] In other words, in November 1994, HCFA purported to have accepted IoM's analysis about the versatility of CMPs and their availability for minor, as well as major, deficiencies. HCFA did not explain how the changes to CMP policy, proposed in July 1996 and implemented in January 1997, were consistent with the rules it had published in November 1994.

HCFA's rationale for imposing the moratorium on the collection of lower level CMPs in July 1995 had been the need to conduct a "real-time evaluation of the enforcement policies and procedures being implemented."[114] In February 1996, HCFA's completed its analysis of state behavior in its Proportionality Study, which evaluated "the relationship between the size of the penalties, the deficiencies cited, and the

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[111] *See* comments of the National Citizens' Coalition for Nursing Home Reform (July 31, 1996); American Association of Retired Persons (July 31, 1996); National Senior Citizens Law Center (July 25, 1996).

[112] 59 Fed. Reg. 56,116, at 56,198 (Nov. 10, 1994).

[113] *Id.*

[114] "HCFA Holds Firm on July 1 Enforcement, But Halts Collection of Fines for 90 Days," NCCNHR, *Quality Care Advocate* 1 (May/June 1995) (quoting June 29 memorandum of Anthony J. Tirone to state Medicaid agencies).

circumstances of the situation."[115] HCFA offered a new provider-motivated rationale for its study: "The impetus for this study was concern that some facilities may be charged CMPs that are disproportionately high, relative to the seriousness of the deficiency for which they are imposed."[116]

HCFA reported that in the initial implementation period, July through November 1995, 12 states had proposed 79 CMPs that were subject to the moratorium.[117] These 79 CMPs reflected only 5% of the 1581 facilities that were surveyed nationwide during that time period.[118]

HCFA chose to evaluate a sample of 41 CMPs – all the CMPs proposed in 11 states and a random sample of CMPs in Texas, which had proposed a disproportionately high number of CMPs.[119] HCFA found that states were using CMPs appropriately, setting higher amounts for more serious deficiencies and for facilities with other deficiencies and/or a poor compliance history.[120] States with prior experience imposing CMPs, as a result of state licensure authority or Medicaid, also appeared more comfortable using the remedy and imposed higher penalty amounts.[121] Finding the process to be working as intended, HCFA had a single recommendation: "fully implement the nursing home enforcement regulation by lifting the moratorium on civil money penalties."[122]

In revising the SOM in December 1996, HCFA did not take its own advice, nor did it explain why it changed its view from November 1994. HCFA's memorandum transmitting the revision to the SOM referred to its Proportionality Study, but rejected its recommendation because of unexplained "experience during this past year:"

> We conducted the study and concluded that the amount of CMPs were, for the most part appropriately determined. However, based on our experience during this past year, we believe that CMPs are most effective when reserved for imposition for more serious noncompliance, i.e., deficiencies cited in boxes G, H & I, deficiencies that constitute substandard quality of care, deficiencies that

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[115] HCFA, Civil Money Penalty Proportionality Study 2 (Feb. 1996).
[116] *Id.* 2.
[117] *Id.*
[118] *Id.* 3.
[119] *Id.*
[120] *Id.* 5-6.
[121] *Id.* 6.
[122] *Id.*

constitute immediate jeopardy, or for a facility identified as a poor performer.[123]

6. *Informal dispute resolution*

A June 1, 1997 revision to the State Operations Manual modified the informal dispute resolution process.[124] It gave new authority to nursing facilities to challenge the scope and severity of certain deficiencies, contrary to the survey process introduced in July 1995, which prohibited facilities from challenging scope and severity determinations under all circumstances. In addition, it encouraged states to offer facilities telephone or face-to-face meetings and to include as a decision-maker at least one person who was not involved in the original survey.

When these changes were circulated in December 1996, residents' advocates were critical and questioned why HCFA had changed its view from November 1994, when it said in the preamble to the final rules that it had no basis for endorsing one state's informal dispute resolution process over another's:

> We believe that specific procedural requirements that determine the manner in which dispute resolution proceeds, for example, such things as how the request is made, the method by which the process is conducted, and who may participate in the process, should be left to the individual States. . . . Any attempt on our part to codify procedural aspects of dispute resolution that would be applicable to all States would limit States' as well as providers' flexibility in utilizing and refining the process, as necessary, to satisfy their needs.
>
> . . .
>
> 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.[125]

HCFA's failure to evaluate the IDR process since July 1, 1995 also meant that HCFA had no factual basis for revising the guidance it had given states in November 1994. Finally, advocates also expressed concern that permitting facilities to challenge the

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[123] Memorandum from Deputy Bureau Director for Survey and Certification to Associate Regional Administrators and State Survey Agency Directors, "Treatment of Civil Money Penalties Held in Abeyance Due to Moratorium" (Dec. 16, 1996).

[124] State Operations Manual, HCFA Pub. 7, Transmittal No. 282 (June 1, 1997), [1997-2] *Medicare and Medicaid Guide* (CCH) ¶ 45,427.

[125] 59 Fed. Reg.56,116, 56,224 (Nov. 10, 1994).

scope and severity of certain deficiencies would encourage providers to assert that they came within one of the limited exceptions and, in practice, to challenge a much wider variety of scope and severity determinations.[126]

With the exception of the revision to the informal dispute resolution process, HCFA made no changes to the enforcement process in calendar year 1997. Instead, the agency appeared to focus its time and resources on implementing a massive internal reorganization,[127] in preparing a Congressionally-mandated evaluation of the federal enforcement system and alternatives to it,[128] and in developing non-regulatory quality initiatives.[129]

HCFA also appeared to renew its efforts to revise the survey process. However, following the negative publicity in December 1996 that resulted from its proposed revisions of the federal survey protocol,[130] HCFA undertook small-scale studies of changes to the survey process, piloted at the state level rather than through national change.

VII. HOW MUCH ENFORCEMENT HAS THERE BEEN?

When HCFA wrote the final enforcement rules in November 1994, it anticipated that the new enforcement system would lead to considerably more enforcement activity than the prior system.[131] That expectation has not been realized. Instead, since the new

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[126] Letter of Griff Hall, Executive Director, National Citizens' Coalition for Nursing Home Reform, to Pat Miller, Center for Long-Term Care, HCFA (Dec. 20, 1996); letter to Toby Edelman to Pat Miller, Center for Long-Term Care, HCFA (Dec. 19, 1996).

[127] 62 Fed. Reg. 24,120 (May 2, 1997).

[128] As part of the fiscal year 1996 appropriations bill for the Departments of Labor, Health and Human Services, and Education, Congress required HCFA to study the effectiveness and appropriateness of current mechanisms for surveying and certifying skilled nursing facilities. Deemed status and non-regulatory quality initiatives were also to be studied. *See* Marvin Feuerberg, "Study on Private Accreditation (Deeming) for Nursing Homes, Regulatory and Non-Regulatory Incentives, and Effectiveness of the Survey and Certification System" (June 17, 1997).

[129] *See* notes 142-150, *infra*, and accompanying text.

[130] Robert Pear, "U.S. Seeks to Limit Inspections' Scope at Nursing Homes," *The New York Times* A1 (Dec. 17, 1996). At the White House press briefing that morning, Deputy White House Press Secretary Michael McCurry announced that the proposed changes to the survey process would not be implemented. *See also* Herbert P. Weiss, "Proposed Changes to Survey Become Political Hot Potato," 31 *Long-Term Care Administrator* 3 (Jan./Feb. 1997).

[131] *See* note 75, *supra*, and accompanying text.

enforcement system was implemented, data compiled by HCFA indicate that although nearly three-fourths of facilities are found out of substantial compliance with Requirements of Participation, remedies are imposed against only a small fraction of them. Moreover, in the second year of the new system, fewer remedies were imposed than in the first year. Other information compiled from HCFA data indicate a decline in the total number of deficiencies per survey cited by state survey agencies and an increase in the number of facilities found to have no deficiencies at all. The promise and mandate of the reform law have not been achieved.

When the Impact Assessment Advisors and the Enforcement Procedures Group were meeting and the Situation Room was operating, HCFA compiled and regularly distributed detailed data about the new enforcement system. HCFA reported some data by state, region, and nation. It also prepared charts showing the numbers of facilities in substantial compliance and not in substantial compliance with requirements, the average and mean numbers of deficiencies cited per survey, and the frequency of scope and severity findings, among other statistics. When it first implemented the new enforcement system, HCFA compiled data weekly. A sample of the data, reported in cumulative format from July 1, 1995, appears below as Table 1.

Table 1

	7/1/95 - 8/4/95	**7/1/95 - 9/13/95**	**7/1/95 - 3/1/96**	**7/1/95 - 5/31/96**
standard surveys	1561	2585	10,609	14,934
compliance decision rendered	985	2425	10,181	14,362
facilities in substantial compliance	552 (56%)	668 (28%)	2,895 (28%)	4320 (30%)
facilities out of compliance	433 (44%)	1,757 (72%)	7,286 (72%)	10,042 (70%)

immediate remedies proposed	17	78	269	139
opportunity to correct	416	1679	7,017	3,589
substandard quality of care	114 (11.6%)	434 (18%)	1,328 (13%)	1,541 (11%)
dispute resolution reviewed	3	127	1,251	1,831
total affirmed	1	70	572	361
total revised	2	57	679	198
facilities verified on revisit in substantial compliance	11	115	4,000	1,591
facilities verified on revisit not in substantial compliance	0	9	871	353

In May 1996, HCFA analyzed the survey findings for the first ten months of the new system. HCFA divided the ten-month period into three substantially equal time periods in order to analyze changes over time that cumulative data would not as clearly demonstrate.[132]

HCFA found that the number of facilities cited by states for providing substandard quality of care had declined from 16% in the first three months, to 11% in the second three months, and to 6% in the third period. The variation in some states was even more dramatic. Substandard quality of care citings declined in Michigan from 59% to

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[132] Marvin Feuerberg, Ed Mortimore, and Katie Phillips, "Analysis of Substandard Quality of Care as Not in Substantial Compliance Citations, 7/1/95-5/7/96," (May 17, 1996) (distributed at June 10, 1996 meeting of the Impact Assessment Advisors).

12% to 10% over the three periods; in Kentucky, from 45% to 0% to 0%.[133] With respect to substandard quality of care, HCFA noted, "the variation around the declining mean has also declined considerably, mainly by 'high' states moving toward the mean."[134]

For noncompliance generally, HCFA found that the variation around the median increased, "mainly by some 'low' states moving away from the median."[135] In addition, the mean number of deficiencies per survey dropped in each period.[136]

The declining numbers of deficiencies and enforcement actions o not reflect HCFA's disagreement with states' early survey and enforcement actions. To the contrary, HCFA found that states were correctly implementing the new systems. In fact, HCFA claimed that it would have been somewhat more aggressive in its deficiency citations. In a paper prepared for the September 26, 1995 meeting of the Impact Assessment Advisors, HCFA explained the data on substandard quality of care:

> Currently, States have found, on average, 18 percent of facilities to be in substandard quality of care. HCFA's review of state findings of substandard quality of care disagrees with only a small fraction of these determinations. HCFA's review suggests that States are, in fact, exercising great caution in citing substandard quality of care. In a number of instances the HCFA review team would have, based on the evidence in the Statement of Deficiencies, cited the facility for substandard quality of care when the State had not.[137]

HCFA also believed that the state differences in citation rates were understandable, reporting to the Impact Assessment Advisors:

> For a country as large and diverse as the U.S., it would be surprising if there were not state differences in citation rates. One reason for this expectation is that there are large state differences in factors that might impact on the average quality of care received in nursing homes. These factors are hard to identify

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[133] *Id.* Table 1.

[134] *Id.*, "Analysis of Substandard Quality of Care, Noncompliance, and Deficiencies, 7/1/95 - 5/17/96, Summary of Results."

[135] *Id.*

[136] *Id.*

[137] HCFA, *Substandard Quality of Care Findings* (Materials prepared for meeting of Impact Assessment Advisors, Sept. 26, 1995).

apriori, but state differences in casemix/acuity, average Medicare covered days per stay, and average reimbursement per discharge are illustrative of factors (other than surveyor inconsistency) that demonstrate both large state variations and potential impact on the patient population, the quality of care received, and the assessment of that care by surveyors.[138]

Once the Impact Assessment Advisors and Enforcement Procedures Group were disbanded at the end of 1996, HCFA stopped publicly distributing data about the survey and enforcement systems. After the new system had been in place for two years, however, HCFA prepared cumulative data for the first two years of the new enforcement system. These data demonstrate that while most facilities were give an opportunity to correct deficiencies in the first year of the new survey system, the same percentage of facilities had deficiencies in the second year and most were again given an opportunity to correct:

Table 2

	7/1/95-6/30/96	7/1/96-6/30/97
standard surveys completed	16,835	17,727
facilities in substantial compliance	5,559 (33%)	5,570 (33%)
facilities with deficiencies D and above	11,276 (67%)	11,457 (67%)
total immediate remedies proposed	142	120
total with opportunity to correct	11,274	11,454
facilities with substandard quality of care	802	1,633
facilities verified on revisit in substantial compliance	9,499	7,100

[138] HCFA, *State Differences* (Materials prepared for meeting of Impact Assessment Advisors, Sept. 26, 1995).

The numbers are striking for their similarity over the two years, with a couple of exceptions. The data indicate that while states cited more than twice as many facilities for substandard quality of care in the second year of the new survey process (1633 compared with 802), they nevertheless allowed most facilities an opportunity to correct and in fact recommended fewer immediate remedies in the second year of the new process (120 compared with 142).

HCFA does not report how many facilities were labeled "poor performing providers" and does not explain why a larger number of deficient facilities was not immediately sanctioned as poor performers. It also does not report any information on informal dispute resolution, although that issue was a category in HCFA's earlier reports.

HCFA reported that the numbers of remedies imposed also declined over the first two years of the new enforcement system:

Table 3

Remedies	1995-1996 Proposed Standard	1995-1996 Proposed Complaint	1995-1996 Imposed Total	1996-1997 Proposed Standard	1996-1997 Proposed Complaint	1996-1997 Imposed Total
state monitoring	1459	563	128	1415	458	50
directed plan of correction	2431	464	36	2080	343	31
temporary management	15	3	1	15	5	1
denial of payment for new admissions	5299	1187	266	6109	1694	189
denial of payment for all residents	73	16	1	47	10	0

directed in-service training	3194	863	140	3403	959	123
civil money penalty	3764	1119	250	3187	870	275
HCFA-approved alternative state remedy	89	13	18	136	18	2
transfer of residents/ closure of facility	1	0	0	0	0	0
transfer of residents	1	0	0	1	0	0
termination	6754	1870	60	6680	1572	14

In both years, the numbers of remedies actually *imposed* were only a small fraction of the remedies *proposed*. Moreover, with the exception of civil money penalties, the number of remedies imposed declined over the two-year period. For example, while 128 state monitors were placed in facilities in the first year of the new system, only 50 were placed in the second year. Denial of payment for new admissions also declined, from 226 to 189; directed in-service training, from 140 to 123.

HCFA has offered no explanation for these declining numbers.

An analysis of national OSCAR data prepared by researcher Charlene Harrington presents an even more vivid – and bleak – picture of enforcement.[139]

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[139] Charlene Harrington, Ph.D., and Helene Carrillo, *The Regulation and Enforcement of Federal Nursing Home Standards* (July 1997).

Dr. Harrington found that the average number of deficiencies per facility declined across the United States each year between 1991 and 1996, from a high of 8.8 deficiencies per facility in 1991 to a new low of 5.5 deficiencies per facility in the first six months of 1996. In the first six months of the new survey process (July 1, 1995 through December 31, 1995), the average number of deficiencies per facility was 6.1. Thus the 5.5 deficiencies per facility in the second six months of the new survey process (January 1, 1996 through June 30, 1996) reflects a decline of 10% from the previous six months.

Over the same period, Dr. Harrington reports that the percentage of facilities with no deficiencies cited at all increased from 10.8% in 1991 to 16.9% in the first six months of 1996. The number of deficiency-free facilities increased from 15.3% in the first six months of the new survey system (July 1, 1995 through December 31, 1995) to 16.9% in the second six months (January 1, 1996 through June 30, 1996), a nearly 10% increase.

The declining numbers of deficiencies reduce the possibility of enforcement since deficiencies form the basis of enforcement remedies.

VIII. WHAT HAPPENED TO ENFORCEMENT?

Since Congress enacted the nursing home reform law in December 1987 and, more particularly, since HCFA wrote the final enforcement regulations in November 1994, several factors have converged to weaken HCFA's commitment to implementing the reform law's mandate for strong enforcement of nursing home quality standards. These factors have led to a new orientation within the agency that results in reduced enforcement activity.

A. The Budget Deficit

First, the perceived need to reduce the federal budget deficit has led to a decrease in many areas of discretionary federal spending. HCFA's budget for survey and certification activities has remained flat, resulting in a reduction of federal funds for survey and certification activities. With increased numbers of health care providers requesting certification, federal and state enforcement agencies have been required to do more work with fewer resources. As an understandable result, HCFA and state survey agencies have looked for ways to focus their enforcement resources on facilities that are considered to provide the worst care.

HCFA has acknowledged that budgetary concerns have led to revisions in the enforcement system. In the December 1995 memorandum revising the revisit policy, HCFA justified its new policy allowing states to forego revisits under certain circumstances as a response to "resource limitations" that prevent revisits in all instances of noncompliance.[140] In an interview with the National Citizens' Coalition for Nursing Home Reform in the summer of 1996, HCFA Administrator Vladeck defended his agency's record in enforcement as focusing enforcement activities on the worst providers, but admitted, "It is true that if we were in a world without resource constraints we might not feel a need to focus as much."[141]

While focusing public oversight on facilities that have the most serious deficiencies has understandable merit and appeal, it negates the federal reform law's mandate to increase oversight and enforcement of deficiencies along the full continuum of facility noncompliance.

B. The Anti-regulatory Orientation

A second key factor is the Clinton Administration's approach to regulatory issues, which calls for a "more flexible, effective, and user-friendly approach to regulation."[142] In an Executive Order issued early in the Clinton Administration's first term, the President established a program to reform the federal regulatory process.[143] In a variety of subsequent Executive Orders and Memoranda and in the Vice-President's Reinventing Government initiative, the Executive Branch expanded on this theme and called for government to be like business.[144]

In response to these directives, HCFA initiated a Plan for Periodic Review of Rules to

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[140] Memorandum from Deputy Bureau Director for Survey and Certification, HSQB, to Associate Regional Administrators, Regions I-X, and State Agency Directors, "Interim Revisit Policy" (Dec. 6, 1995).

[141] "Some Tinkering, No Compromises: Vladeck Defends HCFA's Enforcement Record," NCCNHR, *Quality Care Advocate* 9 (June/July 1996).

[142] The President, "Regulatory Reform–Waiver of Penalties and Reduction of Reports," Memorandum of April 21, 1995, *as reprinted in* 60 Fed. Reg. 20,621 (Apr. 26, 1995).

[143] Executive Order 12866 of September 30, 1993, "Regulatory Planning and Review," r*eprinted in* 58 Fed. Reg. 51,735 (Oct. 4, 1993).

[144] In Executive Order 12862, "Setting Customer Service Standards," the President required "reform of the executive branch's management practices and operations to provide service to the public that matches or exceeds the best service available in the private sector." The Executive Order is reprinted at 58 Fed. Reg. 48,257 (Sept. 14, 1993).

review existing rules and regulations to make them "less burdensome, more effective, and in greater alignment with the President's priorities and regulatory principles."[145] HCFA also incorporated these principles in its new rules and issuances.

In July 1995, Barbara Gagel, director of HCFA's Health Standards and Quality Bureau, announced the Health Care Quality Improvement Project (HCQIP), a collaborative approach between HCFA and health care providers to address health care quality issues in a non-regulatory "quality-management program that emphasizes improving the processes by which care is delivered."[146] Gagel described HCFA's role as shifting from regulator to purchaser of health care services, much like General Motors or Xerox.[147]

The new approach expressly relies on business management systems that allow health care providers to develop plans to improve the care they provide, based on electronically-produced data that compare their performance with the performance of their peers. The primary components of these management systems are quality indicators and customer satisfaction. Provider-developed plans for improvement replace an externally-established regulatory standard of performance.

HCFA has given considerable attention to quality assurance in the regulatory system for nursing facilities. In the SOM, HCFA added a new task on quality assurance to the survey protocol that went into effect with the new enforcement system on July 1, 1995. While Task 5F has the narrow purpose of determining whether a facility has a quality assurance committee, as required by law, and whether the committee has a method to "identify, respond to, and evaluate" issues in quality of care,[148] the task evaluates neither the adequacy nor the effectiveness of a facility's QA committee. Nevertheless, effective July 1, 1995, the new enforcement system gives considerable credibility to QA.[149]

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[145] HHS, Plan for periodic review of rules, 69 Fed. Reg. 3040 (Jan. 20, 1994).

[146] Barbara Gagel, "Health Care Quality Improvement Project," *Health Care Financing Rev.* 15 (Vol. 16, No. 4) (Summer 1995).

[147] *Id.* 16.

[148] HCFA, State Operations Manual 274 (July 1995), Task 5F. The nursing home reform law required facilities to establish quality assurance committees and to guarantee the confidentiality of their records. 42 U.S.C. §§1395i-3(b)(1)(B), 1396r(b)(1)(B).

[149] For example, the State Operations Manual says, "past noncompliance will not be cited by the survey team if a quality assurance program is in place and has corrected the noncompliance. An exception to this policy may be made in cases of egregious past noncompliance." SOM 273 §7510.B.

HCFA has also looked increasingly to non-regulatory methods of addressing quality concerns.[150] While the agency has not developed any initiatives in enforcement since July 1995, it has devoted considerable staff time and resources to non-regulatory matters. In June 1996, HCFA held a symposium on *Nursing Facility Quality Assessment and Assurance* that considered the role of quality assurance committees. The last panel of the day considered an issue raised by the nursing home industry -- ""Is an enforcement mechanism counterproductive in a Continuous Quality Improvement (CQI) environment?" All three speakers at the symposium agreed that while quality assurance may serve a role in assisting facilities in identifying problems, it is not a substitute for a system of public accountability.

Another HCFA symposium, held in July 1996 on *Improving Quality of Life for Nursing Home Residents: The Challenge & The Opportunities*, led to a new HCFA initiative in 1997. The *Sharing Innovations in Quality* initiative is a "non-regulatory collaborative project designed to develop a repository of the innovative ideas and best practices in long term care that have improved outcomes for nursing home residents."

C. Nursing home industry influence

The influence of the nursing home industry on the enforcement provisions of the nursing home reform law has also been extensive and increasingly effective in the post-regulatory phase of implementation. The rulemaking process requires HCFA to publish proposed rules, to offer opportunities for public comment, and to respond to the comments. In contrast, the post-regulatory process does not obligate HCFA to solicit the views of the public or to provide a public explanation for policy decisions.

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[150] *See* "HCFA Retreats from Regulatory Role," *The Nursing Home Law Letter*, 1997 Issue No. 3 (Nov. 7, 1997).

The most recent example of HCFA's new, non-regulatory approach to its role is the proposed Hospital Conditions of Participation, published in December 1997. 62 Fed. Reg 66,726 (Dec. 12, 1997). Describing its "new approach to our quality of care responsibilities," *id.* 66,727, HCFA writes:

> The proposed COPs invest hospitals with internal responsibility for improving their performance, rather than relying on an externally-based approach in which prescriptive Federal requirements are enforced through the punitive aspects of the survey process. This change would enable HCFA and the States to focus more resources on joining with hospitals (in this case, principally non-accredited hospitals) in partnerships for improvement. It should result in fewer compliance surveys and the reduced need to threaten or take adverse actions that could jeopardize a hospital's reputation, financial viability, and participation in the Medicare and Medicaid programs.

Id. 66,729.

Nevertheless, residents' advocates recognized that changes to the enforcement system made since July 1995 reflected solely providers' concerns. They complained that their issues were ignored. Residents' advocates who participated in HCFA's external monitoring groups also protested that the meetings were showcases for HCFA to announce policy decisions, rather than opportunities for discussion of policy options.

Information made public in early 1997 appeared to confirm advocates' view that the nursing home industry had exercised considerable influence on HCFA's post-regulatory decision-making. While it is unlikely that the industry's influence was more pervasive or more successful than in earlier periods, it has been more fully documented for this period.[151] A sample of the 1996 correspondence between HCFA and the American Health Care Association reflects a series of meetings and decisions about enforcement issues that were later presented to the IAA and EPG. HCFA's changed policy on civil money penalties presents a vivid example of the industry's extensive influence.

As discussed above, HCFA had imposed a moratorium on the imposition of civil money penalties just before it implemented the new enforcement system in July 1995. AHCA claimed credit for the delay. HCFA analyzed CMPs that were subject to the moratorium in its Proportionality Study, which found that civil money penalties proposed by states were reasonable and which recommended, in February 1996, that the moratorium be lifted. No action followed.

In a May 7, 1996 letter to HCFA Administrator Bruce Vladeck, AHCA lobbyist Alan Solomont referred to an earlier meeting where civil money penalties were discussed, among other issues. Mr. Solomont referred to Dr. Vladeck's "willingness to take a number of actions," including "making manual changes as to when civil monetary penalties can be imposed." Mr. Solomont referred to a more detailed attachment that expanded on this issue and wrote, "It would be very helpful if you would look at the attachment, put it into your own words, and send it back to us in a letter. That will give us the ability to provide a factual piece of evidence to our board as to our mutual direction." Dr. Vladeck's letter of May 13 to Mr. Solomont appeared responsive to the request. Dr. Vladeck wrote:

> CMPs appear to have been imposed upon facilities where there is, or has been,

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[151] *See* Michael Weisskopf, "The Good Provider: Alan Solomont, the new Democratic fund-raising chief, worked hard for his party. And his industry," *Time* 32 (Feb. 10, 1997); Robert Pear, "Big Donors From Nursing Homes Had Access," *The New York Times* A22 (April 22, 1997).

> a pattern of historical noncompliance or egregious deficiencies. Clarification will be made to the State survey agencies that such criteria, in addition to other criteria such as the seriousness of the deficiency and the facility's failure to correct, should be taken into account before a CMP is initially recommended. This clarification will be accomplished through revisions to the State Operations Manual (SOM) and will be completed within the next 90 days.

A June 19, 1996 letter from AHCA Executive Vice President Paul Willging to Dr. Vladeck referred to a meeting the previous week:

> We did touch on the issue of Civil Monetary Penalties, both those held in abeyance by reason of the moratorium as well as those yet to be proposed. On the former, it was your sense that HCFA would suggest to the states that they be waived, at least for those facilities currently in compliance. As for the three CMP criteria you enunciated to the Independent Assessment Advisors for future consideration, you indicated a willingness to have our respective staffs talk to each other about language, while pointing out that your communications to the states on the issue needed to be suggestive rather than prescriptive. You did agree, however, that any concerns not resolved through staff discussions could be brought back to Friday's group for further review. You offered that same forum for unresolved issues with respect to informal dispute resolution and the proposed substandard care regulation.[152]

In July 1996, HCFA circulated proposed changes to the SOM that would limit use of CMPs to serious deficiencies. Dr. Vladeck's July 26 letter to Dr. Willging referred to the draft manual instruction and continued, "As promised, my staff is available to discuss the language of this instruction before it is final." HCFA did not offer this opportunity to residents' representatives, who opposed the changes.

At the September 25, 1996 EPG meeting, HCFA described that changed orientation to CMPs that it planned to make in the SOM. It described the proposed draft SOM that it had circulated the previous summer and the "diametrically opposed views" of the 18 commenters on the proposals.[153] One consumer representative commented that the

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[152] Letter to Bruce Vladeck, Administrator, HCFA, from Paul Willging, Executive Vice President, American Health Care Association, June 19, 1996.

[153] Description by Kathy Lochary, HCFA, meeting of the Enforcement Procedures Group (Sept. 25, 1996).

proposed change violated the nursing home reform law and that HCFA had been backtracking on CMPs for the last several years "in response to provider political pressure."

In December 1996, HCFA issued its revised SOM reversing its policy on CMPs, as it had promised AHCA it would do in May.

On a second issue of informal dispute resolution, the extraordinary influence of the nursing home industry was also felt. The inclusion of an informal dispute resolution process in the final enforcement rules had been urged by AHCA as one of the trade association's two key concerns about the enforcement rule. HCFA required states to have a process but said in the final rules in November 1994 that it had no reason to endorse the use of any particular state process over another. As long as a state offered a process and informed providers how to use it, HCFA would require nothing further.[154]

During the early implementation of the enforcement system, residents' representatives repeatedly asked HCFA to evaluate the IDR process -- how often it was used, what types of process states used, whether deficiencies were affirmed or changed as a result of IDR, etc. HCFA refused, limiting its analysis to collecting data that indicated how many IDRs were conducted and how many deficiency statements were revised as a result. HCFA claimed that IDR was a success, although it plainly had no basis for the claim.

Despite the lack of information or analysis suggesting that the IDR process needed to be revised at the national level, HCFA changed the policy in June 1997 in ways that give facilities additional opportunities to challenge deficiency determinations. The changes also place additional burdens on state agencies' survey resources by encouraging states to offer telephone and face-to-face proceedings (as well as paper review) and to use a decision-maker who did not participate in the original survey. Unlike other changes to the survey and enforcement systems discussed above, these changes present additional costs to states and cannot be justified as cost-savings measures. Their sole purpose is placating the nursing home industry that seeks to avoid deficiencies.

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[154] 59 Fed. Reg. 56,116, 56,224 (Nov. 10, 1994). *See* notes 124-126, *supra*, and accompanying text.

VIII. CONCLUSION

HCFA has not adequately or effectively implemented the enforcement provisions of the nursing home reform law. It delayed issuing proposed rules for many years beyond the date mandated by Congress.

When HCFA published the final enforcement rules in November 1994, it initially attempted to balance residents' and industry's concerns. Although the agency yielded to the industry on its two major regulatory points (substantial compliance and informal dispute resolution), it also provided residents with policies and with language in the preamble, and to a lesser extent, in the rules, that were responsive to their interest in strong enforcement.

In the State Operations Manual issued seven months later, in late June 1995, HCFA undercut promises to revise the enforcement system that it had made in the final rules. In contradiction of the law and rules, HCFA offered most facilities an opportunity to correct deficiencies before states could impose penalties, thus reinstating terms and concepts that Congress had expressly rejected when it enacted the reform law.

The industry has seen its greatest success in the changes that HCFA has made to the enforcement process since July 1, 1995. These changes have uniformly reduced federal enforcement activity.

Through the post-regulatory process, HCFA has reinstated the enforcement system that the Institute of Medicine criticized in March 1986 and that Congress rejected and replaced in December 1987.

Supported by The Commonwealth Fund, a New York City-based private independent foundation. The views represented here are those of the author and not necessarily those of The Commonwealth Fund, its directors, officers or staff. This newsletter was prepared by Toby S. Edelman, National Senior Citizens Law Center. Annual subscriptions to the *Nursing Home Law Letter* are available for $100. To subscribe please contact Christy Ross at NSCLC's Washington office (202) 289-6976.

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Nursing Home Fraud and Abuse Initiative
(For Discussion Purposes Only)

Summary

The Nursing Home Fraud and Abuse Initiative is a joint effort of the Departments of Justice and Health and Human Services to bolster federal, state and local law enforcement efforts aimed at fraud and abuse in nursing homes and other long-term care facilities, with a particular emphasis on fraud and abuse that results in harm to patients. The Initiative responds to President Clinton's call in July 1998 for stepped up enforcement efforts against nursing homes that commit egregious violations of federal and state laws and fail to ensure humane, safe, and adequate care for nursing home residents. The Initiative also calls for assisting the majority of law-abiding nursing home operators in complying with federal and state laws.

Major Components of the Nursing Home Initiative

- Create a new National Nursing Home Fraud and Abuse Task Force – composed of senior officials from the Department of Justice, HCFA, HHS Office of Inspector General, and the FBI – to implement the Initiative; evaluate the effectiveness of existing laws, regulations, and practices aimed at combating fraud and abuse in nursing homes; and to provide advice on how to improve federal, state and local enforcement and industry compliance efforts.

- Establish new (or expand existing) Nursing Home Fraud and Abuse Task Forces at the state and local level composed of federal, state and local law enforcement, state survey and licensing agencies, and other appropriate agencies to: (1) streamline the process for referring egregious quality of care violations and other potentially fraudulent activity to law enforcement authorities; (2) ensure adequate investigation and/or prosecution at the federal, state or local level; and (3) conduct joint training programs.

- Increase investigative efforts directed against regional and multistate nursing home operators that commit widespread or repeated violations of federal quality of care regulations. Large, multistate providers have escaped such scrutiny due to separate state survey processes and because HCFA currently contracts with individual facilities – not necessarily with the management company or corporate parent. Under the Initiative, HCFA is changing its existing databases to facilitate the identification of nursing home operators that engage in widespread or repeated violations of Medicare rules and regulations.

- Integrate the Veterans Administration into the Nursing Home Initiative to take advantage of the oversight conducted by the VA and to ensure a swift response to abuse and neglect involving VA beneficiaries in nursing homes.

- Expand the assistance currently available to the victims of nursing home abuse and neglect (including, if appropriate, amendments to the Victims of Crime Act and/or the regulations issued under VOCA).

- Assist the majority of nursing home operators who are law abiding by publishing compliance guidance from the HHS Office of Inspector General for nursing homes and other long-term care facilities (similar guidance has been published for clinical laboratories and other segments of the health care industry).

- Increase accountability by toughening the certifications that nursing homes must sign to receive Medicare payments.

- Develop model state patient abuse and neglect legislation, including tough civil and criminal penalties, mandatory reporting of serious instances of abuse and neglect, and mandatory background checks for nursing home employees.

- Conduct several regional training conferences on nursing home fraud and abuse enforcement, with participation from federal, state and local law enforcement agencies, state survey and licensing agencies, and other appropriate participants.

- Propose new federal legislation providing civil penalties and injunctive relief against nursing homes that commit a pattern or practice of violations of Medicare or Medicaid statutes or regulations. Consider criminal sanctions for willful violations of Medicare or Medicaid statutes or regulations, with more serious penalties for violations that result in actual patient harms.

Resources

At this time, the Department of Justice has not requested additional resources for stepped-up enforcement efforts in the FY 2000 budget (currently pending at OMB). Rather, the activities outlined above will be conducted using current resources. However, the use of existing resources will necessarily constrain what can be done and additional resources could be used effectively to implement the Initiative in a more robust manner.

Timing and Status of Interagency Clearance Process

The draft Action Plan, summarized above, has been reviewed at senior staff levels within DOJ and HCFA but has not been fully vetted within each agency. Beyond the necessary substantive review of these proposals, HCFA is (properly) concerned about the resource commitment required to implement this Initiative. HCFA already is devoting substantial resources to the implementation of the efforts announced in July 1998. The final scope of the Initiative may need to be adjusted based on resource limitations.

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FAX COVER SHEET

To:	Chris Jennings	**Fax Number:**	**202-456-5557**
Company:	The White House	**Phone Number:**	202-456-5560
Date:	January 21, 1999	**Time:**	11:30 a
Number of pages including cover:	6	**From:**	Celia D. Harris Assistant to Alan Solomont

Memo:

Alan D. Solomont
400 Centre Street
Newton, Massachusetts 02158
Tel 617-332-5522
Fax 617-332-2196

To: Chris Jennings
From: Alan Solomont ADS
Date: January 21, 1999

Great Speech!

These are people I'd recommend be invited to a meeting to discuss the quality of nursing home care and other issues related to long-term care. I've put my suggestions into three categories and would narrow the list by eliminating people from categories 2 and 3. Bios are attached.

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Alan Solomont
Susan Bailis
Bruce Yarwood

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Paul Wilging, AHCA President
Steve Guillard, AHCA Multifacility Committee, Chair
Dale Thompson, AHCA Past Board Chair
Dixie Taylor, AHCA Member from Tennessee

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Mike Walker, Genesis Health Care Ventures, Inc.

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NURSING HOMES

① process prob → not in budget

② user fee structure
HCFA wants to pass thru
→ OMB does not

③ estimate is too soft - by next week.

④ discussion re: old & new employees.

(Mark Elder 6908722)

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IMPROVING QUALITY IN LONG-TERM CARE

The Institute of Medicine (IOM) has established an expert committee (listed on the back) to examine the means for assessing, overseeing, and improving the quality of long-term care in different settings and the practical and policy challenges of achieving a consistent quality of care regardless of the site of care.

Since the IOM issued its 1986 report, *Improving the Quality of Care in Nursing Homes*, many changes have occurred that have significantly altered where long-term care is received and by whom. In addition, the methods and tools for assessing the quality of care and measuring health outcomes have advanced and have become more patient-oriented. Unlike the earlier IOM study, the current study will examine the full range of long-term care settings and services, including nursing homes, assisted living facilities, and community-based home health care.

Among the questions the new study will consider are:

1. What are the demographic, health, and other characteristics of individuals requiring long-term care and how are they changing?
2. What are the roles of the various long-term care settings in community health care systems, and how do they relate to other components of community care systems?
3. What are the strengths and limitations of existing methods and tools to measure, oversee, and improve quality of care and outcomes in nursing homes and other long-term care settings? How can these methods and tools be improved to promote better quality of care and other outcomes regardless of setting?

The study will involve two meetings at which statements from interested organizations will be heard. The results of the study will be published in early 1999. Funding for the study is being provided by the Robert Wood Johnson Foundation with additional support from the Archstone Foundation and the Irvine Health Foundation.

For more information, call 202-334-2360. The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and its own initiative in identifying issues of medical care, research, and education.

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Date: Tuesday, July 21, 1998
FACT SHEET
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ASSURING THE QUALITY OF NURSING HOME CARE

Overview: *The Clinton Administration, continuing its strong commitment to ensuring high quality* ***nursing*** *home care for those who need it, announced new steps today to ensure that all* ***nursing*** *home residents are treated with dignity and compassion.*

Since 1995, the Administration has been enforcing the toughest ***nursing*** *home regulations in the history of the Medicare and Medicaid programs. The Health Care Financing Administration has sharply increased the number of penalties levied on poor-quality* ***nursing homes****.*

In a new report to Congress, HHS notes significant improvements in the quality of care delivered in ***nursing homes****. But the report also finds a need for further improvement by States,* ***nursing homes****, and others. States have the primary responsibility for conducting on-site inspections of* ***nursing homes*** *and recommending sanctions on those who are providing poor quality care.*

As part of its new initiative, the Administration will work with the States to improve their ***nursing*** *home inspection systems; crack down on* ***nursing homes*** *that repeatedly violate safety rules; require* ***nursing homes*** *to conduct criminal background checks on all new employees; reduce the incidence of bed sores, dehydration, and malnutrition; and publish* ***nursing*** *home quality ratings on the Internet.*

Background

About 1.6 million elderly and disabled people receive care in approximately 16,800 **nursing homes** across the United States. The Federal government, through the Medicare and Medicaid programs, provides funding to the States to conduct on-site inspections of **nursing** home participating in Medicare and Medicaid and to recommend sanctions against those **homes** that are violating health and safety rules.

Clear Evidence of Improvement, But Problems Persist

According to a new report to Congress, there is clear evidence that current regulations are improving the health and safety of **nursing** home residents. Specifically:

- The overuse of anti-psychotics is down from about 33 percent before **nursing** home reform was implemented to 16 percent now;
- Use of antidepressant is up from 12.6 percent to 24.9 percent, a rate more commensurate with the estimated **nursing** home prevalence of depression;
- The inappropriate use of physical restraints is down, from about 38 percent to under 15 percent;
- The inappropriate use of indwelling urinary catheters is down nearly 30 percent; and
- The number of **nursing** home residents with hearing problems who receive hearing aids is up 30 percent.

While there are improvements attributable to the new regulations, the HCFA report makes clear that several areas require greater attention. Among those findings are:

- State-run **nursing** home inspections are too predictable. Inspection teams frequently appear on Monday mornings and rarely visit on weekends or during evening hours. This allows **nursing homes** to prepare for inspections.

- Several States have rarely cited **nursing homes** for substandard care, an indication that their inspections and enforcement may be inadequate;

- **Nursing** home residents continue to suffer unnecessarily from such clinical problems as pressure or bed sores, malnutrition and dehydration. These can be prevented with proper care; and

- Residents continue to experience physical and verbal abuse, neglect, and misappropriation of residents' property.

New Administrative Enforcement Actions

As part of its strategy for continuous quality improvement in **nursing homes**, the Administration is adding new enforcement tools and strengthening Federal oversight of **nursing** home quality and safety standards. Resources for these activities are included in the President's fiscal year 1999 budget request currently before the Congress.

Stronger Enforcement Actions. HCFA will take several steps to toughen enforcement of **nursing** home safety and quality regulations; They are:

- **Nursing homes** found guilty of a second offense for violations harming residents will have sanctions imposed and will not receive a "grace period" that allows them to correct problems and avoid penalties;

- HCFA will permit states to impose civil monetary penalties for each instance of serious or chronic violation. Until now penalties have been linked only to the number of days a facility was out of compliance with regulations.

- **Nursing** home inspections will be conducted more frequently for repeat offenders with serious violations without decreasing inspection frequency for other facilities;

- **Nursing** home inspection times will be staggered, with a set amount to be done on weekends and evenings and;

- Federal and State officials will focus their enforcement efforts on **nursing homes** within chains that have a record of noncompliance with Federal rules.

Stronger Federal Oversight of State Inspections. To target States with weak inspection systems, HCFA will:

- Provide additional training and other assistance to inspectors in States that are not adequately protecting residents;

- Enhance Federal review of the surveys conducted by the States. Standard evaluation protocols will be implemented in every State this fall;

- Ensure that State surveyors enforce HCFA's policy to sanction **nursing homes** with serious violations and that sanctions cannot be lifted until after an onsite visit has verified compliance; and,

- Terminate Federal **nursing** home survey funding to States that fail to adequately perform survey functions or fail to improve inadequate survey systems. HCFA will then contract with other entities to conduct **nursing** home survey and certification activities in those States.

Preventing Bed Sores, Dehydration, and Malnutrition. HCFA will step up its review of **nursing**

homes' ability to prevent bed sores, dehydration, and malnutrition. **Nursing homes** with patterns of serious violations will be sanctioned. HCFA also will work with the Administration on Aging, the American Dietetics Association, clinicians, consumers, and **nursing homes**, to develop a repository of best practice guidelines for residents at risk of weight loss and dehydration.

Combating Resident Abuse. State inspectors will review each **nursing** home's system to prevent, identify, and stop physical or verbal abuse, neglect, and misappropriation of resident property. A description of each **nursing** home's abuse prevention plan will be shared with residents and families. HCFA will also ask states to direct **nursing homes** to inquire about criminal convictions when interviewing potential personnel.

Prosecution of Egregious Violations. HCFA will work with the HHS Inspector General and the Department of Justice to ensure that state survey agencies and others refer appropriate cases to DOJ for prosecution under federal civil and criminal statutes, particularly cases that result in harm to individual patients. The OIG will also work with HCFA to conduct training for and provide technical assistance to Federal survey and certification staff and HCFA contractors on how to make appropriate referrals to the OIG.

Publishing Survey Results on the Internet. Individual **nursing** home survey results and violation records will be posted on the Internet to increase accountability and flag repeat offenders for families and the public.

Continuing Development of Minimum Data Sets. In June 1998, HCFA began collecting information on resident care through a national automated data system, known as a Minimum Data Set. This information will be analyzed over time, to identify potential areas of unacceptable care in **nursing homes**. HCFA will eventually use this data to assess **nursing** home performance in such areas as avoidable bed sores, loss of mobility, weight loss and use of restraints. This assessment will help HCFA and state surveyors better identify **nursing homes** for immediate onsite inspections, detect and correct systematic problems early, and ultimately help **nursing homes** improve quality.

New Legislative Actions

In addition to the administrative steps described above, the Administration will ask Congress to help improve **nursing** home care and safety in the following ways:

Criminal Background Checks. Ask Congress to establish a national registry of **nursing** home employees convicted of abusing residents and to require **nursing homes** to conduct criminal background checks on all potential personnel.

Nutrition and Hydration Therapy. Ask Congress to allow more types of **nursing** home employees, with proper training, to perform crucial nutrition and hydration functions.

Nursing Home Ombudsman Program. Ask Congress to reauthorize a strong long term ombudsman program through the Older Americans Act, administered by the Administration on Aging. Ombudsmen are an excellent source of information about poor-quality **nursing homes** and abuse or neglect of patients.

User Fees. In the President's FY 1999 Budget, HCFA requested legislation to collect a fee from Medicare providers and suppliers requesting participation in Medicare both for initial surveys and for recertification surveys. Under this proposal, HCFA would establish fee amounts that reflect the unit cost of a survey and the appropriate and reasonable costs incurred by State survey agencies for fee collection and associated activities. The fee amount would vary by state, since survey costs also vary by state. The user fee amount will include the Federal government's costs as well as those of the States. The fees received from this activity would be credited to HCFA's program management appropriation. The fee for initial surveys will be payable by the entity at the time of the survey. Fees for recertifications shall be deducted from amounts otherwise payable from a Trust fund to such entity.

Public vs. Private Accreditation

Finally, at Congress' request, the HCFA report also evaluated whether private accreditation of **nursing homes** would be preferable to the current system of public accreditation. HCFA secured an independent evaluation by Abt Associates, to assist in preparation of that portion of the report. The report concludes that the private Joint Commission on Accreditation of Healthcare Organizations (JCAHO) survey process was not effective in protecting the health and safety of **nursing** home residents. According to Abt Associates, granting "deeming" authority to JCAHO would place **nursing** home residents at serious risk. For example, in more than half of 179 cases where both HCFA and JCAHO conducted inspections of the same **nursing homes**, JCAHO failed to detect serious problems identified by HCFA.

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STATEMENT OF
MICHAEL HASH
DEPUTY ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION

BEFORE THE
SENATE SPECIAL COMMITTEE ON AGING
ON NURSING HOME QUALITY

JULY 28, 1998

Senator Grassley, Senator Breaux, Committee members, thank you for inviting us to discuss the need to strengthen assurances that Americans in nursing homes receive high quality care and are treated with dignity and compassion. Clearly, intolerable situations have occurred, and our most vulnerable citizens have suffered.

As the President announced last week, we are taking strong new steps to address what both our own Report to Congress and the General Accounting Office investigation make clear is a serious problem. We can and we will implement many of these new actions on our own now. We also need Congress to give us legislative authority for some additional provisions that will help ensure that we can meet our obligation to protect the very vulnerable Americans who need nursing home care. We want to work with you to make sure that all of these important steps are taken quickly and effectively.

Since 1995, the Administration has been enforcing the toughest nursing home regulations in the history of the Medicare and Medicaid programs. Working with states, who have the primary responsibility for conducting on-site inspections and recommending sanctions, we have sharply increased the number of penalties levied on poor-quality nursing homes. Our new Report to Congress notes improvements in the quality of care delivered in nursing homes as a result of these new regulations. But the report also finds a need for further improvement by states, nursing homes, the federal government, and others.

In our new initiative, we will:

work with states to improve their nursing home inspection systems;

crack down on nursing homes that repeatedly violate safety rules;

require criminal background checks on all new nursing home employees;

focus on reducing the incidence of bed sores, dehydration, and malnutrition; and

publish nursing home quality ratings on the Internet.

BACKGROUND

About 1.6 million elderly and disabled people receive care in approximately 16,800 nursing homes across the United States. The federal government, through the Medicare and Medicaid programs, provides funding to the states to conduct on-site inspections of nursing homes participating in Medicare and Medicaid and to recommend sanctions against those homes that are violating health and safety rules. Since 1995, we have had authority to levy harsher penalties on nursing homes found out of compliance with those rules.

That authority was granted to us through the Omnibus Budget Reconciliation Act of 1987, which reformed the way states and the federal government oversee nursing homes and protect the health of residents. The legislation established new standards for quality, a set of resident rights, a new system to assess the quality of nursing home residents' lives, and a new survey mechanism focused on patient outcomes. The law also created new staffing requirements for licensed nurses and new training

requirements for nursing assistants and others. And it established new, more flexible enforcement rules and penalties to help identify and punish nursing homes that violate the new rules. On July 1, 1995, the Clinton Administration published new regulations implementing key provisions of the law. Under these regulations, the number of civil monetary penalties rose from zero in 1994 to 430 in FY 1997.

The enforcement system under these regulations focused on giving facilities a chance to correct problems and avoid sanctions. There are many instances in which better care has been the result. However, even when sanctions have been imposed, facilities with serious problems often improve only temporarily, and subsequent surveys find residents in real danger once again.

EVIDENCE OF IMPROVEMENT

According to the new Report to Congress, there is clear evidence that the new regulations are improving the health and safety of nursing home residents. Specifically:

overuse of anti-psychotics is down. Before reforms were implemented, about 33 percent of residents were receiving these drugs, now just 16 percent are;

appropriate use of antidepressants is up. Before reforms were implemented, just 12.6 percent of residents were receiving these drugs, now 24.9 percent are;

use of physical restraints is down, from about 38 percent to under 15 percent;

use of indwelling urinary catheters is down nearly 30 percent; and

the number of residents with hearing problems who receive hearing aids is up 30 percent.

NEED FOR FURTHER ACTION

Despite these improvements attributable to the new regulations, the Report to Congress makes clear that several areas require greater attention.

State-run nursing home inspections are too predictable. Inspection teams frequently appear on Monday mornings and rarely visit on weekends or during evening hours. This allows nursing homes to prepare for inspections.

Several states have rarely cited nursing homes for substandard care, an indication that their inspections and enforcement may be inadequate.

Nursing home residents continue to suffer unnecessarily from such clinical problems as bed sores (decubitus ulcers), malnutrition, and dehydration, which are easily prevented .

Residents continue to experience physical and verbal abuse, neglect, and misappropriation of their property.

NEW ENFORCEMENT ACTIONS

Because of these continuing problems, we are adding new enforcement tools and strengthening federal oversight of nursing home quality and safety standards. Resource needs for these activities are reflected in the fiscal year 1999 budget request currently before the Congress. Our strategy includes several administrative actions that we will implement now using our existing authority. It also includes additional steps that require new legislative authority from Congress.

Our administrative steps will target states with weak inspections. As President Clinton said last week, "If state enforcement agencies don't do enough to monitor nursing home quality, we will cut off their contracts and find someone else who will do the job right."

We will establish tougher inspections everywhere, focus on easily preventable problems like bed sores

and malnutrition, combat resident abuse, increase prosecution of egregious violations, publish survey results on the Internet, and continue development of our automated data system to better identify problems and improve quality.

Target States with Weak Inspection Systems.

We will provide additional training and other assistance to inspectors in states that are not adequately protecting residents.

We will enhance federal review of the surveys conducted by the states. Standard evaluation protocols will be implemented in every state this fall.

We will ensure that state surveyors adhere to HCFA's policy to sanction nursing homes with serious violations and prohibit sanctions from being lifted until after an onsite visit has verified compliance.

We will terminate federal funding for nursing home surveys for states that fail to adequately perform survey functions or fail to improve inadequate survey systems, and instead contract with other entities to conduct nursing home survey and certification activities in those states.

Tougher Nursing Home Inspections.

We will impose sanctions without a "grace period" for second offenses involving violations that harm residents; until now even serious repeat offenders have been given a chance to correct problems and avoid penalties.

We will not lift sanctions for serious violations until state inspectors conduct an on-site visit to verify that the problem is fixed.

We will have state surveyors conduct inspections more often for repeat offenders with serious violations, without decreasing inspection frequency for other facilities.

We will have state surveyors stagger survey times for all facilities, with a set amount to be done on weekends and evenings.

We will focus on nursing home chains that have a record of noncompliance with federal rules.

Preventing Bed Sores, Dehydration, and Malnutrition.

We will step up review of nursing homes' performance in preventing bed sores, dehydration, and malnutrition by increasing resident case reviews in these specific areas during the survey.

We will sanction nursing homes with patterns of violations.

We will develop a repository of best practice guidelines for residents at risk of weight loss and dehydration with the Administration on Aging, the American Dietitians Association, clinicians, consumers, and nursing homes.

Combating Resident Abuse.

We will have state inspectors review each nursing home's system to prevent, identify, and stop physical or verbal abuse, neglect, and misappropriation of resident property.

We will share information about each nursing home=s performance in this area with residents and their families.

We will recommend that nursing homes inquire about criminal convictions when interviewing applicants for employment.

Prosecution of Egregious Violations.

We will work with the HHS Inspector General and the Department of Justice to ensure that state survey agencies and others refer appropriate cases to DOJ and/or the OIG where appropriate, for prosecution under federal civil and criminal statutes, particularly cases that result in harm to individual patients.

We will work with the HHS Inspector General to conduct training for and provide technical assistance to federal survey and certification staff and HCFA contractors on how to make appropriate referrals of such cases to the Inspector General.

Publishing Survey Results on the Internet.

We will post individual nursing home survey results and violation records on the Internet to increase accountability and flag repeat offenders, as well as superior performers, for both families and the public.

Continuing Development of Minimum Data Sets.

We will continue development of our national automated data system for information on resident care. We began collecting information on what is known as a Minimum Data Set in June 1998.

We will analyze this information over time to identify potential areas of unacceptable care in nursing homes, and use it to assess nursing home performance in such areas as avoidable bed sores, loss of mobility, weight loss and use of restraints.

We will use these assessments to better identify nursing homes for immediate onsite inspections, detect and correct systematic problems early, and improve nursing home quality.

NEW LEGISLATIVE ACTIONS

In addition to the administrative steps described above, we are asking Congress to provide needed authority for several additional actions to help improve nursing home care and safety.

Criminal Background Checks. We need authority to establish a national registry of nursing home employees convicted of abusing residents and to require criminal background checks on all newly hired personnel.

Nutrition and Hydration Therapy. We need to abe able to allow more types of nursing home employees, with proper training, to perform crucial nutrition and hydration functions.

PENDING LEGISLATION

Nursing Home Ombudsman Program. We need Congress to reauthorize a strong nursing home ombudsman program through the U.S. Administration on Aging. Ombudsmen are an excellent source of information about poor-quality nursing homes and abuse or neglect of patients.

User Fees. We need authority, as requested in our FY 1999 budget proposal, to collect a fee from Medicare providers and suppliers requesting participation in Medicare both for initial surveys and for recertification surveys. Fee amounts will reflect the unit cost of a survey and the costs incurred by both state and the federal government to administer the program. The amounts will vary by state, since survey costs vary by state. The fees will be credited to our program management appropriation, with fees for initial surveys paid by each nursing homes when it is surveyed, and fees for recertifications deducted from payments to the nursing home.

PUBLIC VS. PRIVATE ACCREDITATION

Finally, at Congress' request, we also evaluated how private accreditation of nursing homes compares to the current system. We secured an independent evaluation by Abt Associates to assist in that portion of the report. The report concludes that the private Joint Commission on Accreditation of Healthcare

Organizations (JCAHO) survey process is not effective in protecting nursing home residents. JCAHO surveys focuses on structure and process measures, not on whether residents actually get appropriate care. JCAHO surveyors repeatedly miss instances where residents suffer actual harm because of inadequate care. In more than half of 179 cases where both HCFA and JCAHO conducted inspections of the same nursing homes, JCAHO failed to detect serious problems identified by HCFA. Also, the public does not have access to JCAHO survey findings. According to Abt Associates, granting "deeming" authority to JCAHO would place nursing home residents at serious risk. While we have concluded in this report that JCAHO's current approach to the survey process is unacceptable, we would be willing to consider a public/private partnership that would help us target our survey and enforcement efforts on poor performers.

CONCLUSION

We have made some progress in addressing the deplorable conditions and heart wrenching human consequences in America's nursing homes, but clearly we must do more to assure that Americans in nursing homes receive high quality care and are treated with dignity and compassion. The parallel findings of our Report to Congress and General Accounting Office investigation are a clear call to action. Testimony at this hearing underscores the urgency to act now. We must and we will address weaknesses in state survey and enforcement activities. We will strengthen federal oversight. And we will work with Congress to secure authority for additional steps needed to ensure that we at HCFA meet our responsibility for ensuring the quality of nursing home care.


Return to Testimony Listing

Last Updated August 6, 1998

- ~~Harrington~~ study
- spending on survey & cert use of ____.

continuing concerns

Date: July 21, 1998
WHITE HOUSE FACT SHEET
Contact: HHS Press Office

PRESIDENT CLINTON ANNOUNCES INITIATIVE TO IMPROVE THE QUALITY OF NURSING HOMES

Today, President Clinton announced tough new legislative and administrative actions to improve the quality of nursing homes. These actions include: ensuring swift and strong penalties for nursing homes failing to comply with standards, strengthening oversight of state enforcement mechanisms, developing a national registry to track and identify individuals with a record of abusing residents, and implementing unprecedented efforts to improve nutrition and prevent bed sores.

Background on Nursing Homes. About 1.6 million older Americans and people with disabilities receive care in approximately 16,700 nursing homes. Since the Health Care Financing Administration (HCFA) put new regulations in place in 1995, the health and safety of nursing homes has improved. For example, the inappropriate use of physical restraints has been cut by more than half and the number of nursing home residents receiving hearing aids is up 30 percent. But HCFA's ongoing review, as well as the report that HHS is transmitting to Congress today, shows that tougher enforcement is needed to ensure high quality care in all nursing homes. In response, the President is announcing a tough new initiative to crack down on poor quality nursing homes and ensure high quality care.

The President Is Sending Legislation to Congress This Week That Calls for:

New Criminal Background Checks. An important way to improve the quality of nursing homes is to prevent personnel who have a criminal record from entering the system in the first place. The legislation the President is proposing would require nursing homes to conduct criminal background checks on all potential personnel.

National Abuse Registry. Once inadequate personnel have been identified, they should be kept out of the system for good. The new legislation would establish a national registry of nursing home employees convicted of abusing residents.

Improved Nutrition and Hydration. Currently, too few nursing home staff are available to help feed residents. To improve nutrition in nursing homes, this legislation would allow more categories of nursing home employees to receive training in and then to perform crucial nutrition and hydration functions.

Reauthorization of the Nursing Home Ombudsman Program. The President also called on Congress to reauthorize the nursing home ombudsman program run by the Administration on **Aging**, which provides consumers with critical information on poor-quality nursing homes, including records of abuse and neglect.

The President Also Announced New Administrative Actions To Improve the Quality of Nursing Homes. Today, the President announced a series of new penalties, new inspections, and tougher oversight that HCFA will implement immediately, including:

Immediate Civil Monetary Penalties on Nursing Homes That Violate Federal Standards. To crack down on inadequate providers, HCFA will direct enforcement authorities to impose civil monetary penalties immediately upon finding that a nursing home has committed a serious or chronic violation. Under current practice, enforcement officials often give nursing homes numerous opportunities to come into compliance, rather than imposing immediate sanctions.

Tougher Nursing Home Inspections. Starting today, HCFA will take several steps to strengthen states' inspection of nursing homes, such as:

- **Staggering survey times:** The report that HCFA is transmitting to Congress finds that nursing home inspections are too predictable, allowing inadequate nursing homes to prepare for inspections. Enforcement officials will now stagger survey times and conduct some surveys on weekends and evenings.

- **Targeting chains with bad records:** Federal and State officials will target nursing home chains that have a poor record of compliance with quality standards, to ensure these nursing homes receive frequent inspections.

- **Prosecuting egregious violations:** HCFA also will work with the HHS Office of Inspector General and Department of Justice to refer egregious violations of quality of care standards for criminal or civil investigation and prosecution when appropriate.

Stronger Federal Oversight of State Nursing Home Enforcement Mechanisms. HCFA will increase its oversight of state surveyors and take new tough actions against states that are failing to enforce standards adequately. It will:

- **Terminate Federal nursing home inspection funding to states with continual poor records.** The report being released by HCFA finds that some states have cited few or no nursing homes for substandard care. In states where oversight is clearly inadequate, HCFA will terminate state contracts and contract with other entities to conduct Federally-required inspections.

- **Increase oversight of state inspections.** HCFA will increase its review of the surveys conducted by the states to ensure thorough oversight, as well as provide additional training and assistance to state enforcement officials.

- **Ensure that nursing homes are in compliance with standards before lifting sanctions.** HCFA will increase oversight of state enforcement officials to ensure that they will not lift sanctions until after an on-site visit has verified compliance.

Preventing Bed Sores, Dehydration, and Malnutrition. HCFA will implement new oversight to ensure that nursing homes take actions to prevent bed sores, dehydration, and malnutrition. State surveyors will be required to monitor these activities and to sanction nursing homes with patterns of violations. HCFA also will work with the Administration on **Aging**, the American Dieticians Association, clinicians, consumers, and nursing homes to develop best practice guidelines to prevent malnutrition, dehydration, and bedsores.

Publishing Survey Results on the Internet. To increase accountability and flag repeat offenders for families and the public, HCFA will, for the first time, post individual nursing home survey results on the Internet.

Implementing New Efforts to Measure and Monitor Nursing Home Quality. In June 1998, HCFA began collecting information on resident care through a national automated data system, known as the Minimum Data Set. This information will be analyzed to identify potential areas of inadequate care in nursing homes and to assess performance in critical areas, such as nutrition, avoidable bed sores, loss of mobility, and use of restraints. This assessment will help HCFA and state surveyors to conduct thorough evaluations of nursing homes and detect problems early.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release July 21, 1998

PRESIDENT CLINTON ANNOUNCES INITIATIVE TO IMPROVE THE QUALITY OF NURSING HOMES

July 21, 1998

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-- Staggering survey times: The report that HCFA is transmitting to Congress finds that nursing home inspections are too predictable, allowing inadequate nursing homes to prepare for inspections. Enforcement officials will now stagger survey times and conduct some surveys on weekends and evenings.

-- Targeting chains with bad records: Federal and State officials will target nursing home chains that have a poor record of compliance with quality standards, to ensure these nursing homes receive frequent inspections.

-- Prosecuting egregious violations: HCFA also will work with the HHS Office of Inspector General and Department of Justice to refer egregious violations of quality of care standards for criminal or civil investigation and prosecution when appropriate.

Stronger Federal Oversight of State Nursing Home Enforcement Mechanisms. HCFA will increase its oversight of state surveyors and take new tough actions against states that are failing to enforce standards adequately. It will:

-- Terminate Federal nursing home inspection funding to states with continual poor records. The report being released by HCFA finds that some states have cited few or no nursing homes for substandard care. In states where oversight is clearly inadequate, HCFA will terminate state contracts and contract with other entities to conduct Federally-required inspections.

-- Increase oversight of state inspections. HCFA will increase its review of the surveys conducted by the states to ensure thorough oversight, as well as provide additional training and assistance to state enforcement officials.

-- Ensure that nursing homes are in compliance with standards before lifting sanctions. HCFA will increase oversight of state enforcement officials to ensure that they will not lift sanctions until after an on-site visit has verified compliance.

Preventing Bed Sores, Dehydration, and Malnutrition. HCFA will implement new oversight to ensure that nursing homes take actions to prevent bed sores, dehydration, and malnutrition. State surveyors will be required to monitor these activities and to sanction nursing homes with patterns of violations. HCFA also will work with the Administration on Aging, the American Dieticians Association, clinicians, consumers, and nursing homes to develop best practice guidelines to prevent malnutrition, dehydration, and bedsores.

Publishing Survey Results on the Internet. To increase accountability and flag repeat offenders for families and the public, HCFA will, for the first time, post individual nursing home survey results on the Internet.

Implementing New Efforts to Measure and Monitor Nursing Home Quality. In June 1998, HCFA began collecting information on resident care through a national automated data system, known as the Minimum Data Set. This information will be analyzed to identify potential areas of inadequate care in nursing homes and to assess performance in critical areas, such as nutrition, avoidable bed sores, loss of mobility, and use of restraints. This assessment will help HCFA and state surveyors to conduct thorough evaluations of nursing homes and detect problems early.

Speaking Order:
Secretary Shalala
President Clinton

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release July 21, 1998

PRESS BRIEFING
BY
SECRETARY OF HEALTH AND HUMAN SERVICES DONNA SHALALA
AND
HEALTH CARE FINANCE ADMINISTRATOR NANCY ANN DEPARLE

The Briefing Room

1:10 P.M. EDT

MR. TOIV: Good afternoon. A reminder -- this is an embargoed briefing. This briefing is embargoed until 3:00 p.m.

Q It better be a blockbuster. (Laughter.)

MR. TOIV: Oh, it will be, Helen. It will be. As you all know, the President will be making some announcements today with respect to nursing homes. And here to brief on the announcement are the Secretary of Health and Human Services Donna Shalala, and the Administrator of the Health Care Financing Administration Nancy Ann DeParle.

SECRETARY SHALALA: Good afternoon. Actually, after what Helen said, let me start with a story about my mother, who is 86 and a full-time attorney and represents a number of clients who are in nursing homes. And she regularly says, Donna, I don't care whether they're good nursing homes or bad nursing homes, you have to watch them like a hawk. That's our message for today.

Later this afternoon the President will announce a very strong new initiative to further protect the health and safety of people in nursing homes. One point six Americans are in nursing homes today, so it's important that Congress acts quickly. And some of our recommendations to the President are administrative that we're going to put in place ourselves, that we have the authority to do under existing law, and others require new legislation.

98And it's very important for our future and let me give you one statistic. By the year 2000 the number of elderly Americans in this country will exceed the number of children for the first time in American history. And the number of Americans over the age of 85, those most likely to need nursing home care, will double by the year 2030. So nursing homes are a critical part of our health care system and the quality of them is important to every family in this country.

Our new initiative builds on a very strong record that we now have made, making sure that those who get long-term care get high-quality care. In 1995, over the objections of many people in the nursing home industry and in Congress, we adopted the toughest measures in history to monitor and enforce nursing home quality standards. You remember, in the late 1980s there were nursing home scandals; Congress enacted a law. That law languished until the beginning of the Clinton administration. We wrote the regulations based on that law and asserted the federal oversight over the nursing

home industry in the strongest set of regulations ever proposed.

We have aggressively enforced those regulations, but continue to monitor the system. And when we announce those regulations, we said we were putting an ongoing evaluation system in place, and that, unlike other kinds of regulations and other things the government does, we are not simply going to lock a set of regulations in stone, we were going to design a system so we would continuously improve the regulations.

This is the first shot that we've had at taking the basic regulations that we've put in place and to make a series of regulations based on experience, not based on theory, but based on experience to improve those regulations in our oversight.

The initiative that the President is going to announce today strengthens the health care financing administration's enforcement and oversight. Nancy DeParle is going to give you the details, but let me give you some examples of it. We intend to improve the state's ability to carry out their responsibility to conduct on-site inspections. The federal government does the regulations; the states basically administer and do the inspections of nursing homes. It is a state employee that's basically walking in to a nursing home to inspect them.

But let me give you some examples of things that we've found that we need to change. We found that the inspections are too predictable. If you were inspected on Monday a year ago, the chances are pretty good that you're going to be inspected a year later on a Monday. There are almost no inspections -- and the inspections are supposed to be a surprise, but the way in which some states have designed their systems, they inspect every year but they tend not to vary the time or the date every year. So what we have said is you've got to do it on weekends, you've got to do it in the evenings, and you've got to have a much more random system so people are genuinely surprised. So we're directing the states to conduct more inspections at night and on weekends and vary clearly the day of the week when they're inspecting so someone can't anticipate this is the week in which a state inspector is going to walk in.

We have new incentives for nursing homes to fix their problems early rather than waiting to be caught and penalized. And Nancy Ann is going to talk about these penalties being imposed faster so that they are, in fact, an incentive to fix something, as opposed to waiting until the end of the time and then fixing whatever needs to be fixed.

Again let me say that all of this comes out of a huge report that we've sent to Congress. It's 900 pages long. We didn't think you'd want to see every page of it, but we will detail our findings. Let me also say that the report also indicates that we have reduced many problems that we saw in nursing homes in the 1980s, out of the new regulations. So what we're fixing is things that weren't fixed in the original regulations or things we've learned. In this case, all of our recommendations are based on practical experience in the field and the result of a series of public sessions that Nancy * conducted to listen to what people who have patients in nursing homes, people who are working with nursing home patients say about how our regulations are working.

I've noted already that we're sending a report to Congress on a number of issues. On the final issue, the Congress asked us to do an experiment to test whether private accreditation would be better than basically the old-fashioned way in which we do inspections -- having a state inspector walk into a nursing home. So

we did, in fact, have the private accreditation agency walk in and took a look at their report and had a state inspector also walk in and took a look at his or her report. We have concluded that private accreditation organizations would actually put nursing home residents in jeopardy. They are not tough enough, they miss a lot of things, and we are telling Congress formally now that we will not allow private accreditation agencies to substitute for state reviews of the nursing homes. We've learned a lot out of that experience, we put no one in jeopardy at the same time, but at least the myth that a private accreditation system could substitute for state -- for well-trained state inspectors is now over with and we're making a recommendation to Congress in that area.

Now, let me introduce my colleague to walk you through the pieces of paper. If you don't have the pieces of paper, we'll get them to you.

Q -- in Congress to implement that last point you made?

SECRETARY SHALALA: I think Congress just needed a recommendation from me. They wanted us to test whether private accreditation agencies could substitute for state inspectors. We tested it, and our answer is, no, they cannot, they miss too much, and they actually put nursing home residents in jeopardy.

Q Well, any such private agencies operating today, which are now saying cannot in the future?

SECRETARY SHALALA: No, this is the private accreditation agency for nursing homes. We are saying that we tried that experiment and we are concluding, based on that experience, that we should continue with well-trained state inspectors.

Let me have Nancy Ann lead you through all the detail.

Q You'll come back to questions?

SECRETARY SHALALA: Yes, absolutely.

MS. DEPARLE: What I'll do is just walk through the initiatives.

Q You know as much as she knows about this. You're just allowing her to move into the sun.

SECRETARY SHALALA: That's right, Sam.

MS. DEPARLE: That's exactly right. That's exactly right.

We're here today because we're submitting a report to Congress on nursing home care and the status of it right now. We were specifically asked by the appropriators in 1996 to look at the issue of whether or not we should allow private accreditation agencies to basically take over the function that the federal government and the states had been performing and what -- we hired an outside consultant to look into that.

As the Secretary said, we have a voluminous report that we're submitting today. The answer to that question is decidedly no. In fact, the outside consultant found -- and we agreed with this finding -- that granting what's called "deeming authority" to an outside group would, in fact, place nursing home residents at a serious risk.

We went on, as part of the report, to look at and evaluate, as the Secretary said, what the current status of our enforcement and the state's enforcement efforts were. And we found that there have been some improvements since the law was enacted and since we put out the toughest regulations ever in 1995, but that we needed to do more to improve our efforts. And we're going to do that and that's what we're announcing today.

A few of the items do require congressional action, but most of them do not. Most of them are things that we can do ourselves. And I'm just going to walk through them quickly. They mainly fall in two main categories. One is stronger enforcement actions and the other is stronger federal oversight.

We are going to toughen the enforcement of nursing home safety and quality regulations by first ensuring that nursing homes found guilty of a second offense for violations that cause harm to residents will have sanctions imposed and will not receive a grace period that allows them to correct problems and avoid penalties. That is a situation that we found in our own evaluation and that we needed to tighten up the definition of what is called a poor performer so that, in cases where there is harm to residents, that they will get immediate sanctions. We think that immediate sanctions will give the nursing homes the incentive that they need to comply in the first place and that's what we want to do.

SECRETARY SHALALA: -- financial sanctions.

MS. DEPARLE: Exactly.

SECRETARY SHALALA: It's going to cost them money.

Q They'll get the message.

MS. DEPARLE: Secondly, we're going to permit states -- well, there's a range of sanctions which can include telling them that they can't admit anymore Medicare or Medicaid residents, which is quite a lot. We're spending right now around $30 billion annually in the Medicare and Medicaid programs, paying for nursing home care. So that gives you some idea. There are 17,000 nursing homes, that gives you some idea of the kind of funds that are at stake here.

We will also permit states to impose civil monetary penalties for each instance of a serious or chronic violation. In the past, these penalties have been linked to the number of days a facility was out of compliance and from what we've seen and from our experience, this has allowed some of the facilities to get away with going on longer without correcting problems that could harm residents.

We are going to require states to conduct nursing home inspections more frequently for repeat offenders with serious violations. As the Secretary said, we're going to stagger nursing home inspection times and have a set proportion of them that have to be done on the evenings and weekends, and that was something that we heard repeatedly from meeting with residents and from talking to actually people who run nursing homes, that there is a lot of predictability in the way that states do their surveys now about when they're going to be showing up and in some areas, they can even tell by who has checked into the local hotel or motel. So we're trying to make sure that we're there at times when residents are likely to be maybe not being watched as closely as they should be.

We're also going to focus enforcement efforts on chains,

nursing home chains that have a history of poor performance and noncompliance with federal rules. We are going to impose stronger federal oversight, and that means, first of all, that we'll provide additional training to inspectors in states that aren't adequately protecting residents, but secondly if a state isn't able to improve its operations and do a better job, we will remove their funding to conduct the survey and certification program, and we will contract with other entities to perform these survey and certification activities of nursing homes in those states. So that is something that we have not done before.

We're going to step up our review of a few areas of patient care that we found particularly troubling, and those are: the incidents of bed sores, dehydration and malnutrition, all of which can be prevented through proper care. The way we're going to do that is in several ways. One is that we are going to change our sampling methodology so that we're able to focus more in, in the surveys on these areas and make sure that we're finding those deficiencies and that the nursing homes are being appropriately fined or sanctioned if there are deficiencies. We're also going to work with the Administration on Aging and the American Dietetics Association and clinicians to develop a repository of best practices for residents at risk of weight loss and dehydration.

And we're going to ask Congress to give us the authority to allow more types of nursing home employees with the proper training to perform crucial nutrition and hydration functions.

We are going to change the survey in another way, to require the inspectors to look at each nursing home system to prevent, identify and stop physical and verbal abuse and neglect. That hasn't been a part of the surveys in the past. We're going to require each nursing home to have its abuse prevention plan and present it and give it to the residents and families, so that they know what the plan is at that agency.

And we're also going to ask Congress for the authority to establish a national registry of nursing home employees who have been convicted of abusing residents. And we'll require nursing homes to conduct criminal background checks on all potential personnel.

We will also be working with the HHS Inspector General and the Department of Justice to ensure that state survey agencies and others -- and HCFA -- are making referrals of appropriate cases to the Department of Justice for prosecution under federal, civil and criminal statutes. Some of you may be familiar with the case in Pennsylvania that was prosecuted in the past year.

We will be publishing for the first time ever nursing home survey results and violation records on the Internet. Right now, under current law, the nursing homes are required -- if you go in a nursing home, they're required to post the results of their last survey. I was just in one yesterday and sometimes it can be rather elliptical. That won't be the case anymore because we'll be putting it on the Internet so that families will be able to see not only the results of the nursing home that their loved one might be in, but also the results of other nursing homes in the area. And we think it will help them to be better consumers.

And we are continuing development of some of the things that we started several years ago. One particular item is called the minimum data set which is a national automated data system which will give us more information that will help us improve our surveys, I think.

Finally, I've mentioned two areas we're going to ask Congress to help us in: the national registry of nursing home employees convicted of abusing residents and in allowing more types of nursing home employees, with proper training, to help with nutrition and hydration. The final thing we're going to ask for their help in -- and I think the Secretary mentioned this -- is on the Administration on Aging Ombudsman's Act, the Older Americans Act. That act needs to be reauthorized this year. The ombudsman has been a crucial source of assistance to nursing home residents and to the surveyors and to us in finding out what's really going on in nursing homes. And we think it's essential that a strong ombudsman program be reauthorized and continued.

SECRETARY SHALALA: I think the summary is we're going to be quicker, tougher, more transparent so the public has more information about what's going on. I should emphasize, too, and the report reveals this, that a lot of things have been cleaned up -- the stories about people in restraints, for instance. We found much less incidents of people being put inappropriately in restraints, much less misuse of drugs, for example. So some things out of the first set of tough regulations have been cleaned up. What we're doing with the second set of recommendation is tightening up on the basis of what we've learned over the last three years.

Q When you released the regs in '94 you introduced this concept of substantial compliance, and I think a year later you had reported that a surprisingly low number of nursing homes were, in fact, in substantial compliance with the regs. Where does that stand now? How many nursing homes are in compliance with the regs?

MS. DEPARLE: I believe it's improved, but the important thing that we're talking about today is that we're going to tighten up and, in fact, expand the definition of poor performer, so that more nursing homes that are out of compliance get immediate sanctions. And we thing that by imposing a regime of immediate sanctions they will have a greater incentive to be in compliance in the first place. So we think we're making improvements in that.

Q What's it going to take to be tagged as a poor performer?

MS. DEPARLE: It will take having any incident of actual harm at the current survey, plus it's basically a second offense. In the past it's been that you had to be classified as a substandard provider -- substandard care. And that was a much tougher standard to reach.

Q How many nursing homes are poor performers now and how many are in compliance with the regulations?

MS. DEPARLE: One reason why we're making this change is because in our experience, very few of the facilities were being classified as poor performers --

SECRETARY SHALALA: By the states.

MS. DEPARLE: And it did not comport with what we understood and from our own evaluation thought was going on out there. So this will significantly increase the number of poor performers that we believe are out there and that will --

Q So how many do you have now and how many would you anticipate having under the new system?

MS. DEPARLE: I don't know the exact number, but I think

the number of poor performers was around 1 percent of the nursing homes. And my understanding is this will double or triple it.

Q What are family members going to be able to learn by going on the Internet, and how soon do you expect to have that up, and how comprehensive is it going to be?

MS. DEPARLE: My goal is to have it up by the end of the year, and it will have the entire survey result on it, so it will be very comprehensive. And what they will learn --

Q What's the entire --

MS. DEPARLE: Well, it's a number of pages, and what they will learn from it, I hope, is that it goes into patient care in a number of different domains -- nutrition, are there rodents in the place, are people getting enough food, are there incidents of bedsores.

SECRETARY SHALALA: It will have a front piece on it that will help people to understand what they're reading, but it will be as clear and transparent as we can possibly make it so that people understand what kind of sanctions and how quickly that nursing home has responded.

Q Can you respond to critics who say that you convened this press conference today in advance of Senator Grassley releasing a report from the GAO that took a look at HCFA and actually found -- it is supposedly supposed to be a very scathing report of how HCFA has dealt with nursing homes.

SECRETARY SHALALA: First of all, this 900-page report, which is ready now we've been working on since December, I guess, when you --

MS. DEPARLE: Well, it's actually been over a year.

SECRETARY SHALALA: The consultants started a year ago, so we -- number one, this report is more comprehensive, covers more areas, including more areas of criticism and has a full response from the department. We have seen the first draft of the GAO report, and we'll be at the hearing responding. But what you will see in our response to our own report is that we'll have covered those areas plus considerably more, because we've done ongoing evaluation and expected to have a series of recommendations.

We are not surprised, after putting the first set of regulations in place, that we now have to improve upon them. That was part of the strategy. And it's a very different way of managing major oversight roles. It's not just putting regs in places, as I said before, and then not coming back and taking a look at them; it's the assumption that we'll be making corrections all along, and that's the system that we designed from the beginning. It's also the system we announced at the time.

Q It's been reported that about a half dozen states have cited virtually no nursing homes for substandard quality of care. Can you tell us any of those states?

MS. DEPARLE: You know, I wouldn't want to do that because I might not get it right. I believe that New York is one of them. And I stated that the other day and someone said, well, it isn't none, it's almost none. It's certainly the case that there are about a half dozen states with virtually none. That is one of the things we're going to be looking at and working with the states on.

It is difficult to believe that there are no nursing homes who meet that standard in those states. The whole nature of the law and of these regulations and of what the Secretary and I are talking about today is continuous improvement. We're not going to be satisfied until we continue to move forward and make improvements here. And it's hard to believe that there are no nursing homes that are substandard in those states.

Q Following up on that, there was a question when the regulations went into effect as to whether the states had adequately trained their inspectors and whether they had enough inspectors to do that. Is that a part of this whole question --

SECRETARY SHALALA: There certainly are recommendations here on improving the training of state inspectors. And we have made recommendations over the years in terms of funding levels in these areas. So given what we've found, I'm not surprised that we're recommending now that we go back and do some additional training, but also be clearer and quicker in our response to problems that are identified and much more transparent.

Q What's the problem with the training, though -- I mean, what are the problems?

MS. DEPARLE: Well, we've done a lot of training since those initial regulations were put out. In fact, we do training almost every month with states and have through Picturetele, training that way, if not on the ground. And so I'm not sure there's as much a problem with that now as there is just in -- that we need to tighten up and sharpen our definitions and be clear with the states that they should be doing this kind of enforcement.

SECRETARY SHALALA: They certainly were better than the accreditation people.

Q Secretary Shalala, given these statistics that you cited at the top of the briefing about the aging, the baby boom generation, is the nursing home industry, as it's constituted now, going to be able to keep up with the challenges it's going to face for quality care and the kinds of care that you all are trying to enforce with these announcements today?

SECRETARY SHALALA: What we're saying today is for the part of long-term care that the nursing industry takes responsibility for. It must be a quality system. But we are not assuming that it's the nursing home industry that is going to solve the long-term care problem in the United States. That requires a much more sophisticated system that includes alternative living arrangements, home care. And the administration is in the process -- in fact, we're in the process of doing an internal review of a long-term care strategy in which nursing homes certainly are a part.

The issue here is quality, and we're not willing to put up with a bunch of outlayers that aren't in a quality system, and we're not willing to put up with any slowness in correcting problems in this new set of regulations that we're putting in place.

Q A related question. Are you planning at this point to apply these regulations to any other form of long-term care such as assisted living? Or are you looking into that at all?

MS. DEPARLE: We don't really regulate assisted living. The federal government --

Q That's something you're not considering at all right now?

MS. DEPARLE: Not at this point.

SECRETARY SHALALA: Yes.

Q You said that you are going to increase federal oversights of state inspectors with the possibility I gather of taking away their ability to inspect. Who would do it, if not the state? And can you give us some examples?

SECRETARY SHALALA: We would have to contract out -- it could be another state, for example -- but we would have to contract out for that service. If a state demonstrated that it could not fulfill this function, we would have to contract out with another state, with a private contractor that had well-trained personnel, but it would have to be an alternative that put a system in place pretty quickly.

Q And are the states that have virtually no nursing homes cited as substandard -- are those the states at risk of having this happen to them?

MS. DEPARLE: Well, as I said, that's something that we want to look at, but there are also situations that we found in our evaluation where in some states, the people were changing the surveyors' results to make a nursing home look better.

Q People like state inspectors, or who?

MS. DEPARLE: Other people in the hierarchy. That's something that I also want to take a look at. So I don't want to say right now that I have in mind a certain kind of a state; I just know that this isn't working as well as it could, and we can do better and we're going to do that. Part of the responsibility lies with the states.

SECRETARY SHALALA: Let me also say that we have asked the Inspector General, working with the Health Care Financing Administration and the Justice Department to make sure that they are providing much more vigorous oversight, particularly at the multiple offenders in particular. So the law enforcement piece of this is a very critical piece.

But the whole message should be, we put tough regulations in place, they're not tough enough for the standards that this administration has, and we're going to add or change requirements so that we get the quality that we think the clients deserve.

Q HCFA announced a few weeks ago that it intended to delay some nursing home services because of the need to comply with the year 2000 problem.

MS. DEPARLE: Paula, what that was, was there was a requirement under the Balanced Budget Act that we implement a prospective payment system for skilled nursing facilities, which we did on June 1 of this year. There is one piece of that, that is not a service to residents, but it has to do with consolidated billing, which is just a way that they do their bills, and that involves some complicated systems changes that we are delaying until we finish our year 2000 computer renovation work. But it has nothing to do with resident care. And in fact, I think most of the nursing homes are glad to have the extra time to get their systems up and running.

Q Nancy, is Maryland -- are Maryland, Virginia or the District on this no problem list? And for the Secretary, if the federal government can --

MS. DEPARLE: I don't believe so.

Q If the federal government can contract out for these inspections, why are you telling the states they can't?

SECRETARY SHALALA: Because the law is written that basically says that if they're not in compliance, we have the authority to contract out. The law is not written in a way in which the state's could --

MS. DEPARLE: And importantly, if we contracted out it would be using our process. What I think our report and the associate's report today shows is that they went into 179 nursing homes in a number of states, and they had two duplicate processes going on: the inspection process of that state following the HCFA protocol and the deeming -- the joint-commission approach. And in more than half of the cases, the state inspectors found more serious problems than did the outside contractors. So if we were forced to do this -- which we don't want to do, we would prefer to have the state's doing the job that they need to do -- but if we were forced to do it, they would use our protocol.

SECRETARY SHALALA: We have every reason to believe that what we're going to put in place and what we're recommending to Congress will help the states to do their job better. There are a lot of frustrated people out there who would like to give a penalty faster to a second offender, who would like to make the system more transparent. And this is supportive of people that believe now, after seeing the effect of the first set of tough regulations, that we need some improvements.

Q This is a question on the statistics. The 1.6 million people you referred to at the outset, are those all over 65, or what's the breakdown?

SECRETARY SHALALA: No, they may be disabled, too, because the nursing homes in this country also have some disabled. But the vast majority are senior citizens. They may be severely disabled, too, because the Medicaid system covers both.

Q I believe most of the nursing homes in America are private, and how much money does the nursing home get for each patient?

MS. DEPARLE: I can't give you that number. I've said at the beginning the aggregate number is that for Medicare and Medicaid, the federal government spends around $30 billion a year on nursing home care, and that doesn't include the amount the states spend or the private-pay patients.

Q Can you give us a sense of the scope of the problem, what you anticipate you'll find? You mentioned dehydration and bed sores, but can you give us an idea of what you think will come of this greater enforcement?

SECRETARY SHALALA: Part of the point is to get the corrections faster. It's not that the corrections necessarily aren't being made, but that some nursing homes may be waiting until exactly the last legal moment. We think the corrections ought to be made immediately if they're serious enough so that someone identified

them. So that clearly is possible, and we've identified some things, including nutrition and bed sores that are related to the quality of care that we think we'll get some improvement on if we get a quicker turnaround.

Q Of the 1.6 million people in nursing homes, how many are there with the federal government paying their expenses?

MS. DEPARLE: I don't know the answer to that. I'll have to get back to you.

SECRETARY SHALALA: It's a pretty high percentage.

MS. DEPARLE: It's a very high percentage.

SECRETARY SHALALA: It's a very high percentage. And it's a particular high percentage of people over 85 that end up on Medicare. Because remember, if I can remind everybody, as we get older, we get poorer.

Thank you very much.

END 1:38 P.M. EDT

AGENDA
Nursing Home Initiative Status Report
December 9, 1998

I. Status of the Implementation of the Nursing Home Initiative

II. Status of the Department of Justice/HCFA Collaboration on the 22 Point Plan

III. Nursing Home Commission

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Office of the Administrator
Washington, D.C. 20201

NOV 16 1998

The Honorable Charles E. Grassley
Chairman
Senate Special Committee on Aging
Washington, D.C. 20510-6400

Dear Mr. Chairman:

I am responding to your letter of October 22 about our initiative to improve the quality of our nursing home care, and also updating you on the status of our efforts as of November 15. The nursing home initiative continues to be a top priority for HCFA, and I appreciate the support and leadership you have provided. I have addressed your comments in the October 22 letter in the order in which you raised them.

A1. Materials Provided

We have enclosed copies of the material you specifically requested, including the draft manual instructions that provide guidance to the States on the new Federal Monitoring System, and the August 20, 1998 memorandum to Regional Offices and States clarifying our revisit policy. The Health Care Financing Administration (HCFA) will continue to provide you with copies of any other material that is prepared in response to the nursing home initiative.

A2. Focused Enforcement

As I mentioned in my last update, our goal is to develop a fair and objective method of determining which facilities should be the focus of more intense scrutiny. HCFA developed a list of nursing homes that we proposed for focused enforcement to the States at the end of September. The States provided us with valuable comments on additional sources of data, e.g., the use of substantiated complaints, that we could use in selecting "special focus facilities." We continue to work with the State agencies to refine the methodology, and to select the nursing homes that should receive focused enforcement.

I will be happy to provide you with a copy of the final list when we have finished this process, but you should know that we do not plan a public announcement of the list. I had initially thought it would be a good idea to publish the list (to reassure the public that

HCFA and the states are working to enforce the law), but I have had several discussions with beneficiary advocates who have persuaded me otherwise. They argue that publicizing such a list could have the effect of: 1) unnecessarily frightening families with loved ones in the special focus facilities, or 2) allowing facilities not on the list to claim that they are getting our seal of approval. We would like to meet with you to discuss these issues once the final list is developed.

A3. Civil Monetary Penalties (CMPs)

We have requested that all regional offices contact the States in their respective Region in order to provide us with the following information relative to the distribution of collected CMPs: 1) the amount of money collected by the State in response to imposition of a CMP; 2) how the money collected has been used; and, 3) an indication as to whether or not any of the money collected has been returned to the State's general funds. We are awaiting the responses and will provide this information when we can.

A4. Alternatives

Sections 1819(h) and 1919(h) of the Social Security Act establish alternative remedies that can be used ***instead*** of terminating a nursing home's participation in our programs. Proceeding in another direction, i.e., implementing options other than those provided for in the Act, would require a statutory change or demonstration approval. However, I have discussed this idea with Dr. Harriet Fields, the State monitor for D.C. Village, and we are exploring the possibility of a demonstration to determine whether intense State monitoring in a few facilities that have indicated through inadequate performance that they need assistance would be effective. I will continue to keep you apprised of this possibility as well as any others that fall within our current statutory authority.

A6. The Federal Monitoring System and Abt Associates

We have scheduled two briefings for the Committee, one by David Zimmerman, Ph.D, and Andrew Kramer, M.D., on the development of the quality indicators, and another by Abt Associates on their activities to ensure the integrity of the Minimum Data Set (MDS) and related protocols. Both briefings have been coordinated with your staff and are scheduled for November 30.

A7. Appropriate Personnel

As requested, we have included the name of lead staff and their telephone numbers with each initiative listed on the implementation schedule (see enclosure).

B1. HCFA1(c)

We presented a list of nursing homes that we proposed for focused enforcement to the States at the end of September. The States provided us with valuable comments on additional sources of data--particularly the use of substantiated complaints--that we could use in selecting "special focus facilities." We have continued to work with State agencies to refine the methodology for selecting the nursing homes that should received focused enforcement.

B2. HCFA2(b)

The new Federal Monitoring System (FMS) was transmitted electronically and mailed to all HCFA regional offices, and copies were sent to the President, Association of Health Facility Survey Agencies, to share with the States (see enclosure). I also discussed our plans with representatives of state survey agencies, beneficiary advocates, and others in meetings held in August, September, and October.

C. Sufficient Staffing

The recent nursing home Report to Congress, the GAO report and testimony before your Committee, made clear that inadequate nurse staffing may be a root cause of many of the problems faced by nursing home residents. We are in the process of reviewing the relationship between staffing levels and the quality of care for nursing home residents. Accordingly, on September 28, 1998, a contract modification was awarded to our independent evaluation contractor, Abt Associates, to assist us in completing a comprehensive nurse staffing study. Current plans call for all the analyses to be completed and a report delivered to the Director, Disabled and Elderly Health Programs Group, HCFA, in 12 months, i.e., by September 30, 1999, and then submitted to the Congress by the end of the year.

This comprehensive nurse staffing study will help HCFA determine: 1) if minimum nurse staffing ratios are appropriate; and, if appropriate, 2) the potential cost and budgetary implications of minimum ratio requirements.

D. Budget Implications

We appreciate the decision by Congress, and your support in particular, to approve the FY 1999 funding the President proposed for survey and certification, and for appropriating an additional $4 million to help fund the nursing home initiatives. The FY 1999 Survey and Certification budget included the first significant increase in survey and certification funding in a number of years and sends a positive message to all: the

Administration and the Congress are committed to assuring that the best care is purchased and provided for some of our most vulnerable citizens. Congress' concern is reinforced by its commitment to appropriately fund the mandated Federal/State oversight functions of survey and certification.

With the FY 1999 budget of $171 million, we will continue to improve Federal and State oversight of the care provided in the numerous health care settings by the various care givers, especially nursing homes. While the $13 million increase requested was originally intended to permit an improvement of the oversight efforts of other non-long term care providers through increased survey coverage levels, we will be channeling a portion of those funds, plus the $4 million Congress specifically appropriated, to the implementation of our nursing home initiatives.

I am committed to funding this initiative adequately. As I have said before, however, even with this increased funding, we will need to allocate carefully and phase in the implementation of some of the pieces of our initiative. For instance, while we have changed the definition of "poor performing facility" to one that should be more effective, we expect that the State resource requirements would be higher if we were to schedule full implementation beginning right now. We believe that states will eventually incur additional administrative costs as a result of the tougher definitions because there will be more appeals by facilities. I think that phasing in these policies makes sense, given the magnitude of this entire initiative and the changes we are asking States to make. Thus, we are asking the States to phase in the new decision criteria for poor performers so that full implementation will not affect State surveyor and appeals processes until the end of the fiscal year.

We are in the process of finalizing our FY 1999 spending estimates and allocations. We would be happy to provide you with more information on this as soon as we can. We expect to improve the process and tools, the enforcement of regulations and the Federal oversight mechanism, all integral parts in our quest to improve the quality of care provided to nursing home residents. To further reinforce our collective efforts to improve the quality of health care, I will recommend that the Administration's FY 2000 survey and certification budget recognize the very real needs of the survey and certification program for Nursing Homes, Intermediate Care Facilities for the Mentally Retarded, Home Health Agencies and the many other providers for whom HCFA has oversight responsibility. We appreciate the support that Congress and your Committee have provided this year. Working with the Senate Select Committee on Aging, I expect HCFA to make great strides in accomplishing good things in the health care delivery arena.

I hope the information provided adequately responds to your concerns.

Sincerely,

Nancy-Ann Min DeParle
Administrator

Enclosures

NURSING HOME IMPLEMENTATION SCHEDULE

Project	Completion Dates	Lead (in bold)	Status
GAO Recommendations			
GAO-1.. Stagger Survey Schedules ▸ Working draft manual instructions ▸ Clearance draft manual instructions ▸ Final manual instructions (same as HCFA-1(d))	Completed 11/30/98 12/31/98	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: OCOS; OGC; state govts; RO	Draft manual instructions prepared; analyzing comments.
GAO-2. Increase the Sample Size for Nutrition, Dehydration & Pressure Sore Areas ▸ Develop revised survey task for sampling methodology during surveys. ▸ Final State Operations Manual Instruction ▸ Develop protocol using quality indicators for pressure sores, malnutrition & dehydration	12/31/98 2/28/99 4/30/99	**CMSO** **(Cindy Graunke)** **410-786-6782** **OCSQ** **(John Thomas)** **410-786-2908** Partners: OCOS, RO	Contract let with University of Colorado (Andy Kramer), CHSRA (David Zimmerman), and Alpine Technology on 9/22/98.
GAO-3. Eliminate Grace Period for Homes with Repeated Serious Violations and Impose Remedies Promptly ▸ Release memo ▸ Working draft manual instructions ▸ Clearance draft manual instructions ▸ Final State Operations Manual	Completed 2/28/99 3/31/99 4/30/99	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: OCOS, RO	Memo phasing in policy sent out 9/25/98.

NURSING HOME IMPLEMENTATION SCHEDULE

Project	Completion Dates	Lead (in bold)	Status
GAO-4. Define HCFA's "Revisit" Policy and Ensure Compliance ▸ Issue Policy Letter to all ROs/States on the revisit policy	Completed	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: OCOS; RO	Memo to ROs & States on 8/20/98 clarifying revisit policy.
Presidential Initiatives			
HCFA-1(a). Redefine "Poor Performing" Facility ▸ Issue memo ▸ Working draft guidance ▸ Clearance draft manual instructions ▸ Final State Operations Manual	Completed 2/28/99 3/31/99 4/30/99	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: OCOS, RO	Same status as GAO-3.
HCFA-1(b). Propose CMPs for "Each Instance" ▸ Draft final regulation to HCFA's Regulations Staff ▸ Publish final regulation with comment ▸ Working draft manual instructions ▸ Clearance draft manual instructions ▸ Final manual instructions	Completed 12/31/98 1/31/99 2/28/99 3/31/99	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: OCOS, OGC; RO	Regulation sent to HCFA's Regulations Staff on 9/18/98. Regs team met on 11/2/98, 11/4/98, and 11/10/98. Team revisions have been incorporated and will be returned to the Regulations Staff the week of 11/16/98.
HCFA-1(c). Enhanced Monitoring of Special Focus Facilities (SFF) ▸ List of facilities (by State) developed by CO ▸ RO/States review list and make recommendations for appropriate revisions ▸ Final list and protocol developed ▸ States begin enhanced monitoring	Completed 11/30/98	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: providers; advocates; states, RO; health care professionals	Completed compiling SFF, draft protocol, monitoring and how to get off list; pro/con paper attached.

NURSING HOME IMPLEMENTATION SCHEDULE

Project	Completion Dates	Lead (in bold)	Status
HCFA-1(d). Stagger Nursing Home Inspections (same as GAO-1 above)			
HCFA-1(e). Define "Poor Performing Nursing Home Chain" and Consequences • Working draft manual instructions • Clearance draft manual instruction • Review and comment • Final State Operations Manual	 11/30/98 12/31/98 1/31/99 2/28/99	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: CMSO/DSG; OIS; OCOS; OGC; RO	Memo sent to States/ROs on 9/25/98. Guidance and strategy outline developed through RO/CO workgroup, and sent out for comment.
HCFA-2(a). Provide Additional Training and Assistance to Inspectors that are not adequately protecting residents & Terminate Funding to States that fail to adequately perform survey functions or fail to improve inadequate survey systems. • Convene workgroup to develop criteria • Working draft manual instructions • Clearance draft manual instruction • Final State Operations Manual (Cases with State inadequate performance will be handled on a case-by-case basis prior to publication of criteria)	 Completed 11/30/98 12/31/98 1/31/99	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: states; RO; CMSO/DEHPG/DOI; OCOS; OGC; ASPE	RO/CO workgroup convened on October 6 to begin working on criteria. Workgroup is scheduled to have a face-to-face meeting 11/30/98-12/1/98 and is looking into the 1864 agreement. Since the issues are more complex & require more research than originally anticipated, we've adjusted the 10/31/98 date to 11/30/98 to reflect a more realistic projection of time needed for this task.
HCFA-2(b). New Federal Monitoring System • Draft FMS protocols • Review and comment • Final FMS protocols • Training • Implementation • Information reporting system in place	 Completed Completed Completed Completed Completed Completed	**CMSO** **(Cindy Graunke)** **410-786-6782** Partner: RO	PictureTel training on 9/25/98; over 100 RO staff trained. Train-the-Trainer held October 14-16 in Chicago for data collection and reporting.

NURSING HOME IMPLEMENTATION SCHEDULE

Project	Completion Dates	Lead (in bold)	Status
HCFA-3(a). Repository of Best Practices Guidelines for Caring for Residents at Risk of Weight Loss and Dehydration ▸ Solicit ideas through the "Sharing Innovations In Quality" Network ▸ Approval of ideas to be included ▸ Post on HCFA's Internet Approved Best Practice Guidelines	Completed Completed 12/31/98	**CMSO** **(Cindy Graunke)** **410-786-6782** **OCSQ** Partners: providers, advocates; States; health care professionals; RO	"Sharing Innovations in Quality" workgroup meeting held September 17-18; ideas from the field on nutrition and ADA guidelines; idea guidelines will be posted on a separate page from the clinical guidelines on HCFA's website. HCFA participated in an effort led by ADA on 11/6/98 in Washington, D.C.
HCFA-3(b). National Campaign to Increase Awareness on Prevention of Malnutrition & Dehydration ▸ RO participants identified ▸ Develop promotional themes & plan • Get feedback on plan from partners ▸ Focus test messages; Campaign begins • Print & distribute messages to targeted audiences	Completed 11/30/98 12/31/98 1/31/99 2/29/99	**CBS** **(Michael McMullan)** **410-786-4280** Partners: CMSO/ DEHPG/DOI; OCSQ; RO; OCOS; DHHS	Workgroup members designated. Conducting inventory of existing materials from States for key message development.
HCFA-3(c). Clearer Guidance on Key Quality of Life/Quality of Care Issues (Including Nutrition, Hydration, Pressure Sores and Admissions Contracts) ▸ Draft interpretive guidelines ▸ Review and comment from ROs/States/ Professional/Advocates/Industry • Clearance draft interpretive guidelines ▸ Final interpretive guidelines	Completed 11/30/98 1/31/99 4/30/99	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: OCSQ; OCOS; ASPE; providers; advocates; states; RO; health care professionals	Meeting held with contractor on 11/4/98 to discuss 4/99 product. Contractor will present automating concepts on 11/17/98 and 11/18/98. We had originally contemplated written guidelines and are now, through a contractor, pursuing automated ones. Draft interpretive guidelines given to contractor.

NURSING HOME IMPLEMENTATION SCHEDULE

Project	Completion Dates	Lead (in bold)	Status
HCFA-3(d) Using Effective Drugs ▸ Working draft interpretive guidelines ▸ Review and comment from ROs/States/ Professional/Advocates/Industry • Clearance draft interpretive guidelines ▸ Final interpretive guidelines	 Completed Completed 11/30/98 12/31/98	**CMSO** **(Sam Kidder)** **410-786-6795** Partner: OCSQ; OCOS, RO	Draft instructions developed & sent to ROs, States, advocates & providers on 8/28/98 for review & comment; analyzing comments. Staff from CO and States are scheduled to meet on 11/16/98 with the American Medical Directors Assn., AAHSA, AHCA, NCCNHR, ASCP, etc., to go over the differences in the drug criteria.
HCFA-4(a). Add Survey Task to Look at a Provider's Abuse Intervention System ▸ Working draft manual instructions & survey protocol ▸ Review and comment by ROs/States/professionals and advocates/providers • Clearance draft manual instructions & survey protocol ▸ Final manual instructions & survey protocol	 1/31/99 2/29/99 3/31/99 4/30/99	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: OCOS, RO	Abuse forum held 9/29/98; next meeting in December. Workgroups identified including nursing home survey task and education campaign. Draft survey protocol in review by internal workgroups in preparation for December meeting.
HCFA-4(b). Abuse Intervention Campaign ▸ Letter & List of proposed participants to invite ▸ Meeting with abuse forum representatives • Develop key promotional themes & plans ▸ Get feedback on plan from partners ▸ Focus test messages; Campaign begins • Print & distribute messages to targeted audiences	 Completed Completed 11/30/98 12/31/98 1/31/99 2/29/99	**CBS** **(Michael McMullan)** **410-786-4280** Partners: CMSO/ DEHPG/DOI; OCSQ; RO; OCOS; DHHS	Workgroup members designated. Conducting inventory of existing abuse materials from States for key message development.
HCFA-5. Prosecution of Egregious Violations ▸ Preliminary discussions with DOJ and IG ▸ Conference with DOJ and OIG to develop interagency plan	 Completed Completed	**CMSO** **(Cindy Graunke)** **410-786-6782** Partners: DOJ; OIG; RO; OCOS	Conference with OIG & DOJ held 10/21/98-10/22/98. HCFA participated in teleconference with DoJ on 10/30/98. A second teleconference with DoJ was held on 11/6/98.

NURSING HOME IMPLEMENTATION SCHEDULE

Project	Completion Dates	Lead (in bold)	Status
HCFA-6. Survey Results on Internet ▸ Determine data fields to be included on Internet ▸ Contractor programs system ▸ Focus groups to determine effectiveness ▸ Survey results on Internet - Testing Phase ▸ Roll-out	 Completed Completed Completed Completed 12/31/98	**CBS** **(Michael McMullan)** **410-786-4280** Partners: CMSO/ DEHPG/DOI; CMSO/DSG	Internet site up on 9/30/98.
HCFA-7(a). Criminal Background Checks ▸ Draft legislation	Completed	**OL** **(Don Johnson)** **202-690-7762** Partners: CMSO; OCSQ; state govts; providers; FBI; advocates; RO	Legislation submitted to Congress 7/29/98. Other legislation (P.L. 105-277 Section 124), which was passed, establishes permissive structure supporting checks.
HCFA-7(b). National Registry to Incorporate State Registries ▸ Draft legislation	Completed	**OL** **(Don Johnson)** **202-690-7762** Partners: CMSO; OCSQ; state govt.; providers; FBI; advocates; RO	Legislation submitted to Congress 7/29/98.
HCFA-7(c). Increase Staff Feeding Residents ▸ Draft legislation	Completed	**OL** **(Don Johnson)** **202-690-7762** Partners: RO; CMSO; OCOS; OCSQ; providers; advocates; health care professionals; ASPE	Legislation submitted to Congress 7/29/98.

Health Care Financing Administration
Nursing Home Initiative Update #2
November 16, 1998

HCFA Action on GAO Recommendations:

GAO-1. **Stagger or otherwise vary the scheduling of standard surveys to effectively reduce the predictability of surveyor visits.**

Status:

We have drafted a manual instruction which includes guidance to States to begin some of their surveys on evenings and weekends, to vary the sequencing of surveys in a geographical area to avoid alerting others that the surveyors are in the area, and to vary the month in which surveys are conducted for a specific survey. The draft manual instruction was sent to regional offices, States, providers and advocates for their review and comment. We are in the process of analyzing comments received.

GAO-2. **Review Federal survey procedures to instruct surveyors to take stratified random samples of resident cases and review sufficient numbers and types of resident cases so that surveyors can better detect problems and assess their prevalence.**

Status:

We discussed plans to pilot test the revised survey process with stakeholder groups (listed below) on 8/17; 8/19 and 8/21. The revised survey process will be piloted in April 1999 using quality indicators for nutrition/hydration and pressure sores. A contract was let on 9/22/98 for developing these quality indicators in the survey process. A teleconference was held on 11/4/98 with the contractor to begin planning the April 1999 changes, and a meeting is scheduled for 11/17/98-11/18/98 for contract kickoff and presentation of contractor's system. Internal HCFA meeting held on 11/5/98 to plan next steps to generate better surveyor guidance in nutrition, hydration, and pressure sore areas.

GAO-3. **Eliminate the grace period for homes cited for repeated serious violations and impose sanctions promptly, as permitted under existing regulations.**

Status:

A memo was released on 9/25/98 phasing in elimination of the opportunity for facilities with poor compliance histories to correct their deficiencies before remedies are imposed.

GAO-4. **Require that for problem homes with recurring serious violations, State surveyors substantiate, by means of an on-site review, every report to HCFA of a home's resumed compliance status.**

Status:

Completed. A memo to Regional Offices and States was sent on August 20, 1998. In addition, copies were sent to provider and consumer advocates.

HCFA Action on Presidential Initiatives:

HCFA-1 Stronger Enforcement Actions

HCFA-1(a) • Revise definition of "Poor Performer"

Status:

We discussed a revised definition of "poor performer" facility with stakeholder groups on 8/17; 8/19; and 8/21. We issued a memo on 9/25/98 to the Regional Offices phasing in the definition of poor performer.

HCFA-1(b) • Permit States to impose civil money penalties for "each instance".

Status:

We have requested that a final regulation with comment be included on HCFA's Regulatory Schedule, with the regulation to be published in December 1998. The draft regulation was sent to HCFA's Regulations Staff on 9/18/98. The regulations team met on 11/2, 11/4 and 11/10 to discuss team comments. Team revisions have been incorporated and will be returned to the Regulations Staff the week of 11/16/98.

HCFA-1(c) • Inspect certain nursing homes more frequently without decreasing inspection frequency for other facilities.

Status:

We have developed criteria to identify 100 facilities nationwide which require more intense monitoring. Criteria and names of specific facilities were solicited from stakeholder groups on 8/17; 8/19 and 8/21. We are in the process of working with States to refine the methodology for selecting the homes and finalizing the list.

HCFA-1(d) • Stagger nursing home inspections.

Status:

Same as GAO-1 above.

HCFA-1(e) • Federal and State officials will focus their enforcement efforts on nursing homes within chains that have a record of noncompliance with Federal rules.

Status:

We solicited ideas from stakeholder groups on 8/17; 8/19 and 8/21 for criteria which would trigger a nursing home chain to be considered a "poor performer". A guideline memo was issued on 9/25/98 that recommends a State agency course of action--If a facility is found to have

deficiencies during the survey, and the State is aware that another facility(ies) within the same chain has been designated as a "poor performing" facility, HCFA recommends that the facility being surveyed also be assigned the "poor performing" designation. This means that the surveyed chain facility would NOT be given an opportunity to correct deficiencies prior to the imposition of remedies. Proposed criteria and preliminary review of OSCAR data has been completed. An overall strategy plan has been forwarded to the ROs for comment.

HCFA-2. Stronger Federal Oversight

HCFA-2 (a)• Provide additional training and other assistance to inspectors in States that are not adequately protecting residents; terminate funding to States that fail to adequately perform survey functions or fail to improve inadequate survey systems.

Status:

We solicited ideas from stakeholder groups on 8/17; 8/19; and 8/21 for criteria which would trigger a Federal response to inadequate survey performance. A workgroup of Central Office and Regional Office members has been created to develop these criteria for review and comment by stakeholder groups by 1/31/99.

HCFA-2(b)• Enhance Federal review of surveys conducted by States. Standard evaluation protocols will be implemented in every State this fall.

Status:

A new Federal Monitoring System (FMS) has been developed. The protocols have been piloted and full implementation began on 9/30/98.

HCFA-3. Preventing Bed Sores, Dehydration and Malnutrition

HCFA-3(a)• Repository of best practices guidelines for care for residents at risk of weight loss and dehydration.

Status:

We have solicited and received practice guidelines and protocols to be reviewed and included in this national repository. Awaiting inclusion on HCFA's website.

HCFA-3(b)• National campaign to increase awareness on the prevention of malnutrition and dehydration.

Status:

We have established a workgroup to plan a national nutrition campaign. The first teleconference was conducted on September 21, 1998. The Denver Regional Office is conducting weekly conference calls and environmental scanning of existing/local materials in States for key message development.

HCFA-3©• Clearer guidance on key quality of life/quality of care issues (including nutrition and hydration concerns and admissions contracts for newly admitted residents).

Status:

We are developing a survey protocol using quality indicators for both nutrition, hydration and pressure sores (see also GAO-2 above).

HCFA-3(d) Using Effective Drugs

Status:

Draft manual instructions were sent to stakeholders for review and comment. We are in the process of completing our analysis of the comments received.

HCFA-4. Combating Resident Abuse

HCFA-4(a)• Add survey task to look at a provider's abuse intervention system.

Status:

A Stakeholder meeting was held on September 29 to review our survey task for reviewing a nursing home's abuse intervention system. New survey task and interpretive guideline changes have been formulated in first draft by CO/RO team.

HCFA-4(b)• Abuse Intervention Campaign

Status:

The workgroup for the national abuse prevention campaign has been created. The Philadelphia RO is conducting conference calls and environmental scanning for existing/local materials for key message development.

HCFA-5. Prosecution of Egregious Violations

Status:

HCFA participated in a joint conference with OIG and the Department of Justice October 21-22. The purpose of this conference is to find better ways to communicate and refer questionable cases to either the OIG or DoJ. Karen Morrissette, representing DoJ's Criminal Division, met with HCFA staff on 11/13/98 for an initial discussion of the current HCFA/DoJ Memorandum of Understanding and to discuss various options and time frames for HCFA training for law enforcement officials.

HCFA-6. Publishing Survey Results on the Internet

Status:

We have developed a working internet site and conducted 2 focus groups with area senior citizen centers to test its usefulness to the public. Comments were also solicited from the stakeholder meetings held 8/17; 8/19; and 8/21. The Internet site went up live in a testing phase on September 30, 1998.

HCFA-7. Legislative Activity

HCFA-7(a)• Criminal Background Checks

Status:

Legislative language submitted to Congress on 7/29/98

HCFA-7(b)• National Registry to Incorporate State Registries

Status:

Legislative language submitted to Congress on 7/29/98

HCFA-7©• Increase Staff Feeding Residents

Status:

Legislative language submitted to Congress on 7/29/98

Meetings Held with Outside Groups:

October 18 **American Dietetic Association (ADA)**

In attendance at this meeting was the President of the ADA and several members of the Consultant Dietitians in Health Care Facilities practice group.

The purpose of the meeting was to discuss ADA's partnership with HCFA and to obtain HCFA's comments on a set of draft recommendations to address the President's nursing home initiative. ADA will send a formal letter describing the partnership with HCFA to the Administrator. The group discussed its desire to serve as a resource to HCFA in sharing information and providing technical support in the development of practice/care guidelines and training curricula.

October 20 **Nursing Home Advocates**

Nursing home advocate groups including: National Citizens' Coalition for Nursing Home Reform, American Association of Retired Persons, National Senior Citizens Law Center, National Committee to Preserve Medicare and Social Security, and National Association of State Ombudsman Programs.

The purpose of the meeting was to continue an ongoing dialog with the advocate community. The latest nursing home implementation report was distributed and discussed. There was discussion regarding nursing home staffing and HCFA's

contract with Abt Associates to study the issue. NCCNHR also presented a eight-page set of comments regarding the President's initiatives.

October 20 **Region and State Dietitians Working in Medicare/Medicaid**
The State dietitian surveyors meet annually with HCFA regional and CO dietitians in conjunction with the national meeting of the ADA. The purpose of the meeting is to share information, improve survey skills in the application and interpretation of Federal regulations, and to provide peer review of dietary practices. Of great interest this year was HCFA's approach to the President's nursing home initiative. Dietitians expressed concern with the decreasing number of dietitians being employed in the States and regional offices to address malnutrition, weight loss, dehydration, and pressure ulcers in nursing homes. It is worth noting that unless a resident is well nourished, all other therapies are wasted because the quality of care and life sought will be illusive. Also in attendance at this meeting were members from ADA's leadership.

Oct 21-22 **Department of Justice/Office of Inspector General/HCFA Conference**
The purpose of this conference is to find better ways to communicate and refer questionable cases to either the OIG or DoJ. Representatives from the Veterans Administration, FBI, District Attorneys, States' Attorneys, Medicaid Fraud Units were also in attendance. The next steps is to develop a joint plan which includes both training and altering the Memorandum of Understanding.

October 26 **Association of Health Facility Survey Agencies Conference**
State survey agency personnel, HCFA staff and selected speakers.

HCFA provided both a Keynote address and a 1 ½ hour plenary session on the nursing home initiative. Issues raised included funding of the nursing home initiative as well as asking for clarifications on HCFA policies.

Nov 2-3 **American Association of Homes and Services for the Aging Conference**
Nursing home providers, Assisted Living providers, Continuing Care Retirement Community providers, Trustees, Board Members, and selected speakers.

HCFA was represented on the issues of prospective payment and the nursing home initiative during a session on Health Policy Forum. Providers expressed concern over HCFA's internet site because they believe it could make nursing homes sound worse than they were, the consistency of citation of deficiencies among States, and the definition of "poor performer" which they believe will capture too many nursing homes. On November 3, HCFA staff met with 10 State representatives from the Association to discuss how HCFA and AAHSA can work together. AAHSA State representatives were encouraged to send HCFA good examples of how nursing homes are working.

November 4 **Nutrition Screen Initiative (NSI)**

The NSI is a coalition of health care organizations that advise on nutrition for older Americans. Its Advisory Board consists of the ADA, American Association of Homes and Services for the Aging, American Academy of Family Physicians, American Geriatrics Society, American Health Care Association, American Medical Directors Association, American Society of Consultant Pharmacists, Case Management Society of America, National Association of Directors of Nursing in Long Term Care, National Citizens' Coalition for Nursing Home Reform, National Council on the Aging, and National Gerontological Nurses Association.

The purpose of the meeting was to discuss HCFA's approach to the President's nursing home initiative and seek input on a set of proposed checklists/guidelines on malnutrition, weight loss, dehydration, and pressure ulcers focused toward and general public and others as appropriate. The draft checklists/guidelines will be available in early 1999.

Nov 7-10 **National Citizens Coalition for Nursing Home Reform Conference**

Nursing home advocates, nursing home residents, HCFA staff, and selected speakers.

HCFA participated as a "listener" on Saturday, November 7; staff presented during the conference on the nursing home staffing study and the minimum data set. Administrator DeParle attended the conference to listen and participate in a panel for three hours on November 10. There were also several HCFA staff in attendance during the conference.

Meetings Scheduled:

November 19 Meeting with NCCNHR

Early Dec. Meeting with Abuse Stakeholders group.

Elizabeth Summy <esummy @ os.dhhs.gov>
12/09/98 04:26:04 PM

Please respond to esummy@os.dhhs.gov

Record Type: Record

To: bianchi_s @ a1.eop.gov, Devorah R. Adler/OPD/EOP

cc: Rebecca Werbel <rwerbel @ os.dhhs.gov>
Subject: Nursing Home Compliance

This is a heads-up on nursing home compliance guidance to be released soon by the IG.

"The IG has issued a series of compliance guidelines on fraud and abuse. They include program guidance for hospitals, labs, home health and third party billers. These model guides may be voluntarily used by providers to help keep themselves in compliance with program rules. We have always worked closely with HCFA and DOJ in preparing these guides. We are using the Federal Register notification to get comments from the public and interest groups on the draft plans. We will be sending the next (draft) one on nursing homes to the register--probably next Monday--and thought you might want to know about it. When we get to a final, Nancy Anne will be invited to participate in the release and we will also invite the Secretary if she is interested. These guides have gotten very positive reviews by the industry groups."

Guide to Choosing A Nursing Home

published by the Health Care Financing Administration - Medicare and Medicaid
U.S. Department of Health and Human Services

Table of Contents

Note: This publication discusses how to select a nursing home. It is not a legal document. The official provisions of the Medicare and Medicaid programs are contained in the relevant laws, regulations, and rulings.

Reader Notice

The Health Care Financing Administration (HCFA), the Federal Agency that oversees Medicare and Medicaid, wants you to be aware of the two issues involving nursing homes. First, nursing homes cannot require pre-payment from residents who are relying on Medicare or Medicaid to pay for their nursing home services. Second, nursing homes may not use physical or chemical restraints on residents, except when medically necessary.

Pre-Payment: If you are a Medicare or Medicaid beneficiary applying for admission to a nursing facility for care that will be covered by Medicare or Medicaid, it is unlawful for the facility to require you to pay a cash deposit. Federal law prohibits nursing facilities from requiring a pre-payment as a condition of admission for care covered under either Medicare or Medicaid. The facility may, however, request that a Medicare beneficiary pay coinsurance amounts and other charges for which a beneficiary is liable. You pay those charges as they become due, not before. A facility may also require a cash deposit before admission if your care will not be covered by either Medicare or Medicaid.

Restraints: You should also be aware that Federal Law prohibits nursing homes from using physical or chemical restraints on residents for discipline or for the convenience of nursing home staff. Restraints increase the chances that residents will develop incontinence, impaired circulation, and swelling. Restrained residents also tend to suffer decreased functional ability, lower self-esteem, and feelings of depression, anger, and stress. Restrained residents are not safer than they would be if left unrestrained. Restrained individuals are more likely to suffer serious injuries when they fall. It is important that nursing home residents, whenever possible, be left unrestrained.

Restraints may be used only when necessary to treat medical symptoms. Physical restraints include articles, such as belts or vests, that secure a resident's limbs or bind a resident to a bed, chair, or other stationary item. In addition, common nursing home items, such as lap trays and bed rails, when employed solely to keep a resident from moving about, are considered restraints. Chemical restraints include drugs that are administered to keep a resident subdued.

If you know of a nursing facility that is improperly demanding pre-payments or restraining residents, you should contact your State's survey agency immediately. You will find their phone number and address under the "Phone List" section of this publication.

Introduction

Selecting a nursing home is one of the most important and difficult decisions that you may be asked to make. Though it may be difficult to admit, you may spend several years in a nursing home. So it is important that you make the best decision possible, and base your decision on the most complete and timely information available.

The Health Care Financing Administration (HCFA) wants you to make a good choice when choosing a nursing home. This booklet is designed to help you choose a nursing home. It provides you with a step-by-step process that will assist you. It also provides you with some key resources that will help you conduct a wise search for the nursing home or long-term care facility that best fits your needs.

Step 1: Building a Network

Before you begin searching for a nursing home, it is a good idea to put together a network of people who can help you make the right choice. This team should include the family and friends who are important to you. It should also include the doctors and health professionals who understand your needs. Clergy and social workers may also be valuable network

members.

Consult with your network. Family and friends may be willing to share responsibilities and should be treated as partners. Remember that two heads are better than one, and many heads are better than two.

If you are helping to select a nursing home for a relative, make every effort to involve your relative in the selection process. If your relative is mentally alert, it is essential that his or her wishes be respected. People who are involved in the selection process are better prepared when the time comes to move into a nursing home.

Finding a nursing home that provides the right services for you in a pleasant, comfortable environment atmosphere often requires research. Ideally, you will have ample time to plan ahead, examine several nursing homes, and make the appropriate financial plans. By planning ahead, you will have more control over the selection process, more time to gather good information, and more time to make certain that everyone in your network is comfortable with the ultimate choice. Planning ahead is the best way to ease the stress that accompanies choosing a nursing home, and helps assure that you will make a good choice.

Unfortunately, a great many people must select a nursing home with little notice -- frequently during a family crisis or right after a serious illness or operation. If you are in this situation, this booklet should still be helpful. Though you may not be able to follow all of the steps in the upcoming pages, by reading this booklet you will gain valuable information about nursing homes, learn about the people who might be able to help you, and pick up some tips about what to look for in a nursing home.

Step 2: Long-Term Care Options

Until recently, few alternatives to nursing homes existed for people who could no longer take care of themselves. Even today, some people are placed in nursing homes simply because neither they nor their family know about the alternatives to nursing homes. Today, people who cannot live completely independently may choose from a variety of living arrangements that offer different levels of care. For many, these alternatives are preferable to nursing homes.

Home and Community Care Most people want to remain at home as long as possible. A person who is ill or disabled and needs help may be able to get a variety of home services that might make moving into a nursing home unnecessary. Home services include meals on wheels programs, friendly visiting and shopper services, and adult day care. In addition, there are a variety of programs that help care for people in their homes. Some nursing homes offer respite care -- when they admit a person for a short period of time to give the home caregivers a break. Depending on the case, Medicare, private insurance, and Medicaid may pay some home care costs.

Subsidized Senior Housing There are Federal and State programs that subsidize housing for older people with low to moderate incomes. A number of these facilities offer assistance to residents who need help with certain tasks, such as shopping and laundry, but residents generally live independently in an apartment within the senior housing complex. In this way, subsidized senior housing serves as a lower cost alternative to assisted living -- though assisted living communities are frequently newer and more luxurious.

Assisted Living (Non-Medical Senior Housing)
Some people need help with only a small number of tasks, such as cooking and laundry. Some may only need to be reminded to take their medications. For those people who need only a small amount of help, assisted living facilities may be worth considering. Assisted living is a general term for living arrangements in which some services are available to residents (meals, laundry, medication reminders), but residents still live independently within the assisted living

complex. In most cases, assisted living residents pay a regular monthly rent, and then pay additional fees for the services that they require.

Board and Care Homes
These are group living arrangements (sometimes called group or domiciliary homes) that are designed to meet the needs of people who cannot live independently, but do not require nursing home services. These homes offer a wider range of services than independent living options. Most provide help with some of the activities of daily living, including eating, walking, bathing, and toileting. In some cases, private long-term care insurance and medical assistance programs will help pay for this type of living.

Continuing Care Retirement Communities (CCRCs)
CCRCs are housing communities that provide different levels of care based on the needs of their residents -- from independent living apartments to skilled nursing in an affiliated nursing home. Residents move from one setting to another based on their needs, but continue to remain a part of their CCRC's community. Many CCRCs require a large payment prior to admission, then charge monthly fees above that. For this reason, many CCRCs are too expensive for older people with modest incomes.

What is a Nursing Home?
A nursing home is a residence that provides room, meals, recreational activities, help with daily living, and protective supervision to residents. Generally, nursing home residents have physical or mental impairments which keep them from living independently. Nursing homes are certified to provide different levels of care, from custodial to skilled nursing (services that can only be administered by a trained professional).

Before deciding which care setting is most appropriate for you or your relative, talk to your doctor or a social worker and get a realistic assessment of care needs. If you are considering home care, be sure you understand all the work that comes with caring for a chronically ill person. If you are considering independent living, consider the risks associated with an unsupervised environment.

Be sure to discuss long-term care options with family members who will be the main home care givers and/or visitors to your new home. Consider how you will pay for your own long-term care .

Remember that caring for someone who is very sick requires a lot of work. Nursing homes are designed to meet the needs of the acutely or chronically ill. The options discussed above may work for people who require less than skilled care, or who require skilled care for only brief periods of time, but many people with long-term skilled care needs require a level and amount of care that cannot be easily handled outside of a nursing home.

Step 3: Gathering Information

Once you have decided that a nursing home is the right choice for you, it is time to gather information about the nursing homes in your area. A good first step in this process is finding out exactly how many nursing homes there are in your area (because nursing homes are frequently located in out of the way areas, there might be more than you think).

There are a number of ways that you can learn about the nursing homes in your area. The easiest ways to find out about local nursing homes begin with the phone book. Your yellow pages list many of the nursing homes in your area. In addition, your local Office on Aging (in the Blue Pages of your Phone Book) should have a listing of nursing homes in your area and will be able to refer you to your local Long-Term Care Ombudsman.

You can get information on the nursing homes in your area from a variety of sources. Word of mouth can be a good source of information. Ask your friends and neighbors if they know

people who have stayed in local nursing homes. Learn all you can from these different sources.

Some Facts About Nursing Homes
On any given day, nursing homes are caring for about one in twenty Americans over the age of 65. Almost half of all Americans turning 65 this year will be admitted into a nursing home at least once. One fifth of those people admitted into nursing homes stay at least one year--one tenth stay three years or more.

The Long-Term Care Ombudsman
One of the best sources of information is your local long-term care ombudsman. Nationwide, there are more than 500 local ombudsman programs. Ombudsman visit nursing homes on a regular basis -- their job is to investigate complaints, advocate for residents, and mediate disputes. Ombudsman often have very good knowledge about the quality of life and care inside each nursing home in their area.

Ombudsman are not allowed to recommend one nursing home over another. But when asked about specific nursing homes they can provide information on these important subjects:

- the results of the latest survey,
- the number of outstanding complaints,
- the number and nature of complaints lodged in the last year,
- the results and conclusions of recent complaint investigations.

In addition, the ombudsman may provide general advice on what to look for when visiting the various area nursing homes. The phone number of your State Long-Term Care Ombudsman is provided under the "Phone Lists" section.

Other Community Resources
In addition to the Long-Term Care Ombudsman, there are many other resources that you should consult before selecting a nursing home. Some other people who might be helpful are:

- hospital discharge planners or social workers,
- physicians who serve the elderly,
- clergy and religious organizations,
- volunteer groups that work with the elderly and chronically ill,
- nursing home professional associations.

By using these resources, you will tap into a community of people who understand nursing homes and have a good deal of knowledge about the homes in your area. You should now be able to make a list of the homes in your area which have good reputations.

Other Information You Will Need
There are also some types of basic information that should help you narrow your list of nursing homes. Consider some of these factors -- a quick phone call to the nursing home should answer these concerns:

Religious and Cultural Preferences: If you have religious or cultural preferences, contact the nursing homes on your list and see if they offer the type of environment which you would prefer.

Medicare and Medicaid Participation: If you will be using Medicare or Medicaid, make certain that the nursing homes on your list accept Medicare or Medicaid payment. Often, only a portion of the home is certified for Medicare or Medicaid, so make sure that the home has Medicare or Medicaid "beds" available. For more information how Medicare and Medicaid pay for nursing home care, scroll to the end of this section.

HMO Contracts: If you belong to a managed care plan that contracts with a particular

nursing home or homes in your area, make sure the homes you are considering have contracts with your HMO.

Availability: Make certain that the nursing homes on your list will have space available at the time you might need to be admitted.

Special Care Needs: If you require care for special medical conditions or dementia, make sure that the nursing homes on your list are capable of meeting these special circumstances.

Location: If you have a large number of nursing home choices, it is usually a good idea to consider nursing homes that your family and friends can visit easily.

Why Location is Important: In most cases, it is a mistake to select a nursing home that is difficult to visit on a regular basis. Frequent visits are the best way to make sure that you or your relative does well in the nursing home. Visitors are important advocates for chronically ill residents. Frequent visits often make the transition to the nursing home easier for new residents and their families.

You may will now be able to figure out which homes in your area may or may not be worth visiting. You will also now be better informed when you begin visiting your area's nursing homes.

Paying for Nursing Home Care
Nursing home care is expensive (a skilled nursing home will cost about $200 a day in many parts of the country). For most people, finding ways to finance nursing home care is a major concern. there are serveral ways that nursing home care is financed:

Personal Resources: About half of all nursing home residents pay nursing home costs out of personal resources. When most people enter nursing homes, they usually pay out of their own savings. As personal resources are spent, many people who stay in nursing homes for long periods eventually become eligible for Medicaid.

Long-Term Care Insurance: Long-Term Care Insurance is private insurance designed to cover long-term care costs. Plans vary widely, and you would be wise to do some research before purchasing any long-term care policy. Generally, only relatively healthy people may purchase long-term care insurance. For further information on this type of insurance, contact the National Association of Insurance Commissioners and ask for their free booklet, *The Shopper's Guide to Long-Term Care Insurance.* Call (816) 374-7259 for your copy.

Medicaid: Medicaid is a State and Federal program that will pay most nursing home costs for people with limited income and assets. Eligibility varies by state, and you should check into your state's eligibility requirements before assuming that you are either eligible or ineligible. Medicaid will only pay for nursing home care provided in Medicaid-certified facilities.

Medicare: Under certain limited conditions, Medicare will pay some nursing home costs for Medicare beneficiaries who require skilled nursing or rehabilitation services. To be covered, you must (after a qualifying hospital stay) receive the services from a Medicare-certified skilled nursing home. HCFA's book, *Your Medicare Handbook,* discusses the conditions under which Medicare will help pay for nursing home costs in a Medicare-certified nursing home. To obtain a free copy of *Your Medicare Handbook,* call (800) 638-6833.

Medicare Supplemental Insurance: This is private insurance (often called Medigap) that pays Medicare's deductibles and co-insurances, and may cover services not covered by Medicare. Most Medigap plans will help pay for skilled nursing care, but only when that care is covered by Medicare.

In addition, some people have nursing home costs covered, or partially covered, by managed care plans or employer benefit packages.

If you have any questions about how you will pay for nursing home care, what coverage you may already have, or whether there are any government programs that will help with your expenses, there are people who can help. Your State's Insurance Counseling and Assistance (ICA) program has counselors ready to help you figure out how you can finance your long-term care. Your State's ICA phone number is printed under the " Phone List" section.

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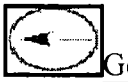
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