Nursing home regulation: History and expectations

This article contains a broad overview of the history of Federal regulation of nursing homes from the perspective of an individual involved directly for a number of years in the development and enforcement of Federal regulatory requirements. The article also contains a summary of the major statutory changes in

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the Omnibus Budget Reconciliation Act of 1987 that affect nursing homes. Finally, the results of these changes are projected in terms of new outcome-oriented requirements and a broad range of new enforcement authorities.

Introduction

Two major sets of Federal regulatory requirements affect nursing homes. One set contains the requirements that facilities must meet to participate in Medicare and Medicaid (Code of Federal Regulations, 1987a and 1987b). The second set contains the enforcement process that the Federal Government and its agents, the State survey agencies, must follow in inspecting nursing homes and approving or disapproving them for participation (Code of Federal Regulations, 1987c). Both sets of regulations are interrelated in the sense that enforcement is impossible without clear measures of compliance, and, similarly, the best compliance measures are useless without a fair, accountable process for enforcing these measures. In this article, I trace the development of both sets of regulations and attempt to project their short- and long-range future.

Early years

In 1965, when Medicare coverage for hospital services was enacted, the task facing the Federal Government for the regulation of hospitals was relatively simple. Congress had mandated that hospitals accredited by the Joint Commission on Accreditation of Hospitals (now the Joint Commission on Accreditation of Healthcare Organizations) be accepted for participation in Medicare. The Federal Government had only to face the task of dealing with approximately 2,000 nonaccredited hospitals. The solution was simple: Adapt the Joint Commission's requirements. In essence, this is exactly what the Federal Government did through the regulatory process.

The problem of long-term care facilities was not so simple. No regulatory model existed for either skilled (extended care) or intermediate care facilities. Only the Joint Commission "hospital" or "medical" model existed. The task at hand, then, was to take the fundamentals of the hospital regulations and derive a new set of regulations for nursing homes.

The struggle to develop Federal requirements for nursing homes focused on two central concerns:

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physical safety and adequacy of treatment and services

The first, physical safety, was conceptually easy to address. At the most elementary level, facilities should be fire safe and clean. Also, staff should not abuse the patients. These concerns were relatively easy to translate into Federal regulation. Today, these requirements are sometimes derisively referred to as the "bricks and mortar" requirements. However, at a time when fire, filth, and patient abuse were not uncommon, these requirements caused a major improvement in America's nursing homes.

The second set of concerns, adequacy of treatment and services, was not so easily addressed. Good outcomes, or at least no adverse outcomes, were the goals. Our aim for hospitals was for patients to have successful operations and to be cured, if possible; our aim for nursing homes was improvement in patient function, or at least no more deterioration than was unavoidable. Clearly, we could not mandate good results through regulation, and the state-of-the-art was such that the idea of regulating for outcomes was little more than a hope for the future. Consequently, surrogate measures that took the form of qualifications, policies, and procedures were the next best thing. For example, one cannot regulate successful surgery in hospitals. However, one can hope to attain the outcome, successful surgery, by requiring that surgeons be qualified, procedures be adequate, etc. In the case of nursing homes, the same general principles apply, and detailed staff qualifications, policies, and procedures were developed and put in place in lieu of direct outcome measures.

Enforcement went through a similar evolution. Early enforcement efforts were focused on safety of the physical plant, sanitation, and other obvious items. Other than physical plant problems that could not be fixed, most deficiencies in facility performance were dealt with through plans of correction. Facilities were rarely terminated from participating in Medicare or Medicaid; the thrust was to get facilities into the programs and to correct problems over time.

Attempting change

The regulations and their enforcement remained largely unchanged into the 1980's. During the early part of the decade, congressional hearings, research, and discussion contributed to a growing body of

concern and knowledge about the nature and regulation of nursing homes. Concurrently, the Federal Government was attempting to develop new sets of regulations. Two particular efforts are worthy of note: the attempt in 1980 to issue regulations that contained new standards for facilities to meet and the attempt in 1982 to issue new enforcement regulations.

For the purposes of this article, a detailed explanation of all of the provisions of these regulatory proposals is of little interest. The significance of these proposals is in their failure. They proved that the Federal Government, for a myriad of reasons, was unable to establish sufficient consensus to reregulate the nursing home industry. The various conflicting forces, including consumer, industry, and State government, made it, in effect, impossible for the Federal Government to establish a reasonable, respectable set of proposed regulations. This had two major results.

New survey process

The first significant result was the development and implementation of the patient care and services survey process. This process was the first major step in implementing a state-of-the-art, outcome-oriented review of nursing homes. Unable to promulgate regulations, the Federal Government instead used the survey process to implement state-of-the-art observation techniques about patient care and health status. Now, instead of just checking a facility's policies and procedures, surveyors observed and interviewed the residents and arrived at compliance decisions based on the outcomes of care. These new techniques were incorporated into the inspection forms and were linked directly to current regulations. The net result was a vastly improved survey process that provided a better way to look at the compliance status of a facility. In effect, it formalized what the better inspectors were doing as a natural part of their regular activities. Formalizing the process forced all surveyors to use this improved methodology, thus assuring uniformity.

Institute of Medicine study

The second significant result of the failure to change regulations was the study conducted by the Institute of Medicine (IOM, 1986). Clearly, suspicion of any proposed Federal action made the use of a disinterested third party critical to the development of any regulation. Funded by the Health Care Financing Administration under congressional pressure, IOM used its prestige and skills to focus the attention of experts on how to regulate nursing homes.

The new long-term care survey process had been in place almost 2 years when the IOM study was completed and results furnished to the Health Care Financing Administration. The IOM study results contained little new information or recommendations that were startling in terms of concept or approach. The key value of the IOM study was that it

represented a consensus of experts. For the first time, agreement was reached on major aspects of Federal regulation, including such critical areas as patient rights, quality of care, and quality of life. Thus, the study afforded a unique foundation for the development of new Federal regulations.

The next logical step in the process was to actually implement the IOM recommendations through regulations. The task, although conceptually simple, proved difficult. The primary problem was in the breadth and scope of the IOM recommendations. In brief, the IOM recommendations in many key areas were so general that a simple translation into the concrete specificity of Federal regulation was impossible. For example, IOM recommended that there be a major set of Federal requirements dealing with "quality of life." Such an intention is noble, but the concept is somewhat difficult to translate into something that nursing homes can implement and inspectors can enforce.

The analysis and translation of the IOM recommendations went on for several months. The result was two proposed rules. The first dealt with the requirements that nursing homes must meet to participate in Medicare and Medicaid (Federal Register, 1987a), and the second dealt with the processes that the Federal Government would employ to enforce compliance with the requirements (Federal Register, 1987b).

New legislation

While the Department of Health and Human Services was going through these processes, Congress was moving to pass nursing home legislation. This effort culminated in enactment of the 1987 Omnibus Budget Reconciliation Act, which contained a significant amount of nursing home reform legislation.

Given the fact that two notices of proposed rulemaking already had been published, one might ask why Congress would pass legislation that implemented the IOM recommendations. I believe there were three principal reasons:

- The fact that proposed rules already were published did not offer sufficient assurance that the Federal government would actually publish final rules. The amount of time (more than a year) that it took to produce proposed rules after IOM published its recommendations and the political problems during the last 10 years that resulted in no new Federal regulations certainly caused some to seek a legislative base to guarantee new regulations.
- Although the proposed rules were a practical translation of the IOM recommendations into regulation, some of the specific differences between the two caused concern. Legislation would ensure total implementation of the IOM recommendations.
- Nursing home reform to implement the recommendations of the prestigious IOM was a sure political winner.

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Many individual details of the legislation and the proposed rules differ. The major differences fall into three broad categories.

- The legislation contains additional, detailed requirements that nursing homes must meet in the area of patient rights, more detailed requirements for statements of patient funds, a requirement for qualified activities professionals, and more detailed requirements for patient assessments.
- The legislation contains a dramatically different enforcement philosophy incorporating new responsibilities for Federal and State governments. The law provides a new range of penalties, including fines and the appointment of temporary management for nursing homes at the discretion of the Federal or State governments. This is the most significant change. Previously, the role of the Federal Government was limited to terminating a facility's participation in Medicare and/or Medicaid and banning new admissions. Although many State governments had a variety of other penalties under their licensure laws, the Federal Government had no such authority. This new legislation not only adds requirements that all States implement a series of new sanctions, but it provides the Federal Government with three major new penalties: denial of payment after a finding of noncompliance; civil money penalties of up to \$10,000 for each day of noncompliance, and appointment of temporary management to ensure either orderly closure or improvements.
- The legislation also went beyond the scope of the proposed Federal regulations in prescribing staffing criteria for nursing homes. The law requires a social worker for facilities with more than 120 beds, and training and competency evaluations for nurses aides. It also establishes a nurses aide registry, and facility administrator qualifications.

Future regulation

The evolution of nursing home requirements and their enforcement has clearly resulted in numerous changes affecting patients, facilities, and government. The two most significant changes in the future will be in the emphasis on patient outcomes and in the responsibility of government (both State and Federal) for compliance by nursing homes.

The basic change overriding all others is the impact on the long-term care system of emphasis on patient outcomes. This emphasis will affect Federal standards, what facilities must do to comply with these standards, and how the Government will enforce the standards.

A major challenge in writing good (i.e., understandable and enforceable) Federal regulations is stating a requirement in clear terms—in the case of nursing homes, defining what is expected for patients. It is all well and good that a facility have appropriate policies on patient rights and care, but the core issue is always the same: What is the status of patients and

what is the expected outcome of treatment of these patients?

Changes in our understanding of what constitutes quality in long-term care have resulted in the Federal Government's being able to state requirements in clear, outcome-oriented terms. The basic structural requirements will always remain; for instance, we still want to be sure facilities are fire-safe. However, most of the new regulations will be direct statements of expectations for patient care, quality of life, and patient rights. The fundamental principle underlying these requirements is that residents of long-term care facilities should receive care that improves their health and functional status, or at least minimizes and delays further deterioration to the extent possible.

Explicit statement of expected outcomes (including the avoidance of negative outcomes) will promote effective patient care and strengthen our ability to enforce the standards. Simply put, if there has been any doubt in the nursing home industry about what is expected in terms of patient care, the new requirements should eliminate these doubts. The same generic approach will be carried into the areas of quality of life and patient rights, and we expect similar improvements in those facilities where practices have been less than ideal.

The enforcement of the new Federal standards will be conceptually simpler and more objective than earlier enforcement efforts. Until the implementation of the new long-term care survey process, surveyors were left largely on their own to translate detailed, process-oriented regulations into judgments on patient care. New regulations that tailor the survey process to outcome standards written in clear, resident-oriented terms will assure thorough and rigorous oversight and objective assessment of the quality of care and treatment of nursing home residents.

The actions resulting from a survey determination that a facility is not in compliance will change drastically, with equally dramatic effects on industry and government. Under the new enforcement process, nursing homes generally will not be terminated from participation in Medicare and/or Medicaid. Instead, incremental penalties such as fines or denial of payment will be used, and, ultimately, managers will be appointed to oversee facility operation. In our future enforcement activities, we will determine compliance based on the new outcome standards. The thrust of the enforcement effort will be to provide realistic, effective incentives for facilities to avoid penalties by preventing or correcting quickly the causes of deficiencies. The notion of more severe penalties for more severe problems will at first provide an incentive to stay in compliance or to get into compliance quickly to reduce fiscal penalties. To the extent that a provider is unable to correct deficiencies, government now will assume responsibility for the patients as a practical matter. By the appointment of temporary management to ensure orderly facility closure or improvement in performance, government is now faced with the ultimate responsibility for the care of the residents.

This, coupled with the new responsibility for assuring qualifications of administrators and nurses aides, increases the role of Federal and State governments in nursing home management.

It is always difficult to make predictions. Certainly, the next few years will be somewhat developmental as concepts evolve into practical realities. Many statutory requirements will not take effect until 1990. After that, the new system will operate, be critiqued, and be subject to the close public scrutiny that takes place for all regulatory efforts for nursing homes. Although modifications and refinements will take place, the amount of consensus necessary to redirect regulatory requirements makes it likely that there will be stability and continued momentum to implement reforms. Debate and arguments over specifics of implementation will occur, but the larger view is that the nursing home problem has now been fixed through legislation. Although consensus is difficult in these areas, the overriding perception is that these new requirements will result in generally better care for nursing home residents.

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