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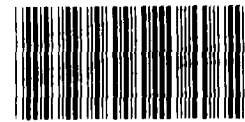
BY THE COMPTROLLER GENERAL  
Report To The Chairman  
Select Committee On Aging  
House Of Representatives  
OF THE UNITED STATES

*Released*

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**Analysis Of Proposed New Standards  
For Nursing Homes Participating  
In Medicare And Medicaid**

In July 1980, the Department of Health and Human Services published proposed new regulations for nursing homes participating in the Medicare and Medicaid programs. These regulations would consolidate requirements now stated in separate regulations for two types of nursing homes--skilled and intermediate.



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The proposed regulations generally do not significantly lessen the current requirements. While new requirements are imposed on both types of facilities, the greatest and most costly changes affect intermediate facilities. The costs of meeting the proposed regulations are controversial. The Department developed a tentative cost estimate of about \$80 million, whereas the industry estimated an annual cost of \$535 million.

This report includes several recommendations to resolve problems GAO identified, and comments on the final rule and related cost estimates proposed by the Department in January 1981.



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COMPTROLLER GENERAL OF THE UNITED STATES  
WASHINGTON, D.C. 20548

B-201562

The Honorable Claude E. Pepper  
Chairman, Select Committee on Aging  
House of Representatives

Dear Mr. Chairman:

This report discusses revisions in nursing home regulations proposed by the Department of Health and Human Services (HHS) in July 1980. The proposed changes involve the requirements that facilities must meet to participate in the Medicare and Medicaid programs. These requirements had not been significantly changed since January 1974.

Our review was made pursuant to your April 21, 1980, request, in which you asked nine specific questions. These questions and our responses are summarized below and detailed in the referenced pages of the report.

1. What language has been lost from the January 1974 Conditions of Participation as promulgated in the Federal Register and the new proposed draft?

HHS is deleting or relaxing a few requirements, such as reports to the States on staffing levels and fire safety waiver periods, which the Department believed were either unnecessarily burdensome or were not effective in achieving the desired results. (See pp. 19 to 21.)

2. What language has been added?

New requirements have been added to both the intermediate care facility (ICF) and skilled nursing facility (SNF) programs, and the language of some existing requirements is being made more specific. However, the major thrust of the new language is to make the ICF standards conform to the SNF standards. (See ch. 2.)

3. Are these changes in conflict with any law or regulation?

The proposed changes in requirements are consistent with applicable laws and regulations. (See p. 22.)

4. What will be the effect of the deleted language?

While we believe it is too early to tell, HHS believes that the impact from deleting or relaxing certain requirements will be small because in most instances the desired results can be achieved through the nursing home survey and inspection processes. (See pp. 21, 58, and 61.)

5. What will be the probable effect of the additional standards or conditions?

The greatest impact of the additional standards should be on the ICF program because ICFs will be subject to some new requirements. We believe that the new requirements generally should result in better care for both ICF and SNF patients, if nursing homes comply with the requirements. Historically, however, some facilities have not complied with requirements. (See p. 22 and ch. 4.)

6. To what extent could the proposed regulations result in reduced protections for nursing home patients?

The proposed regulations should not result in reduced protections for nursing home patients. In fact, new requirements in such areas as patient rights and patient care management are designed to increase protection. (See p. 52.)

7. Are the regulations being simplified and made more readable from GAO's point of view?

We believe that the proposed conditions are more readable and somewhat more simplified than those currently in effect. (See p. 21.)



8. Will the standards likely result in saving taxpayers' dollars at either the State or Federal level? What ballpark figure do you project for such savings? What changes are responsible for these savings?

Neither HHS nor the nursing home industry believes the proposed conditions will save money at either the State or Federal level because requirements are being increased. We believe that the HHS estimate of increased annual cost of \$80 million is too low and that the industry estimate of \$535 million is probably too high. However, both HHS and the industry agree that the most significant cost increases will be incurred in the areas of patients' rights, patient care management, and increased staffing and training requirements. In our opinion, a better cost estimate could be made if information were obtained from State governments on their existing requirements for nursing homes. (See ch. 3.)

9. Will these new regulations significantly shift enforcement attention from "paper compliance" to greater emphasis on patient care?

Some portions of the proposed regulations, such as patient care management and utilization of consultants, are aimed at shifting enforcement attention from "paper compliance" to outcome-oriented evaluations of the patients' needs and related care. As an adjunct, HHS is also working on various changes in guidelines and aids in an effort to increase the effectiveness of nursing home surveys and inspections and the related corrective actions by the facilities. (See pp. 8 and 10 and ch. 5.)

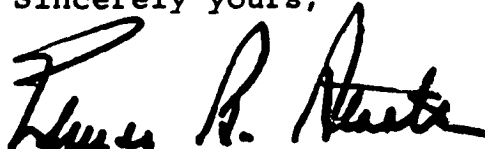
Public Law 96-536, approved December 16, 1980, provides continuing appropriations for HHS through June 5, 1981. Section 119 of the law provides that none of these funds may be used to publish in the Federal Register, or implement or enforce, the proposed July 1980 regulations before the receipt of revised HHS cost estimates and a final draft of this GAO report.

In view of the apparent congressional concern regarding the costs of the proposed regulations, we also reviewed the basis for the HHS January 1981 revised cost estimate pertaining to patients' rights and specifically the proposed requirement for visiting hours which represented the single largest difference between the HHS July 1980 cost estimate and the industry estimate.

This report contains recommendations to the Secretary of HHS. At your request, we did not take the time to obtain official agency comments. However, we have discussed our findings with HHS representatives.

As agreed with your office, we are making a general release of this report to the Congress 1 day after the date of this letter so that the requirements of section 119 of Public Law 96-536 can be met.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Thomas R. Austin". The signature is written in a cursive style with a large initial "T".

Comptroller General  
of the United States

COMPTROLLER GENERAL'S  
REPORT TO THE HOUSE  
SELECT COMMITTEE ON AGING

ANALYSIS OF PROPOSED NEW  
STANDARDS FOR NURSING  
HOMES PARTICIPATING IN  
MEDICARE AND MEDICAID

D I G E S T

At the request of the House Select Committee on Aging, GAO analyzed the impact of changes in nursing home quality of care standards included in a proposed regulation published by the Department of Health and Human Services (HHS). This proposed regulation, published in July 1980, applied to nursing homes participating in Medicare and Medicaid. (See p. 1.) Two types of nursing homes are affected by these changes. One type--called skilled nursing facilities (SNFs)--provides covered care to both Medicare and Medicaid patients. The second type--called intermediate care facilities (ICFs)--provides a slightly lower level of care and participates in only the Medicaid program, which is administered by the States. A third type of home--ICFs for the mentally retarded--is not affected by these proposed changes.

CHANGES WOULD UPGRADE  
REQUIREMENTS IN ICFs

In some instances, both SNFs and ICFs would become subject to additional requirements, but the greatest impact will be on ICFs--either by introducing new requirements to conform to existing SNF requirements or by more explicitly stating existing ICF requirements. The objectives of the new regulations include:

- Elevating patients' rights in SNFs and ICFs to a condition of participation in the programs.
- Introducing a patient care management system aimed at managing the care of the "whole person."

--Upgrading the qualifications of key supervisors employed by the facilities, particularly at ICFs. (See p. 8.)

Compared to existing regulations, the presentation of requirements in the proposed regulation has been improved by consolidation; the use of short, numbered paragraphs or sentences; and the elimination of many cross-references. (See p. 21.)

Although the July 1980 proposed regulations improve the presentation of requirements, the new regulations should establish requirements for supervision of physician extenders which are consistent with the Rural Health Clinic Services Program and clearly state those functions which are the responsibility of the patient with respect to the self-administration of medications. (See p. 22.)

COST TO COMPLY WITH JULY 1980  
PROPOSED REQUIREMENTS  
IS CONTROVERSIAL

HHS estimated that the annual cost to facilities to comply with the July 1980 requirements will be about \$80 million. However, the Department stressed that this estimate was very tentative and that it would be refined based on comments received on the proposed regulations. A study of the proposed regulations commissioned by representatives of the nursing home industry shows that the annual cost of complying with new requirements will be about \$535 million.

Both the HHS and industry cost estimates made many assumptions about the extent that new Federal requirements were truly new requirements for participating facilities. These assumptions were made because neither study group had complete information on what each State may already require of nursing homes in terms of licensing standards or special Medicaid rules pertaining to such matters as patient rights, training of staff, and minimum qualifications requirements for supervisory

Furthermore, the preciseness of any cost estimates and the complexity of translating such costs in terms of the day-to-day operations of nursing homes should be viewed in the context of the \$16 billion nursing home industry. For instance, an increased cost of \$20 million equates to a cost of 5 cents per patient day when spread over the entire nursing home population. (See p. 39.)

COMPLIANCE PROBLEMS COULD MINIMIZE  
EFFECTS OF PROPOSED CHANGES

Historically, nursing home compliance with existing standards and the individual requirements comprising these standards has been spotty. Recent nursing home surveys indicate that many facilities are not complying with certain requirements which will be key components of the proposed Patient Care Management System. To help implement this system, HHS plans to make training aids available for sale to nursing homes. Many homes also are not complying with requirements in such areas as dietetic services, physical environment, and staff training.

HHS attributes at least some of the nursing homes' compliance problems to ambiguity of some requirements in current regulations and to the failure of facilities to employ adequately qualified personnel to supervise such services as dietetics, social services, and patient activities. The Department believes that the proposed regulations will alleviate these problems because requirements are stated more explicitly and because these regulations include (1) qualifications requirements for key positions in ICFs and (2) incentives for both SNFs and ICFs to hire more qualified personnel as supervisors. (See p. 48.)

Although the proposed regulations present the requirements more clearly, GAO has reservations about whether the regulations upgrading the quality of supervisory employees will have

the desired impact in reducing noncompliance because:

--A wide range of expertise is permitted in determining who is "qualified" to fill key supervisory positions, which may result in the degree of upgrading varying greatly among facilities.

--Upgrading of employees does not automatically result in increased compliance, as evidenced by the rates of noncompliance at SNFs, whose regulations now include qualifications requirements. (See p. 52.)

#### HHS PLANS TO IMPROVE COMPLIANCE ENFORCEMENT PROCEDURES

The failure of facilities to comply with requirements demonstrates the need for adequate oversight and enforcement at the Federal and State levels. Past enforcement efforts at the State level--by both State Survey Agencies and State Medicaid Agencies--have been widely criticized. Much of this criticism has been directed at the tendency of State inspectors to determine only "paper compliance" and the frequency with which different inspectors have conflicting findings when inspecting the same facility.

HHS is developing guidelines and aids to help State personnel do a better job in assuring compliance with requirements and facilitating corrective actions.

Because much of the methodology to assist State personnel in performing their evaluations is still being developed and HHS has not made a final decision on the proposals to change oversight requirements, GAO cannot determine whether compliance enforcement will be improved. GAO believes, however, that HHS should modify one of the proposals if it decides to adopt them. (See p. 62.)

staff. Both studies admitted to this shortcoming as well as to a lack of current, valid cost data for some areas of nursing home operations. (See p. 24.)

GAO is unable to determine which estimate is more realistic. HHS did not include estimates for certain new requirements which GAO believes have cost implications. On the other hand, the industry study included estimates for some new requirements not covered by the HHS study. However, about \$290 million of the industry estimate is based on costs to adopt procedures which GAO believes are not absolutely necessary to comply with the proposed requirements.

The principal questionable item in the industry study is the \$184 million cost assigned to the proposed July 1980 requirement that each nursing home have 12-hour visiting days and reasonably open access to the facility and its patients. Although over half of the facilities already have 12-hour visiting days, the industry assumes that certain procedures will be necessary to prove that visiting hours and open access requirements are being met and to maintain some degree of facility security. GAO believes that the procedures proposed by the industry are not necessary to demonstrate compliance with these requirements and that the facility security considerations are not fully attributable to the new requirements. In three States with experience in implementing their own patients' rights laws, State inspection and nursing home association officials agreed with GAO's assessment. (See p. 33.)

The wide variance in costs between the HHS and industry studies emphasizes the need for the Department to obtain information from the States on their current nursing home requirements to adequately refine its estimate and to reconcile differences with the industry estimate. In this regard, section 119 of Public Law 96-536, approved

December 16, 1980, has the effect of requiring the Department to submit revised cost estimates to the Congress before finalizing the July 1980 proposed regulations. (See p. 43.).

In January 1981, HHS developed a new estimate pertaining to the section of the proposed regulations dealing with patients' rights which was the only section in the July 1980 proposed regulations it planned to submit as a final rule, but which has been withdrawn. According to HHS, the remaining portions of the July 1980 proposed regulations require further analysis. The new cost estimate, which features 10-hour visiting days at a cost of \$9.3 million, was \$19.8 million as compared with the earlier estimate of \$15.8 million for this section and the industry estimate of about \$196 million. The industry's estimate included the \$184 million cost assigned to the 12-hour visiting days, and according to HHS, the industry misunderstood this requirement.

GAO reviewed the support for the HHS January 1981 cost estimate relating to the cost of the modified visiting hour requirement because this item represented the largest single difference between the July 1980 HHS and industry estimates. The revised HHS estimate was based on a survey of about 300 nursing homes--six in each State. GAO believes that the assumptions used in developing the HHS estimate were reasonable; however, the HHS sampling methodology does not permit a nationwide statistical projection. (See p. 38.)

Although GAO cannot determine the effect of this flaw in the sampling methodology on the HHS estimate, information obtained in three States with experience in implementing their own patients' rights laws indicated that the cost of the modified Federal visiting hour requirement in these States would be negligible or not measurable. (See p. 43.)



RECOMMENDATIONS TO THE  
SECRETARY OF HHS

As part of the further analysis of the proposed July 1980 standards contemplated by HHS and to clarify new requirements of these proposed regulations, the Secretary of HHS should direct the Administrator of the Health Care Financing Administration to:

- Establish uniform requirements for supervision of physician extenders under the Rural Health Clinic Services and long-term care programs.
- Modify the proposed conditions of participation to clearly define medication self-administration, including those pharmaceutical services standards for which the patients are accepting responsibility.  
(See p. 23.)

Also, to help reconcile the large differences between the July 1980 HHS and nursing home industry estimates of cost to comply with new requirements, the Administrator should require the States to give HHS information on existing State requirements that are comparable to proposed new HHS requirements.  
(See p. 43.)

To facilitate implementation of the Patient Care Management System, the Administrator should distribute guidelines and training aids free of charge to all participating facilities. (See p. 53.)

Regarding proposals to improve general oversight and enforcement of compliance with requirements in the conditions of participation, the Administrator should continue requiring State agencies to determine and report on compliance with individual requirements within a standard, should the Department elect to not cite facilities for noncompliance with requirements below the standard level. (See p. 63.)

At the request of the House Select Committee on Aging, GAO did not take the time to obtain official agency comments. However, the matters covered in the report were discussed with Department officials.

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#### ABBREVIATIONS

AHCA	American Health Care Association
FSES	Fire Safety Evaluation System
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
ICF	intermediate care facility
IOC	Inspection of Care
MCE	medical care evaluation
MMACS	Medicare and Medicaid Automated Certification System
PCMS	Patient Care Management System
PSRO	Professional Standards Review Organization
SNF	skilled nursing facility

## CHAPTER 1

### INTRODUCTION

On July 14, 1980, the Department of Health and Human Services (HHS) 1/ announced that it was proposing to revise current regulations establishing the conditions which skilled nursing facilities (SNFs) and intermediate care facilities (ICFs) must meet in order to participate in Medicare and Medicaid. The proposed revisions are designed to simplify and clarify the regulations, to focus on patient care, to promote cost containment while maintaining quality care, and to achieve more effective compliance.

In response to an April 21, 1980, letter from the Chairman, House Select Committee on Aging (see app. I), we analyzed the proposed regulations to determine what requirements had been added or deleted and to provide information on the possible effects of these changes, including cost implications.

### HISTORY OF CURRENT NURSING HOME REGULATIONS

HHS, on January 17, 1974, published in final form regulations for the SNF and ICF programs. 2/ The SNF standards were effective on February 19, 1974, and the ICF standards on March 18, 1974. These regulations were significant in that they represented the first uniform SNF requirements for both the Medicare and Medicaid programs and the first time that Federal regulations were established for the ICF program. The SNF requirements were developed by the Social Security Administration, the agency responsible for Medicare, and the ICF requirements were developed by the Social and Rehabilitation Service, the agency at the Federal level responsible for Medicaid. In a 1977 reorganization, the Health Care Financing Administration (HCFA) was established and assumed responsibility at the Federal level for both the Medicare and Medicaid programs.

The SNF and ICF requirements are stated in the Code of Federal Regulations. The current SNF requirements are grouped by subject matter, with each group representing a condition

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1/Department of Health, Education, and Welfare before May 4, 1980.

2/Federal Register: SNF, 39 FR 2238; ICF, 39 FR 2223.

of participation. Each condition generally has a series of standards, and each standard may be comprised of two or more elements. Because ICF care is not covered by Medicare, the ICF program does not have conditions of participation--the current requirements are stated as a series of standards, and some of the standards are comprised of two or more elements.

There have been some revisions to SNF conditions and ICF standards since 1974. None of these changes substantially changed the substance of the requirements. 1/ The following recodifications of the Code of Federal Regulations dealing with nursing home requirements have also occurred since 1974.

September 1977: The reorganization of HHS that established HCFA resulted in the following:

--SNF conditions were transferred from title 20, section 405, subpart K, to title 42, section 405, subpart K.

--ICF standards were transferred from title 45, section 249.12, to title 42, section 449.12.

September 1978: The ICF standards were "reorganized and redesignated" to make them more readable. 2/ (title 42, part 442, subpart F)

Also in 1978, 3/ HHS published in the Federal Register a notice of its intent to make changes in SNF and ICF requirements and invited public comments. HHS also held public hearings on these proposals in Rockville, Maryland; Washington, D.C.; Atlanta; Chicago; and San Francisco between June and August 1978, and the comments received at the hearings and by mail were considered in drafting the proposed July 1980 regulations.

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1/A Medical director requirement (42 CFR 405.1122) was added to the SNF program in October 1974.

2/These changes were made as part of the Department's "Operation Common Sense," which was intended to rewrite regulations in clearer, simpler language. The public notice (43 FR 45176, Sept. 29, 1978) included a certification that no substantive change had been made.

3/43 FR 24873, dated June 8, 1978.

According to the preamble accompanying the July 1980 proposed regulations, HHS' decision to issue the revised requirements was based on the following:

- It was committed to revising and recodifying its regulations to produce clear, readable, and helpful documents.
- It wanted to incorporate a patient care management system into the requirements.
- Existing regulations warranted review and appropriate revisions in light of new technology and new developments in the field of aging.

#### STATE ROLE IN NURSING HOME PROGRAM

The States have an important role in the administration of the nursing home program which involves two basic and sometimes overlapping functions:

- Inspecting and certifying facilities to participate in Medicare and Medicaid.
- Exercising controls over utilization under Medicaid.

#### State Survey Agency

By law and regulation, HHS delegates to the State Survey Agency--usually the health department--the responsibility for determining whether SNFs and ICFs meet program requirements. Homes found to be in compliance with the requirements are certified for continuance in the Medicare and Medicaid programs. The Survey Agency provides homes found not in compliance with a list of deficiencies that must be corrected in order to obtain or maintain certification. These homes must develop a plan for correcting the deficiencies cited, and the State agency is supposed to follow up to assure that corrective action is taken. The survey and certification program is not designed to eliminate providers from the programs but to identify those with deficiencies and to help them meet requirements through implementation of the corrective action plan.

The surveys must be conducted at least annually. HHS regulations do not specify the types of disciplines that make up the survey teams. Generally, however, at least two disciplines are represented--registered nurses and either an

engineer or a fire marshal. Other disciplines that may be represented on the team include physicians, pharmacists, dietitians, therapists, social workers, and administrative specialists.

Although the State Survey Agencies perform the surveys, HHS maintains oversight by making field visits to examine aspects of State agency management and by making independent surveys of facilities recently inspected by the State and comparing results. HHS has also developed the Medicare and Medicaid Automated Certification System (MMACS), which permits the Department to readily determine which requirements are not being met and the States where the compliance problems are occurring. It also permits HHS to ascertain such things as those facilities which have not been certified or re-certified timely and the recent history of a facility in meeting requirements.

HHS also gives the State Survey Agencies guidance, including:

- Standard form checksheets cross-referenced to the SNF and ICF requirements.
- Other standard forms used as input to the MMACS.
- Interpretive Guidelines and Survey Procedures.
- A basic health facility surveyor training course which HHS recommends that all surveyors attend.
- A State operations manual for guidance of the State Survey Agency.

#### State Medicaid Agency

By law and regulations, the State Medicaid Agency-- usually the welfare department--is responsible for utilization control. <sup>1/</sup> As part of its responsibility for utilization control, the Medicaid Agency must assure that procedures are followed to

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<sup>1/</sup>Legislation relating to the Professional Standards Review Organizations (PSROs) specifies that the Medicaid Agency may be exempted from responsibility for utilization control at homes where PSROs review care.



- review the need for admissions and the level of care,
- review the need for continued stay of patients in the facility for extended times,
- analyze patterns of care and quality of care,
- verify that a physician initially certifies the need for care and recertifies this need at least every 60 days thereafter, and
- verify that services were provided under a plan of care established and periodically reviewed and evaluated by a physician.

The State Medicaid Agency also must at least annually conduct Inspection of Care (IOC) reviews in each facility. These inspections must include a review of the care provided to each Medicaid patient.

The IOC reviews are intended to determine whether:

1. The services available in the facility are adequate to

- meet the health needs of each recipient and the rehabilitative and social needs of each recipient in an ICF and
- promote each recipient's maximum physical, mental, and psychosocial functioning.

2. It is necessary and desirable for the recipient to remain in the facility.

3. It is feasible to meet the recipient's health needs--and in an ICF, the recipient's rehabilitative needs--through alternative institutional or noninstitutional services.

4. Each recipient in an institution for the mentally retarded, or persons with related conditions, is receiving "active treatment" as defined in HHS regulations.

The law requires that HHS perform timely onsite validations at the State Medicaid Agency or nursing homes to establish whether the State is meeting its utilization control responsibilities. HHS is required to assess financial penalties where utilization control requirements are not met.

HHS has provided some guidance to State Medicaid Agencies for performing IOCs; however, it has been much more limited than the assistance under the survey program. The guidance basically consists of:

--A guideline issued in 1972 for making inspections at SNFs. 1/

--Utilization control regulations which include a section on IOC (42 CFR 456, subpart I).

Unlike regulations for the survey program, HHS regulations specify makeup of the IOC teams. The teams must include a registered nurse and a social worker and a physician must be available for consultation as needed.

#### OBJECTIVES, SCOPE, AND METHODOLOGY

In accordance with the request of the House Select Committee on Aging, our objectives were to determine the changes in requirements--both additions and deletions--which would result from the revised regulations and to assess the possible impact of these changes, including any cost savings (see app. I).

Consequently, our review consisted primarily of comparing requirements stated in the current SNF conditions of participation and ICF standards to those in the proposed conditions of participation; reviewing a draft regulatory impact analysis prepared by HHS, which included estimates of cost to meet new requirements; and interviewing HHS officials to obtain clarification of the intent of the new regulations and the basis of certain assumptions made in developing the impact analysis.

We also obtained information on the recent history of facility compliance with current nursing home regulations; determined HHS plans to change and improve State oversight processes and procedures; reviewed data regarding the use of physician extenders, including a study prepared by the Congressional Budget Office; and analyzed a nursing home industry study of the economic impact of the proposed regulations.

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1/"Medical Assistance Manual: Medical Review in Skilled Nursing Homes and Mental Hospitals" (MSA-PRG-25, 11/13/72).

It should be noted that neither HHS nor the nursing home industry had firm data on which to base estimates of cost in complying with some new requirements. In fact, a significant data problem encountered by both organizations involved estimating the extent to which new Federal requirements actually represent new requirements for nursing homes because current requirements of all States were not known. Accordingly, we reviewed the comments received from the States to determine the extent that the States had provided information on this issue during the public comment period.

In January 1981, HHS developed a new cost estimate pertaining to the section of the proposed regulations dealing with patient rights which was the only provision in the July 1980 proposed regulations it planned to submit as a final rule. We reviewed the assumptions and related support for the revised estimate and visited two States (Florida and Connecticut) that have had patient right statutes since 1975 and 1976 and have periodically amended them and one State (Oklahoma) that in 1980 passed a comprehensive bill on nursing home standards, including patient rights, in order to obtain the States' input as the probable cost impact of the January 1981 proposal.

## CHAPTER 2

### ANALYSIS OF CHANGES IN REQUIREMENTS

HHS contends that the proposed single set of conditions of participation for both SNFs and ICFs does not result in "watering down" current SNF regulations--that the net effect is to tighten wording and make ICF requirements more specific than in existing standards. We generally concur with HHS' conclusions.

Our analysis indicated that, while SNFs will become subject to some additional requirements, the greatest impact will be on ICFs--either in introducing new requirements or in more explicitly stating existing requirements. In a few instances, current requirements will either be deleted or relaxed. According to HHS officials, those requirements either are unnecessarily burdensome or are not effective in achieving the desired results. In our opinion, the proposed changes in requirements are consistent with appropriate laws and regulations. We also believe that the proposed conditions are more readable and somewhat more simplified than those currently in effect.

The July 1980 proposed regulations state requirements under 18 conditions of participation. We compared the SNF and ICF requirements under current regulations to requirements in the proposed conditions of participation. Because of the volume of changes, the results of this comparison are detailed in appendix II. In this chapter, we focus on the changes involving issues that have been of continuing concern to the Congress, the public, and the nursing home industry.

HHS claims that the proposed conditions contain two significant innovations:

- Elevating patient' rights to condition of participation status. HHS hopes that this increased visibility will improve enforcement of patient rights as part of the survey process.
- Introduction of a Patient Care Management System (PCMS). HHS hopes this system will eliminate the fragmented approach to patient care and facilitate treatment of the whole person.

According to HHS, the patient rights section primarily consists of a reaffirmation of the patients' constitutional and legal rights. PCMS primarily consists of consolidating various existing requirements stated in current SNF and ICF standards or in Medicaid utilization control regulations applicable to nursing homes.

EFFECT OF JULY 1980 PROPOSED REGULATIONS  
ON ISSUES OF CONTINUING CONCERN

Some nursing home issues are of longstanding concern. Various reports, such as a 1974-1975 Senate Special Committee on Aging series of reports on nursing home care in the United States 1/ and a 1975 HHS report on its nationwide study of randomly selected SNFs, 2/ discuss various problem areas in nursing home care, including personnel qualifications and training, facility staffing requirements, physician services, administration and monitoring of medications, 3/ and fire safety.

The problems within these areas included overreliance on poorly educated and inexperienced nurses aides and orderlies; lack of continuing education programs for all staff; need for additional qualified staff in such fields as dietetics, social services and patient activities; need for minimum nurse-to-patient ratios; adverse effect on medical and nursing care resulting from physicians' inattention; drug administration errors and undetected adverse drug reactions resulting from allowing untrained or unlicensed personnel to distribute medications; and failure to adequately enforce fire safety standards and lack of uniform interpretation of those standards. The following sections discuss how the proposed conditions deal with these concerns.

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1/"Nursing Home Care in the United States: Failure in Public Policy." Senate Special Committee on Aging, Subcommittee on Long Term Care. Introductory report and various supporting papers dated December 1974 through September 1975.

2/"Long Term Care Facility Improvement Study: Introductory Report." Department of Health, Education, and Welfare (now HHS). July 1975.

3/We recently reported that problems still exist in monitoring patient drugs. See "Problems Remain in Reviews of Medicaid-Financed Drug Therapy in Nursing Homes." (HRD-80-56, June 25, 1980).

## Personnel qualifications and training

The proposed conditions of participation:

- Provide more specific requirements regarding qualifications of personnel directing various nonnursing services in ICFs.
- Permit phasing-out of consultant use in certain non-nursing services.
- Establish minimum initial training hours for newly employed nurses aides and orderlies.

The current SNF regulations require that certain non-nursing services--medical records, food and nutrition services, 1/ rehabilitative services, social services, and patient activities--be directed by employees having the appropriate qualifications or that the facility have a contract with a qualified consultant to assure that the services meet the requirements stated in the conditions of participation. The regulations also contain specific requirements regarding the qualifications for each position. Current ICF regulations also require use of qualified personnel--either employees or consultants--for all of the above services except medical records. However, ICF regulations include specific qualifications requirements only for rehabilitative services. Under the proposed conditions, ICFs would be required to have a director of medical records. ICFs would also be required to employ, or retain as consultants, persons meeting the same qualifications applicable to SNFs for each of the above services.

The current SNF and ICF regulations also require facilities to retain the consultants in the applicable nonnursing services for whatever duration these services are not directed by a qualified employee. The proposed conditions would permit nursing home administrators some latitude in the use of consultants for four of these services--medical records, dietetics, social services, and patient activities.

This provision has been added because of HHS concern that the use of consultants had inadvertently created a subsidiary of the long-term care industry. According to HHS, consultants were intended to be backup resources for

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1/Referred to hereafter as dietetics.

full-time staff, who lacked the required training, education, and experience. However, the Department believes that what resulted instead was continued use of unqualified staff and a near total dependency on the consultant for professional judgment and the performance of routine activities that the facility should have the in-house capability to perform.

We asked HHS officials why this problem was not solved by merely requiring facilities to employ persons meeting the specified qualifications and abolishing the use of consultants. According to HHS representatives, that option was rejected because of the potential cost and because persons not having formal education or training have shown the capability to direct the various services in accordance with requirements after receiving some initial assistance by consultants. The Department also questioned whether facilities in manpower shortage areas could realistically be expected to hire and retain full-time employees meeting the qualification requirements for each service. The potential cost impact of the proposed changes in use of consultants is discussed in chapter 3.

The proposed conditions will also require that personnel who provide direct patient care, but who are not required to be licensed, registered, or certified, must receive at least 30 hours of training from a physician or registered or licensed nurse within 30 days following employment. This requirement is directed at nurses aides and orderlies, who according to HHS, provide between 80 and 90 percent of the care in nursing homes. The Department cites studies showing that most of these employees have little or no previous experience or formal training and that such training is critical in reducing turnover and assuring good performance. HHS plans to make available various curriculum guides to help nursing homes develop training programs. The proposed conditions also require each facility to provide for continuing education and training to develop the skills of most nursing home personnel. Current SNF and ICF regulations include a similar requirement.

#### Staffing requirements

The proposed conditions of participation:

--Delete the minimum weekly consultation time for registered nurses at ICFs.

- Continue to permit the waiver of the 7-day-per-week registered nurse supervision requirement at SNFs.
- Do not require minimum nurse-to-patient ratios or minimum nursing hours per patient day.
- Place certain restrictions on the use of pool nurses. 1/

The proposed conditions require that ICFs which do not employ a registered nurse as director of nursing must have a formal contract with a registered nurse to provide consultant services "at least weekly." The current ICF regulations contain a similar requirement except that it specified the consultation must be at least 4 hours per week. HHS deleted the 4-hour requirement as part of its effort to reduce dependency on consultants. As with other types of consultants, the Department believes that instances of inadequate registered nurse consultations will be identified through the survey process.

The proposed conditions continue to permit waiver of the 7-day-per-week registered nurse supervision requirement at SNFs.

Neither the proposed conditions nor the current SNF and ICF regulations specify any minimum nurse-to-patient ratios or minimum nursing hours per patient day. According to HHS, minimum ratios or hours may still be added but a final decision has been deferred pending a study of the experiences of those States having such requirements. The Department hopes to have this study completed before the effective date of the proposed regulations.

The Department also considered banning the use of pool nurses. Although no final decision has been made, the proposed conditions specify only that these nurses cannot serve as charge nurse on the day shift or as director of nursing.

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1/Nurses supplied by entities to facilities on a temporary basis.



Extent and frequency of  
physicians' services

The proposed conditions of participation:

- Establish maximum time limits between physician visits to ICF patients.
- Permit physicians more latitude in establishing patient visit frequencies without justifying these actions.
- Allow the use of physician-directed physician extenders to provide services where permitted, and in the scope authorized, by State law (Medicaid only). The regulations do not provide for onsite supervision by physicians, which we believe should be a requirement.
- Require attending physicians to adhere to standard operating procedures developed by the facility.

The proposed conditions require attending physicians to visit all patients at least every 30 days for the first 90 days after admission. After the 90th day, the physician must visit SNF patients at least every 60 days and ICF patients at least every 120 days. The required frequency of visits for SNF patients is the same as cited in current SNF regulations. However, the current SNF regulations require physicians to document reasons why any patients are not seen every 30 days, and these justifications are to be reviewed by the facility utilization review committee and by the State Medicaid Agency if the patient is a program recipient. The proposed conditions do not require a justification or independent review. An HHS official told us that the independent review requirement was deleted as ineffective because the revised visit schedules generally are automatically approved.

Current ICF regulations generally set no maximum time intervals for visits, specifying only that the physician either visit the patient every 60 days or justify in the medical record why this frequency is not necessary. 1/

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1/Some State Medicaid Agencies have set maximum time intervals for visits to ICF patients. For example, Kansas requires a visit at least every 6 months and California at least every 90 days.

The current ICF regulations do not require an independent review of this justification, and neither a justification nor related independent review is required by the proposed conditions.

The proposed conditions do require attending physicians for both SNF and ICF patients to record an intended visit schedule in the patient's medical record. An HHS official told us that, while the proposed conditions allow visit frequencies to be based more on the attending physician's medical judgment, increased emphasis will be placed on enforcing visit frequencies as part of the State survey process.

The proposed conditions also permit physician-directed physician extenders--physicians' assistants and nurse practitioners--to provide physicians' services where permitted, and in the scope authorized, by State law. 1/ As of 1979, 43 States had laws permitting the use of physician extenders. According to a 1978 study funded by HHS, most of the States allowed the physicians to establish the scope of services that the extenders could provide. The extent of the supervision required by State law varied from requiring "over the shoulder" supervision to telephone consultations as needed.

HHS included physician extenders in the proposed conditions because of the many favorable public comments that were received when this proposition was included in the 1978 agenda for public comment. The use of physician extenders was also recommended in a 1975 report issued by the Senate Special Committee on Aging. 2/

The Department is deferring to State law with regard to any limits on the services that the extenders can provide and the extent of physician supervision. With regard to the latter, the conditions state that "Direction need not be on-site." This position on supervision is different from that set out in regulations regarding Rural Health Clinic

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1/This applies only to the Medicaid program because Federal Medicare statutes permit direct reimbursement for physician extenders only in the Rural Health Clinic Services program.

2/"Nursing Home Care in the United States: Failure in Public Policy." Supporting Paper No. 3. "Doctors in Nursing Homes: The Shunned Responsibility," February 1975.

Services, which requires that the physician periodically visit the clinics and perform such supervisory functions as review of patient records. 1/ We believe that the use of physician extenders in nursing homes presents a situation comparable to that existing in the Rural Health Clinic Services program. Therefore, HHS should establish consistent requirements for supervision of physician extenders.

In the related issue of quality of care provided by physician extenders, a 1979 report by the Congressional Budget Office 2/ stated that various studies had concluded that the medical care provided by physician extenders compared favorably with that delivered by physicians for medical conditions for which physician extender care is thought to be appropriate. The areas in which extenders were rated as performing as well as physicians included proper diagnoses, management of "indicator" medical conditions, 3/ frequency of patient hospitalization, manner of drug prescription, documentation of medical findings, and patient satisfaction. The report also stated that physician extenders appeared to spend more time with their patients than physicians do.

The proposed conditions would continue the requirement that SNFs have a medical director. The conditions would also retain provisions in current SNF regulations for waiver of the requirement in areas with physician shortages if the facility has made a good faith effort to secure a medical director. The Department found in analyzing comments to the 1978 proposals that many respondents favored retaining this position because it filled the void caused by medical abandonment of patients by the attending physicians.

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1/42 CFR 481. These regulations do not specifically require over the shoulder supervision.

2/"Physician Extenders: Their Current and Future Role in Medical Care Delivery," April 1979.

3/An indicator condition is a distinct disease, symptom state, or injury occurring frequently in primary care with an outcome that can be influenced favorably or negatively by choice of treatment and for which diagnostic and therapeutic procedures are well established.

An HHS representative stated that the medical director requirement was not extended to ICFs because the costs appeared to outweigh the benefits and because many of the ICFs are located in rural areas where it would be difficult to retain a physician in that capacity. The proposed conditions also contain a requirement that, in ICFs, the administrator and director of nursing establish standard operating procedures for physician practices, which attending physicians will be expected to follow.

#### Administration and monitoring of medications

The proposed conditions of participation:

- Continue to permit unlicensed personnel to administer medications where permitted by State law.
- Require registered pharmacists to monthly review the medications of ICF patients as well as SNF patients.
- Require that patients be allowed to self-administer medications unless specifically prohibited by the attending physician. The regulations do not define self-administration or clearly state the functions (e.g., storage, recordkeeping) that are the responsibility of the patient. We believe the regulations should address these issues.
- Establish tolerance limits for various aspects of drug management, including drug administration errors.

The current SNF and ICF regulations permit nonlicensed personnel to administer medications if the individual has completed a State-approved training program in medication administration. The proposed conditions will continue this requirement. HHS considered requiring medications to be administered by licensed personnel but decided against it for the following reasons.

- The requirement would be contrary to State law where nonlicensed personnel are permitted to administer medications.
- The projected additional annual cost to the nursing home program (about \$35 million).
- Proposed requirements and current technology were considered adequate to assure patient safety.

HHS perceives a twofold problem on patient medications-- (1) assuring that drugs are properly administered and (2) detecting drug reactions. The proposed conditions provide for tolerance limits on the rate of drug administration errors (5 percent). The Department has also recently devised and field tested standard procedures for determining whether drugs are properly administered. HHS believes that these factors, coupled with the advent of the unit dose system 1/ and appropriate supervision by the director of nursing, should provide adequate assurance that nonlicensed personnel will properly administer drugs.

In HHS' opinion, the critical element, therefore, is whether the medication aides are trained to recognize drug reactions. The Department found that the curriculum of most State-approved medication aide training programs includes drug reactions. It concluded that this training, along with supervision of the aides by a licensed nurse, should provide adequate assurance that drug reactions will be detected. 2/

The proposed conditions also contain a provision not included in current SNF and ICF regulations which could decrease the nursing homes' responsibility for drug administration. The proposed nursing services conditions specify that patients must be allowed to self-administer medications unless prohibited in writing by the attending physician. The proposed conditions do not include a definition of self-administration or specify which functions or related standards (e.g., storage, recordkeeping) are not applicable if the patient assumes responsibility for drug administration. Since the nursing homes normally are held accountable for meeting all pharmaceutical service standards, we believe the

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1/In unit dose systems, the pharmacy prepares a tray or other container with each patient's drugs. Each dose is individually packaged and marked; the package is not opened until the dose is to be taken. The pharmacist, rather than the nursing staff, is responsible for checking the drugs against the physician's orders. HHS does not have any information on how many nursing homes are using the unit dose system.

2/State agency surveys indicate that some facilities are allowing aides who have not taken this training to administer medications.

conditions should contain a definition of self-administration which clearly states those functions that are the patients' responsibility.

The proposed conditions also require that a registered pharmacist monthly review each ICF patient's medications. Current SNF regulations require this review, whereas current ICF regulations specify that the review be made by a registered nurse. HHS made the change both because research has shown that medication reviews by clinical pharmacists can make a positive impact and because it will free consultant registered nurses in ICFs to take an active part in patient care management activities.

The proposed conditions do not include a qualifications requirement for the pharmacist position. The current SNF regulations include a qualifications requirement which specifies that the pharmacist have training or experience in the specialized functions of institutional pharmacy. HHS does not believe it is necessary to include a training or experience requirement for this position. According to an HHS representative, the key question is whether the pharmacist's performance is adequate. If the survey process discloses that it is not adequate, HHS will expect the facility to take appropriate action.

The proposed conditions also do not include a definition of the required scope of a medication review or provisions to limit the circumstances under which the pharmacist who supplies drugs to nursing home patients will be allowed to review the medications of those patients. We recommended in a June 1980 report 1/ that HHS define the scope of medication review and take action to prevent potential conflicts of interest. In response to these recommendations, the Secretary of HHS stated that:

--It is inappropriate to define the required scope of review in the regulations but that guidelines HHS is preparing for use by State surveyors in determining nursing home compliance with the regulations will include directions in the assessment of medication reviews.

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1/See footnote 3, p. 9.

- Barring pharmacists from acting as both vendor and reviewer of patients' drugs could significantly increase program costs for medication review and this cost is not justified in the absence of any evidence that abuses are occurring.

### Fire safety

The proposed conditions of participation:

- Increase maximum waiver periods on noncompliance with construction-type requirements from 1 to 5 years.
- Increase maximum waiver periods on noncompliance with construction features requirements from 1 to 2 years.

Current SNF and ICF regulations require that facilities meet requirements in the Life Safety Code of the National Fire Protection Association. These regulations also provide for waivers of specific requirements by the Secretary or the State Survey Agency if (1) the waiver would not adversely affect the health and safety of the residents and (2) rigid application of the requirements would result in unreasonable hardship for the facility. HHS guidelines specify the circumstances under which waivers may be granted.

At present, only 1-year waivers are granted for deviations from the Life Safety Code for construction types (e.g., brick or frame, one-story or two-story) and construction features (e.g., width of corridor and doors). HHS proposes to increase the waiver periods to 5 years for construction types and 2 years for construction features with the stipulation that any changes in building construction or renovations would call for complete reevaluation of the waivers.

The change was intended to decrease the number of waivers, which HHS estimates are currently granted to about 21 percent of SNFs and 35 percent of ICFs. The Department believes that the current 1-year waiver policy has compounded paperwork for surveyors and facilities, because a yearly justification was needed. The construction types and features were selected for longer waiver periods because neither usually changes once evaluated.

In a separate but related action, HHS announced in July 1980 1/ that it had adopted the Fire Safety Evaluation System (FSES) as a means of evaluating alternative arrangements for achieving compliance with the Life Safety Code. FSES was developed at HHS' request by the National Bureau of Standards, Department of Commerce. Surveyors will continue to inspect each facility using Life Safety Code 2/ requirements. When a facility does not meet a requirement, FSES will be used to measure whether other fire safety systems and arrangements, which are in place or which could be installed, provide protection equivalent to that required in the code.

If the alternative systems and arrangements in place are equivalent, the Survey Agency can consider the requirements of the code to be met and a waiver is not required. If the alternative systems and arrangements are not in place or are not equivalent to the code, waivers will be required when justified. In the latter instance, FSES can be of valuable assistance to the facility because it may indicate one or more options which can be selected to achieve equivalence with code requirements.

According to HHS, the two chief advantages of FSES are that it:

- Provides a series of options to the facility in developing the least costly and most appropriate corrective action to meet or exceed the level of fire safety required by the Life Safety Code.
- Reduces paperwork by eliminating the need to issue waivers to facilities having alternative features providing equivalency to code requirements.

In July 1980, 3/ HHS also issued a notice of proposed rulemaking which would require automatic sprinkler systems in SNFs and ICFs constructed in the future. Public comments previously received by HHS on this issue raised questions as to the cost effectiveness of this requirement because many

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1/Federal Register, 45 FR 50264, July 28, 1980.

2/The proposed conditions generally require SNFs and ICFs to meet the 1973 edition of the code.

3/Federal Register, 45 FR 50268, July 28, 1980.



experts believe the systems are effective only against multiple death fires, which occur much less often than single death fires. 1/

#### Other changes in requirements

The proposed conditions delete two requirements included in current SNF regulations, although as of September 1980 HHS ostensibly had not made a final decision as to whether such action is desirable. As discussed in chapter 5 of this report, both requirements were included in proposed changes in the oversight process on which HHS recently conducted public hearings. The two deleted requirements are:

--SNFs must perform medical care evaluation studies as part of utilization review.

--SNFs must submit quarterly staffing data to the State Survey Agency.

According to an HHS official involved in analyzing proposed changes to the oversight process, no final decisions will be made on these matters until early 1981.

#### IMPROVEMENTS IN PRESENTATION OF REQUIREMENTS

The July 1980 proposed conditions are generally more readable and somewhat more simplified than those regulations currently in effect, particularly the SNF regulations. Some improvement in ICF regulations had been made in 1978, when HHS "reorganized and redesignated" them. At that time, HHS rearranged the requirements by subject matter and set out the individual requirements under each subject in a series of short, numbered sentences or paragraphs. However, many of the requirements in this regulation lacked specificity. The current SNF regulations also have requirements grouped by subject matter. However, the regulations generally consist of a series of long paragraphs containing multiple requirements, making individual requirements difficult to identify. The current SNF regulations also contain many

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1/We reported in 1976 that the National Fire Protection Association found no record of a multiple death fire in any nursing home fully protected with an automatic sprinkler system. "Federal Fire Safety Requirements Do Not Insure Life Safety in Nursing Homes" (MWD-76-136, June 3, 1976).

cross-references to other requirements, forcing the reader to flip back and forth to fully understand the requirement.

In contrast, the July 1980 proposed conditions are grouped by subject matter, and individual requirements under each subject are presented in a series of short, numbered sentences or paragraphs. We believe this technique visually highlights the requirements and allows the reader to more readily absorb them. The proposed conditions also state the requirements for ICFs more explicitly. It also appears that requirements are better grouped by subject matter and that use of cross-references to related requirements has been reduced. These improvements, along with combining SNF and ICF standards in one regulation, should make it easier for nursing home officials and personnel to understand the requirements for each level of care.

### CONCLUSIONS

The major effect of the proposed conditions of participation is to bring ICF requirements in line with SNF requirements. In our opinion, neither SNF or ICF requirements are being "watered down." Although some current requirements are being deleted, none appeared to have had substantial impact on nursing home operations in the past. On the other hand, additions to requirements could have significant impact on the quality of care and the rights of the patient, and the ICF program should be generally strengthened. HHS may add additional requirements to the regulations. No final decision has been made on two issues--minimum nursing staffing and nursing pools. We believe that the proposed conditions are generally more readable and somewhat more simplified than the current separate regulations for SNFs and ICFs. In our opinion, the proposed changes in requirements are consistent with appropriate laws and regulations.

While we generally do not disagree with the proposed conditions, we believe that in further analyzing them HHS should:

- Establish a consistent requirement for supervision of physician extenders in comparable programs, such as the Rural Health Clinic Services program and the long-term care program.
- Clearly define medication self-administration, including those functions and standards which are the responsibility of the patient because the nursing homes normally are held accountable for meeting all pharmaceutical services standards.

RECOMMENDATIONS TO  
THE SECRETARY OF HHS

We recommend that the Secretary direct the Administrator of HCFA to:

- Establish uniform requirements for supervision of physician extenders under the Rural Health Clinic Services and long-term care programs.
- Modify the proposed conditions of participation to clearly define medication self-administration, including those pharmaceutical services standards for which the patients are accepting responsibility.

### CHAPTER 3

#### NEW REQUIREMENTS WILL INCREASE

##### PROGRAM COSTS

The proposed regulations will not result in a net savings at the State or Federal level. In fact, HHS estimated that the increased cost of complying with the July 1980 requirements would be about \$80 million per year. We believe that the Department's estimate is understated because it did not include the increased costs for some changes in requirements and because some of the assumptions made, such as the low number of patient assessments to be performed under PCMS, do not appear to be valid. The Department does not have firm data on which to base cost estimates in most areas and hoped to revise the estimates based on input received from the public during the comment period, which was scheduled to end on October 14, 1980. In this regard, a September 1980 study prepared for the American Health Care Association and the National Council of Health Centers estimated that the cost of complying with the July 1980 requirements would be over \$500 million a year. The industry study indicated costs for certain actions (particularly those related to facility visiting hours) that we believe may exceed the new requirements.

Both HHS and the industry were hampered in making their estimates by a lack of data, particularly in the following areas:

- Estimating the extent of impact new requirements would have on facilities. For example, some facilities may already meet certain new requirements because of State regulations or self-imposed policies.
- Such matters as staff and patient turnover, occupancy rates, and current wage rates.

In January 1981, HHS proposed a final rule which included only a modified version of the section of the July 1980 proposed regulations dealing with patients' rights. HHS concluded that the remaining sections of the July 1980 proposals required more analysis. The revised estimated cost of the modified patients' rights section was about \$20 million.

Although the assumptions used by HHS to develop the largest portion of this estimate dealing with visiting hours appears to be reasonable, the sampling methodology used does not permit a reliable nationwide projection. While the effect of the flaw in the sampling methodology is not determinable, our visits to three States with over 1,000 participating nursing homes and which have been involved with implementing patients' rights requirements under their State laws indicated that the probable cost impact of the HHS modified visiting hours requirement in these States would be negligible or not measurable.

In connection with its further analysis of the remaining July 1980 proposals, we believe that HHS would be in a better position to refine its July 1980 estimates or reconcile the differences with the industry estimates if it required each State--both Survey Agency and Medicaid Agency--to give the Department a comparison of the proposed requirements with any existing or proposed State requirements.

HHS COST ESTIMATE FOR THE JULY 1980  
PROPOSED REGULATIONS NEEDS ADJUSTMENTS

HHS' preliminary estimate of the annual cost increase to meet the proposed July 1980 requirements was about \$80 million. <sup>1/</sup> The Department made cost estimates for new requirements in four general categories--patient rights, patient care management, physician involvement, and manpower. The major costs were in patient care management (\$35 million) and manpower (\$27 million). A more detailed breakdown of the HHS estimate is contained in appendix III. In the following sections we briefly discuss each category and our views as to the appropriateness and reasonableness of HHS' assumptions.

Patient rights

HHS estimated that increases in requirements for patients rights would cost about \$15.8 million per year. The Department believed facilities could comply with requirements for 12-hour visiting days and the procedures for use of restraints and involuntary transfers at an additional cost of no more than

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<sup>1/</sup>The estimate was included in a regulatory analysis dated June 30, 1980. The analysis was made pursuant to Executive Order 12044, Improving Government Regulations. This order requires that an analysis be made whenever regulation may have major economic consequences for the general economy, individual industries, geographical regions, or levels of government.

\$6 million. The major item of cost was \$8.8 million to support residents' councils. The estimate was based on the assumption that 30 percent of facilities already have councils and that the other facilities could support patient councils by providing one employee for about 2 hours per week. The 30-percent estimate was based on input from industry and other sources.

Other patient rights requirements which could have cost implications but for which no estimates were made include:

- Dealing with federally funded ombudsmen and with patients' representatives, including providing access to medical records.
- Accommodating and accounting for patients' personal property.

The industry estimate also indicated that these two requirements had cost implications but assigned no specific amounts to them.

#### Patient care management

HHS estimated that increases in requirements for patient care management would cost about \$35 million per year. Almost the entire amount was for staff time to perform patient assessments, which would be required on all new patients with an anticipated length of stay greater than 45 days. Based on field tests of various patient assessment techniques, the Department believed that one of the following techniques would be used: (1) full team assessment--the attending physician, director of nursing, staff nurse, nurses aide, dietitian, social service director, and activities director would meet and jointly review the case--or (2) core team assessment--the above team members provide their input but may accomplish this individually, perhaps during regularly scheduled visits in the case of physicians and consultants. <sup>1/</sup> For estimating purposes, HHS assumed that 10 percent of patients would receive full team assessments and 90 percent core team assessments. The Department computed an average cost based on the following two scenarios.

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<sup>1/</sup>HHS estimated that a full team assessment would require 1 hour's time by each team member and a core team assessment would require from 15 to 30 minutes of each team member's time.

1. One assessment per year on all patients who stay more than 45 days (54 percent of SNF, 65 percent of ICF) assuming 100-percent bed occupancy and no patient turnover--\$19.5 million.
2. One assessment per patient per year based on estimated patient turnover rates and assuming full occupancy--\$48.8 million. 1/

HHS then computed the average of these two estimates to arrive at the \$34.15 million amount included in the overall cost estimate. Our primary question regarding the assumption used is whether it was reasonable to assume that each patient would receive only one assessment per year. The proposed conditions specify that assessments would be redone as dictated by the patient's condition, but not less often than annually. Because the assessments are the basis for developing the plan of care, which must be updated whenever the patient is visited by the physician, we believe it is reasonable to assume that some reassessment will be done at least every 60 days on SNF patients and 120 days on ICF patients. HHS officials agreed with this observation but stated that reassessments may not take as much time. The industry study estimated that about 4.2 million reassessments would be performed in addition to annual assessments and that the annual cost would be about \$12.5 million.

Questions could also be raised about the reasonableness of assuming that only 10 percent of patients will require full team assessments and about HHS' estimates of time required for assessments. For example, selected homes in Maryland which tested an assessment technique found that each professional team member averaged about 1.75 hours per patient to make the assessment and prepare the care plan in the early stages of the test. This time was reduced to about 20 minutes after gaining experience. While the time required to prepare assessments and care plans may decrease with experience, some facilities may have difficulty in achieving this level of proficiency because of staff turnover.

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1/Beds in SNFs certified for Medicare only were not included because data show that these patients' average stay is 24 days. HHS also computed the cost using this scenario but various occupancy rates. For example, at 85-percent occupancy, the estimated cost is \$32.4 million.

HHS officials agreed that our questions on the assumptions made were valid and would be taken into consideration. However, they also pointed out that the estimates included certain assumptions which probably overstated costs and that PCMS has certain cost savings implications which were not used as offsets.

These include the following:

- The costs were computed based on the assumption that facilities currently spend no time making patient assessments. HHS believes that many facilities are performing assessments and that at some of these homes little or no increase in staff time will be required.
- Because PCMS ensures that the patient's medical, physical, and psychosocial needs are identified, interpreted, and met, patients should be maintained at their maximum functional level and some increase in the number of patients discharged may be realized.
- Staff may spend less time in searching patient records because all key data items will be reflected in the assessment and care plan documents rather than scattered throughout the file in such places as daily nursing notes and progress notes. Also, fewer patient forms will probably have to be filled out.
- PCMS could reduce time required for State surveys and IOCs because all important information is concentrated in the assessment and care plan documents.

#### Physician involvement

HHS estimates that increases in requirements for physician services would cost no more than \$2 million per year. The Department used an estimate of \$1 million to reflect possible additional visits by the attending physicians of ICF patients based on the assumption that, while physicians of ICF patients would visit patients at least three times in the first 90 days, they could decrease the frequency of their visits after that period--i.e., from every 60 days to



every 120 days. <sup>1/</sup> HHS assumed no change in frequency of attending physician visits to SNF patients because requirements generally will remain the same.

HHS also used an estimate of \$1 million to cover the time spent by ICF administrators and directors of nursing in developing standard operating procedures to be followed by attending physicians. The Department also considered possible costs savings resulting from the use of physician extenders in lieu of physicians. It concluded, however, that no savings probably would be realized because there would continue to be costs for physician supervision of the extenders in States where this is required. An HHS official also told us that the physician extender provisions were included in the proposed conditions to improve quality of care rather than as a cost-saving tool.

Two questions could be raised on HHS' assumption that frequency of physician visits will not increase appreciably as a result of new requirements.

--Physicians would be required to sign all verbal orders within 5 days. This could result in an increased volume of visits to comply with the requirement.

--HHS estimated that, while visits to ICF patients would increase during the first 90 days, the subsequent frequency would decrease from every 60 to every 120 days, thus causing little net increase. This was based on the assumption that ICF patients now receive visits every 60 days. Although the current ICF regulation states that patients should be visited every 60 days, it also specifies that the physician can visit the patient less frequently when justified. No reliable statistics are available as to the current average frequency of physician visits to ICF patients.

#### Staffing and training requirements

HHS estimated that annual manpower costs resulting from additional staffing and training requirements would be about \$26.6 million. The estimate included the additional salary costs that ICFs, which may not now have qualified patient

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<sup>1/</sup>This cost would be incurred by the Medicare and Medicaid programs but usually would not be part of the nursing home operating cost.

activities directors or dietetic services supervisors, would incur when filling these positions. The balance was HHS' estimate of the cost to SNFs and ICFs for providing 30 hours of initial training to new nurses aides and orderlies.

The Department estimated that it would cost ICFs about \$7.3 million more per year to employ qualified patient activities directors. This was based on the assumption that 50 percent of ICFs already have qualified incumbents, another 25 percent of incumbents will upgrade themselves to meet qualifications, and 25 percent of the facilities will meet the requirement through new hires. The Department estimates that it would cost ICFs about \$9.3 million more per year to employ qualified dietetic services supervisors. This was based on the assumption that 60 percent of ICFs already have qualified incumbents, another 20 percent of incumbents will upgrade themselves, and 20 percent of the facilities would meet the requirement through new hires. The Department also assumed that those incumbents in the above positions who choose to upgrade themselves would do so at their own expense and would not receive additional pay after doing so.

The Department estimated that the initial training for novice nurses aides and orderlies would cost SNFs and ICFs about \$10.1 million more per year. This estimate was based on a turnover rate of 50 percent per year 1/ and assuming (1) about 70 percent of facilities already meet the requirement, (2) about 10 percent of new hires are experienced aides and orderlies, and (3) about 8 hours of the students' time and 19 hours of the instructors' time is nonproductive with respect to patient care or normal duties.

HHS officials told us that estimates of the number of homes having qualified patient activities directors and dietetics supervisors and providing initial training of aides were obtained from industry and other sources and that the accuracy is not known. Aside from questions as to the accuracy of those estimates, we question some of the assumptions made. We believe it is unreasonable to assume that incumbents in the above positions who do not meet the qualifications will upgrade themselves at their own expense or

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1/According to the HHS analysis, various studies have reported the turnover rate to be as high as 75 percent. One study reported that turnover was reduced from 67 percent to 49 percent as a result of a direct training program for aides.

that they will not demand higher pay after improving their qualifications. HHS also did not estimate the cost of (1) converting part-time food service supervisory personnel to full-time employees (\$40.9 million according to industry estimates) and (2) hiring qualified consultants for dietary and patient activities supervisors based on the assumption that most facilities will fill these positions with fully qualified personnel. We believe it is reasonable to assume that at least some ICFs will employ persons who are not fully qualified and thus will need consultation for at least 1 year. The industry estimate assigned about \$4.3 million to dietary and patient activities consultants at ICFs.

We also believe that HHS should have assumed there would be additional costs for the following new staffing requirements.

- Salaries of more qualified persons at ICFs in charge of medical records and social services.
- Podiatrist consultant costs at SNFs and ICFs.
- Dentist consultant costs at ICFs.
- Cost of pharmacist time in reviewing patient medications at ICFs.
- Cost of establishing a pharmaceutical services committee in each ICF.

HHS officials generally concurred with our observations that increased costs would be incurred in meeting the above five requirements. They also stated that additional salary costs for a director of medical records and a social services director had not been computed due to oversight. The industry estimate assigned about \$41.9 million of additional costs to the above items excluding dentist consultants.

INDUSTRY ESTIMATE OF COST OF COMPLIANCE  
WITH THE JULY 1980 REGULATIONS IS  
MUCH HIGHER THAN HHS' ESTIMATE

On September 4, 1980, the American Health Care Association (AHCA) and the National Council of Health Centers--groups representing the nursing home industry--released a study which estimated the annual recurring cost of complying with July 1980 requirements to be about \$534.8 million.

A detailed breakdown of this estimate is shown in appendix IV. The industry study report discusses problems encountered in making cost estimates, including (1) lack of readily available, reliable, and valid data, such as current State-level regulations in each State, (2) uncertainty or lack of consensus by study participants as to what facilities must do in order to comply with some new requirements, and (3) the short time period (i.e., 60 days) available to conduct the study.

The estimate represents costs to the nursing home industry 1/ and does not include any costs that may be incurred by State agencies or by the Medicare and Medicaid programs for additional ancillary services, such as physician visits, which were considered in the HHS estimate. The study report also indicates that the cost estimate would have been higher but that lack of data precluded making some estimates. For example, the cost of the increased qualification requirements for a social services director in SNFs was not computed because of a lack of reliable data on the wage differential between persons holding graduate and undergraduate degrees in social work.

A comparison of the HHS and industry cost estimates showed that the approximately \$455 million variance in estimated annual costs can be accounted for as follows.

	<u>Cost estimate</u>		
	<u>HHS</u>	<u>Industry</u>	<u>Industry variance</u>
	—————(millions)—————		
New requirements for which both studies estimated cost	\$75.5	\$313.9	\$238.4
New requirements for which only HHS estimated costs	4.0	0	(4.0)
New requirements for which only the industry estimated costs	<u>0</u>	<u>220.9</u>	<u>220.9</u>
Total	<u>\$79.5</u>	<u>\$534.8</u>	<u>\$455.3</u>

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1/The study estimates that about \$161 million of the increase will be absorbed by private pay patients.

On those requirements for which both HHS and the industry made cost estimates, the variance (\$238 million) is due to various factors, including differences in assumptions made and use of different data in such matters as number of facilities affected and wage rates. The largest variance involves the estimate of cost to meet requirements for 12-hour visiting days and assuring appropriate access to the nursing home and patients. HHS estimated the cost to be about \$5 million, whereas the industry estimate is about \$185 million.

Costs in the second category above involve four requirements for which the industry did not assume any annual recurring costs. HHS estimated annual costs of \$1 million each for developing patient assessment forms, complying with patient restraint requirements, preparing standard operating procedures for physicians at ICFs, and paying for the increased volume of physician visits to ICF patients.

The costs estimated by the industry to meet requirements for which HHS made no estimates generally are based on assumptions in which we concur, although we are unable to render an opinion as to the amounts involved. Included in this portion of the industry estimates were such matters as periodic reassessments of patients during the course of a year (\$12.5 million), increased wages paid to food service supervisory personnel as a result of converting from part-time to full-time employees (\$40.9 million), and pharmacists' charges for reviewing medications of ICF patients (\$10.1 million). Also included were recurring annual costs for qualified consultants in medical records (\$14 million), social services (\$11.2 million), and dietetics (\$3.8 million), indicating that study participants believe that some facilities would not attain independence from consultants.

However, this portion of the industry estimate includes costs for meeting requirements in two areas--nursing staffing (\$62.7 million) and drug administration (\$48.2 million)--in which we question the validity of assumptions made. We believe that the actions assumed necessary in the industry cost study to meet those two requirements, as well as requirements relating to 12-hour visiting periods and access to nursing homes and patients, are considerably more than would be necessary to meet requirements in the proposed regulations. The following is a discussion of each of the three estimates.

### Twelve-hour visiting periods and access to patients and facilities

The study estimates that, complying with proposed requirements for 12-hour visiting days while protecting patient rights and property, will cost about \$184.9 million per year. The study indicates that about 53 percent of facilities currently have at least a 12-hour daily visiting period. However, the study estimates that about 80 percent of facilities will have to hire receptionists to screen visitors and maintain a register showing visitors' names, dates, and times of visits. The industry believes that these procedures will be needed not only to ensure security but also to have proof that facilities have 12-hour visiting days and are providing required access to patients.

While expanded visiting hours may increase security problems, we believe the need for security is more related to environment and that many of the facilities with a security problem may already have made provisions to deal with it. A spokesman for AHCA stated that many urban facilities have security systems, that facilities in rural areas may not need additional security, and that the greatest need probably will be at suburban facilities.

In our opinion, and HHS agrees, it would not be necessary for facilities to maintain registers to prove 12-hour visiting days or visitor access. Therefore, we question whether it is reasonable to attribute the entire amount in the cost estimate to new requirements because (1) some of the cost of providing security may not be directly related to extension of visiting hours and providing access and (2) maintenance of special records is not required under the proposed conditions. 1/

### Nursing cost

The industry study estimates that, because of restrictions on the use of "pool" nurses, both SNFs and ICFs will have to hire more qualified full-time nursing personnel at an additional annual cost of about \$62.7 million--about \$29.9 million in SNFs and \$32.8 million in ICFs. This

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1/Our view on this issue is discussed in more detail in the section of this chapter dealing with HHS' January 1981 proposed final rule.

assumption was made based on the proposed requirement that "pool" nurses cannot be used to fill the positions of director of nursing or charge nurse on the day shift. According to the study, facilities have been using "pool" nurses to temporarily fill these positions while the director of nursing and charge nurse are on vacation or otherwise absent. Because of this proposed ban, the study estimates that many SNFs will have to replace a licensed nurse with a registered nurse and that many ICFs will have to replace a nurses aide with a licensed nurse in order to provide backup coverage.

As discussed below, the actions proposed by the industry study appear to exceed that required by both current and the July 1980 proposed regulations for SNFs. While it appears that this is also true for ICFs, the proposed regulations regarding nursing supervision need to be clarified by HHS. Briefly, the current and proposed regulations for each type of facility generally require the following.

#### SNFs

Current and proposed:

- A full-time director of nursing who is a registered nurse.
- A charge nurse for each shift who is at least a licensed nurse. 1/
- A registered nurse on duty 7 days a week during the day shift. 2/

#### ICFs

Current:

- A registered or licensed nurse to supervise health services full time, 7 days a week, on the day shift.

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1/A licensed practical nurse or licensed vocational nurse.

2/Waivers can be granted for 2 days of the 7-day period.

Proposed:

--A full-time director of nursing who is a registered or licensed nurse.

--A registered or licensed nurse full time, 7 days a week, on the day shift.

Neither the current nor proposed SNF regulations require that facilities have a substitute director of nursing during short absences, such as vacations or sick days. Also, as shown above, the charge nurse in SNFs does not have to be a registered nurse. Therefore, it is not required for SNFs to have a backup registered nurse to serve temporarily as either director of nursing or charge nurse. With regard to meeting the current and proposed requirement that SNFs have a registered nurse on duty 7 days a week on the day shift, facilities can continue to use "pool" registered nurses provided a staff nurse (e.g., licensed nurse) serves as charge nurse.

The proposed regulations for ICFs do not require facilities to have a substitute director of nursing during short absences. Although the proposed regulations require ICFs to have a licensed nurse on duty 7 days a week on the day shift, it is unclear whether facilities can use "pool" nurses to meet this requirement. The proposed regulations prohibit use of "pool" nurses as charge nurses; however, the regulations (section 483.23(e)) indicate that the charge nurse position applies only to SNFs. We believe that HHS should clarify the regulations regarding use of "pool" nurses in ICFs. However, assuming that the licensed nurse who must be on duty during the day shift cannot be a "pool" nurse, some ICFs may have to hire a backup licensed nurse to meet requirements as was assumed in the industry study.

We also noted that, although the industry study included the cost to upgrade backup nursing positions in SNFs and ICFs, it did not offset this cost with savings that should be realized from decreased use of the reportedly more expensive "pool" nurses. AHCA testimony in August 1980 before the House Select Committee on Aging indicated that member nursing homes were paying premiums for "pool" nurses which were 60 to 100 percent more than the homes paid to permanent staff nursing personnel. Testimony at these hearings by the American Association of Homes for the Aging cited as an example a California facility which was paying a 57-percent



premium for licensed nurses and an 82-percent premium for registered nurses. Based on this testimony, it would appear that the cost of upgrading SNF and ICF nursing positions would be offset by any savings from reduced use of "pool" nurses.

### Drug administration

The industry study estimates that drug administration quality control procedures will cost facilities about \$48 million per year. The study indicates that these procedures will be needed so that facilities can determine whether drug administration error rates and drug discard rates are within tolerance limits specified in the proposed regulations.

Current regulations require both SNFs and ICFs to utilize a registered pharmacist to assist in developing procedures for ordering, storing, administering, and disposing of and accounting for medications. The current SNF regulations are also fairly specific regarding verification of drugs and dosages to physicians' orders, properly recording medications administered, and adequately storing and safeguarding drugs. While current ICF regulations are less explicit in these areas, we believe it is reasonable to assume that at least some SNFs and ICFs already have in effect procedures designed to assure that medications are properly administered and recorded and that drug wastage is held to a minimum.

An ACHA representative told us that, while some facilities may already have procedures to generally determine the drug administration error rates or the discard rates, the low tolerance rates (5 percent and 4 percent) permissible under the proposed regulations would require all facilities to monitor these rates more precisely and that this monitoring would require about 10 hours of clerical time each week.

The proposed July 1980 regulations did not require facilities to make weekly computations of the medication administration error rates and discard rates. These rates were to be computed by State Survey Agency personnel during the annual surveys. As discussed in chapter 5, HHS has been field testing a methodology to be used in computing these rates. While some facilities may choose to initiate detailed, frequently followed procedures to monitor these rates, the establishment of such procedures is not required by the regulations.

HHS REVISED COST ESTIMATES PERTAINING TO  
JANUARY 1981 PATIENTS' RIGHTS PROVISIONS

In January 1981, HHS decided to publish only modified patients' rights provisions from the July 1980 proposed regulations and reserve the remainder of the proposed regulations for further analysis. 1/ HHS estimated that the increased costs of complying with these modified patients' rights provisions would be about \$20 million per year (see app. V)--about \$4 million more than the July 1980 proposed patients' rights provisions. We looked at HHS' method of computing the estimate for the visiting hours standard (\$9.3 million) because the cost of complying with this requirement represented the single largest difference between HHS and industry estimates. 2/ We did not analyze HHS estimates for the other provisions--use of restraints, involuntary transfers, and resident councils--because they were either token amounts or relatively close to the September 1980 nursing home industry cost estimates.

HHS surveyed about 300 nursing homes--6 facilities in each State and the District of Columbia made up of 3 SNFs and 3 ICFs. HHS questioned the facilities' staffs about the extent of their visiting hours and use of receptionists. In developing the estimated cost for 10-hour visiting periods, HHS assumed that

- those facilities not having a receptionist (about 50 percent) would not need to hire one irrespective of their visiting hours,
- those facilities having a receptionist and daily visiting periods of 10 hours or more (about 37.5 percent) would not need to increase their receptionist coverage, and
- those having a receptionist, but less than a 10-hour visiting day (about 12.5 percent) would need to increase their receptionist coverage by the difference between the 10-hour requirement and the average visiting period (6.5 hours)--or 3.5 hours.

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1/On January 19, 1981, the Secretary of HHS approved the modified version, but on January 21, 1981, the Acting Secretary withdrew approval of the rule.

2/The July 1980 proposed regulations and related cost estimates provided for a 12-hour visiting day, whereas the January 1981 modified version provided for a 10-hour visiting day.

We believe these assumptions are reasonable and perhaps conservative, because our analysis of the HHS survey data showed that those facilities in the third category already had receptionists for an average of 8.5 hours, 1/ thus the 3.5-hour variable was overstated. The HHS survey methodology did not, in our view, yield data that could be statistically projected to all facilities nationwide. The facilities were selected and the resulting data extrapolated without regard to the total number of facilities in each State that met HHS' survey criteria.

The ultimate cost impact of this flaw in the sampling methodology on the HHS January 1981 estimate is not determinable, however, it should be recognized that the preciseness of any cost estimate and the complexity of translating such costs in terms of the day-to-day operations of nursing homes should be viewed in the context of the \$16 billion nursing home industry. For example, a \$20 million total increased cost would equate to a cost of 5 cents per patient day when spread over the entire nursing home population.

To obtain additional insight regarding possible cost implications of the January 1981 proposed regulations, we contacted State government and ombudsman officials, and present or past officials of State nursing home associations in Connecticut, Florida, and Oklahoma because these States have had prior or recent experience with their own patients' rights laws. Most officials did not believe that complying with the proposed Federal visiting hour standard would result in increased costs. Many officials questioned the basic premise of the HHS and industry cost estimates for complying with the visiting hour standard. These officials did not believe that the need for receptionists is related to the length of visiting hours. They told us that the need for receptionists is more likely to be based upon the size of the facility or the facility's location.

#### STATE INITIATIVES TO IMPROVE QUALITY OF NURSING HOME CARE

Between April 1979 and October 1, 1980, at least eight States 2/ have enacted legislation aimed at improving the

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1/For those facilities which employ a receptionist for more than 10 hours, we did not include any hours greater than 10 in our analysis.

2/California, Connecticut, Florida, Massachusetts, Oregon, Oklahoma, Tennessee, and Washington.

care provided by SNFs and ICFs. In two of these States (Massachusetts and Washington) the legislation essentially provides penalties for (1) abusing, mistreating, or neglecting patients or (2) failing to report such actions to appropriate authorities. In our view, these laws are not comparable to HHS' proposed new standards and should not affect the costs to implement the standards.

On the other hand, the recent legislation for the other States does include provisions for (1) a bill of rights for patients (four States), (2) resident councils (two States), (3) limits or conditions for involuntary transfers (two States), (4) freedom from physical and chemical restraints (three States), and (5) minimum visiting hours (one State)--all of which are included in HHS' proposed standards and, according to the industry's estimates, have cost implications. Also, the laws for four States authorize implementing regulations which could expand on these and other State provisions that may be comparable to HHS' proposed requirements.

In this regard, HHS had invited the States to comment on the July 1980 proposed regulations where similar requirements were already in effect; however, States were not required to do so. Our review of the States' comments indicated that only one State (Washington) had submitted information systematically showing existing State requirements comparable to the proposed Federal requirements. Washington also indicated that the patients' rights and Patient Care Management System provisions in the proposed July 1980 regulations should not affect providers in the State. Washington State laws already cover most of the patients' rights provisions, according to the State's comments, and the State has required a greater scope of professional assessments than those proposed by HHS in July 1980.

We visited three States (Florida, Connecticut, and Oklahoma) to determine the extent to which the patients' rights provisions of earlier or the more recent State laws and/or regulations meet or exceed those in the proposed Federal regulations for visiting hours, resident councils, restraints, and involuntary transfers (see app. VI). These States have about 1,000 nursing homes (Florida, 350; Connecticut, 281; and Oklahoma, 375) participating in Medicare and/or Medicaid.

Florida and Connecticut have had patients' rights statutes since 1976 and 1975, respectively, and have periodically amended them. Oklahoma's patients' rights legislation became effective in October 1980. Although implementing regulations were proposed in December 1980, they had not become fully

effective as of February 2, 1981, because the legislature in conjunction with the executive branch has agreed to rescind portions of the patients' rights legislation and regulations in view of a projected \$74 million deficit for the Medicaid program.

Florida State officials have not adopted any regulations to implement patients' rights legislation because the language of the statutes is considered to be sufficiently specific. Although Connecticut has adopted regulations to implement patients' rights legislation, the regulations are for the most part no more specific than the language in the statutes.

### Visiting hours

The January 1981 HHS proposed regulations require 10 hours of visiting time per day. Although Florida statutes do not specify a minimum period for visiting hours, Florida State officials believe the visiting hour provisions in its statutes constitute an adequate requirement. The State laws provide for flexible hours giving consideration to out-of-town visitors and working relatives and friends. Furthermore, the Florida Long Term Care Ombudsman Committee reports that inadequate visiting hours have not been a problem in State nursing homes. In fiscal years 1979-80 less than 1 percent of all complaints received by the Committee involved visiting hours.

Connecticut regulations also do not specify a minimum visiting period, but State officials expect to implement new regulations in July 1981 which require no less than 8 hours of visiting time per day. Ombudsman program statistics in Connecticut also indicate that visiting hours under the current regulations have not been a problem. Because an 8-hour visiting standard is already in effect for members of the proprietary nursing home association in Connecticut, State officials do not believe the new State regulation or the proposed 10-hour Federal regulation will have a measurable cost impact on nursing homes.

The proposed Oklahoma regulations are silent on visiting hours; however, State law requires 10 hours of open access to patients for the representatives of certain public organizations. This provision is expected to remain in effect. A Governor's committee established to determine whether changes in the patients' rights statutes or regulations could eliminate cost increases in the Medicaid program indicated that the July 1980 proposed 12-hour Federal requirement would not constitute an additional expense because currently most Oklahoma nursing homes do not limit visiting hours, with the expectation that visitors exercise prudent judgment.

### Resident councils

Florida and Connecticut statutes and the proposed Federal and Oklahoma regulations provide essentially the same right--to join with other patients and work for improvements free from interference. The proposed Federal regulations specify that the facility provide meeting space and assistance to patients in attending meetings.

### Restraints

Each patient shall be free from drugs which limit physical or mental capabilities and physical restraints unless authorized by a physician. This is the basic right granted by the Florida, Connecticut, Oklahoma, and Federal laws or regulations, in force or proposed. Only the Oklahoma and Federal proposed regulations are more specific--both require periodic observation. The January 1981 proposed Federal regulations also require periodic release from physical restraints.

### Involuntary transfers

Although the specifics differ, the Florida, Connecticut, Oklahoma, and Federal laws and regulations, in force or proposed all provide the same right--patients shall be discharged or transferred only for medical reasons or for the welfare of other patients, and reasonable notice must be provided to the patient. Reasonable notice varies for different types of transfer (intra- vs. interfacility) and reasons for transfer (medical vs. nonpayment of bills). Although only the proposed Federal regulations deal with intrafacility transfers, Florida officials believe that the State statutes could be applied to intrafacility transfers if they presented a problem. State officials believe and the Ombudsman complaint statistics indicate that such a problem does not exist.

### CONCLUSIONS

HHS, in estimating the cost impact of the proposed changes, was hampered by a lack of cost and other data on which to base assumptions. Because of this the Department considered the July 1980 estimates to be tentative and planned to make revisions where better data were provided to them or where assumptions made were demonstrated to be inappropriate. While recognizing the caveats placed by HHS on these July 1980 estimates, we believe that costs may be understated because no estimates were made for some new requirements having cost implications and because some of the assumptions made were of questionable validity. A study commissioned by representatives of the nursing home industry indicates the cost could be much more.

A major data problem encountered by both HHS and the nursing home industry in preparing their cost estimates was determining the impact of each new Federal requirement because they did not know whether some States already had regulations with comparable requirements. We believe that HHS would be in a better position to refine its estimates and reconcile the difference with the industry estimate if it required each State--both Survey Agency and Medicaid Agency--to give it information on existing State requirements that are comparable to proposed new HHS requirements. In this regard, section 119 of Public Law 96-536, approved December 16, 1980, has the effect of requiring the Department to submit revised cost estimates to the Congress before finalizing the July 1980 proposed regulations.

In January 1981, HHS complied with this requirement by proposing a final rule which included only a modified version of the section of the July 1980 proposed regulations dealing with patients' rights. The revised estimated cost was about \$20 million, of which \$9.3 million pertained to visiting hours and the need for receptionists. Although the assumptions used by HHS to develop this portion of the nationwide estimate appear reasonable, the sampling methodology used by HHS does not permit such a national projection. While the effect of the flaw in the sampling methodology is not determinable, information obtained in States with experience in implementing patient rights laws indicated that the probable cost impact of the HHS modified visiting hour requirement in these States would be negligible or not measurable. Accordingly, in the absence of empirical evidence to the contrary, we can see no valid objection from a cost standpoint to issuing the January 1981 proposed regulations as a final rule.

#### RECOMENDATION TO THE SECRETARY OF HHS

In connection with the further analysis of the proposed July 1980 standards contemplated by HHS and to help reconcile the large differences between the HHS and nursing home industry estimates of cost to comply with the July 1980 requirements, we recommend that the Secretary direct the Administrator of HCFA to require the States to give the Department information on existing State requirements that are comparable to the proposed HHS new requirements.

## CHAPTER 4

### COMPLIANCE PROBLEMS COULD LESSEN IMPACT

#### OF PROPOSED JULY 1980 CHANGES IN REQUIREMENTS

As discussed in chapter 2, while language in certain SNF requirements is being clarified and some new requirements are being added, the major effect of the proposed conditions of participation is to bring ICF requirements in line with SNF requirements. Therefore, the greatest impact should be on ICFs. We believe that the changes represented in the proposed conditions could improve the care and lifestyle of patients and better protect them. However, additions to, or clarification of, requirements are meaningless unless facilities comply with them and Federal and State agencies enforce them.

State surveys have disclosed that many facilities have not complied with certain current requirements, including some which would be key elements in the proposed PCMS. HHS attributes problems in compliance at least in part to (1) ambiguity in current regulations and (2) the tendency of facilities to employ unqualified staff in key nonnursing supervisory positions and then overrely on consultants for direction. The Department believes that the proposed conditions should alleviate these problems by more clearly stating requirements and by including provisions designed to upgrade the qualifications of employees in key supervisory positions. These provisions include establishing qualifications requirements for the positions in ICFs and financial incentives to encourage SNFs and ICFs to employ more qualified personnel, thereby reducing reliance on consultants. HHS is also taking steps designed to better identify facilities that are not meeting requirements and to foster corrective actions. (See ch. 5.)

We believe that the July 1980 proposed conditions generally state requirements more clearly, thus reducing ambiguity. However, we have reservations as to whether the proposed provisions to upgrade the qualifications of employees in key non-nursing supervisory positions will assure the desired impact because:

- The qualifications for each position allow for a considerable range of expertise.
- The positions in SNFs are subject to qualifications under current regulations and yet the rate of non-compliance is comparable to that of ICFs on certain similar requirements.



LACK OF COMPLIANCE WITH  
CURRENT REGULATIONS

We obtained, through HCFA's MMACS, summary statistics on the number of SNFs and ICFs which, at the time of their most recent survey, were not in compliance with each requirement for the applicable level of care. 1/ In the following sections we discuss the survey findings for certain requirements in current regulations involving (1) key components of the proposed PCMS, (2) dietetic services, (3) physical environment, and (4) staff training. The incidence of noncompliance in these areas is summarized in the following table.

<u>Area of deficiency</u>	<u>Percent of noncompliance</u>	
	<u>SNF</u>	<u>ICF</u>
Patient care management:		
Inadequate plans of care	21	7
Plans not reviewed or updated	23	11
Inadequate medical records	30	N/A
Documentation of treatments/ services	N/A	11
Documentation of drugs administered	N/A	9
Dietetic services:		
Inadequate supervision	10	7
Unsanitary conditions	29	21
Menu planning and nutritional adequacy	9	11
Planning, preparing, serving, and supervising therapeutic diets	20	8
Physical environment:		
Handling of linens	20	N/A
Housekeeping	18	N/A
Staff training:		
Orientation for new employees	12	7
Continuing education program	10	10
Content of education program	16	N/A
Medication aides had not attended State-approved course	3	9

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1/The statistics were as of March 31, 1980. MMACS had survey data on 7,680 SNFs having about 665,000 beds and 10,854 ICFs having about 920,000 beds.

## Patient care management

Current SNF conditions of participation require that patients receive an assessment of needs in conjunction with their admission and that a plan of care be developed which addresses these needs. The plan of care must be periodically reviewed, evaluated, and updated. ICF standards are silent on patient assessments 1/ but specify that a plan of care be developed for each patient and that the plan be reviewed, evaluated, and updated at least quarterly. Neither the SNF conditions nor ICF standards establish minimum requirements as to an acceptable plan of care, although guidelines prepared for State surveyors do provide some general guidance. The actual criteria used by individual surveyors, however, may vary.

According to survey results, 21 percent of SNFs were not preparing plans of care which met requirements, and 23 percent of SNFs had not met requirements for reviewing, evaluating, and updating plans of care. The survey results for ICFs were 7 percent 2/ and 11 percent, respectively. The adequacy of plans of care has also been examined by HHS personnel as part of the onsite evaluations required by Medicaid utilization control statutes. According to an HHS representative, onsite evaluations conducted in the last 2 years had disclosed that five State Medicaid agencies had failed to assure that participating nursing homes prepared adequate plans of care. 3/

Patient assessments and plans of care are to be key features in the PCMS that will be required under the proposed conditions. Another essential requirement for PCMS

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1/Assessments of ICF patients are required under other Medicaid regulations (42 CFR, part 456).

2/Statistics for an ICF records requirement indicated that about 12 percent of the facilities did not have adequate plans of care in patient records. The reason for this apparent conflict is not known.

3/While HHS used uniform criteria in determining adequacy of plans of care, these criteria may be different from those used by individual State surveyors. Organizations in HCFA are developing standard criteria for acceptable patient assessments and plans of care which will be used by both State Survey Agencies and State Medicaid Agencies.

to work well is good medical records. Surveys indicated that contents of medical records at 30 percent of SNFs did not meet requirements. Contents of patient records at ICFs were also deficient, including lack of entries describing treatment and services rendered (11 percent) and medications administered (9 percent).

HHS is planning to provide assistance in implementing PCMS. The Department is making available self-teaching aids which can be used to train nursing home personnel, surveyors, and other professionals in the concepts of PCMS--including use of assessment instruments--and to test and develop their skills. Two aids are involved. One was originally issued in 1978 and as of September 1980 was being revised. A second aid, which is designed both for use by the PCMS coordinator and as a teaching aid, was to be published in 1980. HHS plans to make both documents available through the Government Printing Office for a "nominal charge." We believe that wide distribution and use of such documents would be facilitated if they were distributed free to all participating nursing homes.

#### Dietetic services

At 10 percent of the SNFs, dietetic services were not under the full-time supervision of a qualified dietetic services supervisor, and 12 percent of the SNFs were not receiving adequate input from their dietetic consultants. At 29 percent of the SNFs, requirements for storing, preparing, distributing, and serving food under sanitary conditions were not met. Twenty percent of SNFs did not meet requirements for planning, preparing, serving, and supervising therapeutic menus.

Significant numbers of ICFs do not meet current standards. For example, 11 percent failed to meet requirements for menu planning and nutritional adequacy, and 21 percent failed to meet the requirements for procuring, storing, preparing, distributing, and serving food under sanitary conditions. The current SNF requirements for dietetic services are comparable to those in the proposed conditions, which would apply to ICFs in the future.

### Physical environment

Twenty percent of the SNFs did not meet requirements for handling, storing, processing, and transporting linens, and 18 percent did not meet housekeeping requirements. The current SNF conditions are comparable to those in the proposed conditions, which would apply to ICFs in the future.

### Staff training

Twelve percent of SNFs and 7 percent of ICFs did not have adequate orientation programs for new employees. Ten percent of SNFs and 10 percent of ICFs did not meet current requirements for planning and conducting continuing education programs for staff. The continuing education program at 16 percent of SNFs did not include all required subjects. Three percent of SNFs and 9 percent of ICFs were allowing nonlicensed staff members to distribute medications, although they had not attended a State-approved medication aide course.

The proposed conditions also require staff development through in-service training. In addition, the conditions also require that new employees who provide direct patient care and who are not licensed, registered, or certified receive at least 30 hours of training from licensed personnel within the first 30 days of employment.

### ACTIONS PLANNED BY HHS TO INCREASE COMPLIANCE

HHS attributes problems in achieving compliance to at least two factors: (1) the ambiguity of some requirements in current regulations and (2) the tendency of facilities to use unqualified personnel in key supervisory positions. The Department believes that the proposed conditions of participation should alleviate both problems. Although the proposed regulations do present the requirements more clearly, we have reservations as to whether the new requirements intended to upgrade the quality of staff, particularly for ICFs, will have the desired impact because of (1) the wide range of education, training, and experience permitted in the proposed conditions to be considered "qualified," and (2) the incidence of noncompliance with current requirements in SNFs, which now have comparable qualifications requirements.

HHS believes that the proposed conditions state requirements more clearly and specifically--particularly for the ICF level of care--and, therefore, problems in misinterpretation of requirements should be alleviated. As discussed in chapter 2, we also believe the requirements are stated more clearly and specifically and are presented in a format that should make it easier for nursing home personnel to identify individual requirements.

HHS also believes that facilities are particularly prone to using unqualified staff in the areas of medical records, dietetics, social services, and patient activities. Current SNF and ICF requirements specify that, during any periods when an employee who holds a certain supervisory position does not meet the qualifications for that position, the facility must retain a qualified consultant for that position. In SNFs, these positions include medical records, dietetics, social services, 1/ rehabilitation services, and patient activities. The positions in ICFs include director of nursing and all of the above, except for medical records. The current SNF requirements define the qualifications for each position, whereas ICF requirements generally do not.

One action taken by the Department to remedy the perceived problem of unqualified staff was to include in the proposed conditions a requirement that ICFs have a director of medical records. HHS has also made the qualifications requirements for persons serving in the records, dietetics, social services, and patient activities supervisory positions applicable to ICFs as well as SNFs.

While HHS' action to establish qualifications requirements for key supervisory positions in ICFs may result in facilities hiring more qualified personnel, it should be noted that these requirements allow for a considerable range of expertise in each position. The following shows the general range of qualifications requirements for each position for which no consultant supervision is required and the qualifications levels for which at least 1 year of supervision by a qualified consultant is required.

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1/This applies only if the facility (SNF or ICF) elects to provide social services in-house. A facility may elect to make alternate arrangements for providing social services.

**Director of medical records:**

**Without supervision:** Eligible for certification as a registered record administrator or accredited record technician.

**With supervision:** Have training, experience, and demonstrated competency appropriate to the scope and complexity of services performed.

**Dietetic services supervisor:**

**Without supervision:** Registered dietitian or eligible for registration and have at least 1 year of supervisory experience in the food and nutrition service of a health care facility, and participate annually in continuing education.

**With supervision:** Graduate of a formal training course or received equivalent training and experience in a military service.

**Social services director:**

**Without supervision:** Graduate degree in social work or in social or behavioral sciences with a specialty in gerontology.

**With supervision:** Ranges from bachelor's degree to an associate of arts degree with varying experience requirements.

Patient activities director:

Without supervision: Ranges from completion of a 4-year college course and eligibility for registration to graduates of therapy training programs to personnel having equivalent training and experience. 1/

With supervision: No specific requirement.

HHS anticipates that most facilities will elect to fill the above positions with personnel who have sufficient qualifications that consultant supervision will not be needed. The Department also anticipates that many of the smaller facilities will use one person to serve as both social services director and patient activities director.

HHS also believes that the trend has been for facilities to employ unqualified staff in supervisory positions and then depend almost totally on consultants for professional judgment and the performance of routine activities which the facilities should have the in-house capability to perform.

The Department believes it fostered this trend by requiring facilities to retain consultants for periods during which the specified positions were filled by employees not meeting qualifications. As a financial incentive for developing in-house capability, the proposed conditions specify that the facility administrator can discontinue consultants for medical records, dietetics, social services, and patient activities under the following conditions: (1) the lesser qualified employee filling the supervisory position has received consultant services for at least 1 year and (2) in the administrator's judgment, the incumbent is meeting the requirements for that service as specified in the conditions of participation.

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1/This represents the range of qualifications for persons designated as therapeutic recreation specialists, occupational therapists, and occupational therapy assistants. Also designated as fully qualified are persons with graduate degrees in social fields described above under social services director.

As shown in the table on page 45, the level of non-compliance in some dietetic services requirements was comparable for SNFs and ICFs although current SNF regulations required dietetic services' supervisors to meet certain minimum qualifications while current ICF regulations have no specific qualifications requirements. We therefore believe that upgrading ICF staffing requirements in itself will not necessarily reduce compliance problems.

### CONCLUSIONS

We believe that, if there is compliance with the proposed conditions of participation, the care and lifestyle of patients should be improved and the patients should be better protected. However, past performance has shown that many homes do not comply with at least some of the requirements.

HHS believes that the July 1980 proposed conditions of participation should increase the level of voluntary compliance. HHS said that ambiguous requirements in current regulations have been clarified and provisions have been made to require or induce facilities to hire more qualified personnel for key supervisory positions. While the provisions to upgrade the qualifications of employees probably will improve the quality of services, we believe the impact may be less than desired because (1) the wide range of expertise the proposed conditions permit in being considered "qualified" to fill key supervisory positions could result in the degree of upgrading varying widely among facilities and (2) upgrading of staff does not automatically result in increased compliance, as evidenced by the high rate of noncompliance at SNFs, which currently have qualifications requirements similar to those being proposed for ICFs.

The Department plans to improve the general quality of care by requiring that nurses aides and orderlies receive initial training which includes certain subjects specified in the conditions. It plans to help facilities meet this requirement by making available various training materials that have been developed over the years. Although this training could improve the general quality of care and possibly reduce staff turnover, we believe that the quantity and quality of training at each facility must be closely monitored because many facilities are not meeting current requirements for continuing education.



HHS believes that the proposed PCMS should have a major impact on the quality of care and, as a side benefit, should enable Federal and State officials to more objectively assess the quality of care provided by each facility. Patient assessments and plans of care are key elements in the system. However, Federal and State inspections have shown that many facilities are deficient in these areas. HHS is developing teaching aids which it believes will help facilities to make adequate assessments and develop appropriate plans of care. HHS plans to make these teaching aids available for purchase through the Government Printing Office. We believe that HHS should distribute these materials free of charge to all participating facilities through the State Survey Agencies.

RECOMMENDATION TO  
THE SECRETARY OF HHS

To facilitate implementation of the proposed Patient Care Management System, we recommend that the Secretary direct the Administrator of HCFA to distribute guidelines and training aids free of charge to all participating facilities.

## CHAPTER 5

### PROPOSED CHANGES IN STATE OVERSIGHT

#### OF THE NURSING HOME PROGRAM

In addition to revising the nursing home regulations, HHS is taking or considering various actions designed to improve State oversight of nursing homes. The State Survey Agencies have responsibility for determining whether SNFs and ICFs participating in Medicare and Medicaid are in compliance with requirements and helping facilities not in compliance to promptly establish and carry out a plan of corrective action. State Medicaid Agencies are responsible for utilization control, which includes determining the adequacy of services at participating facilities. Past oversight efforts have been widely criticized, particularly the tendency of State personnel to determine only "paper compliance" 1/ with requirements and the conflicts among the various oversight organizations in findings on the quality of facilities' services.

HHS has recognized these problems and is developing improved evaluation techniques and studying possible changes in survey, certification, and other regulations. Because most of the actions HHS proposes to improve oversight are still in the developmental or study stage, we are unable to conclude what their impact will be. We believe that some of the proposed actions, if implemented, could reduce discrepancies in inspection results and help to shift emphasis from "paper compliance" to outcome-oriented appraisals. However, we believe that the following two proposed changes will be of questionable benefit in improving the oversight process:

- HHS proposes not to cite nursing homes for failure to meet requirements below the standards level. We believe that, if HHS implements this proposal, it should continue to require the State Survey Agencies to determine compliance with individual requirements comprising the standard and report instances of non-compliance to the Department.

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1/This term is generally used in the context of undue emphasis on the facility's policies, procedures, physical structure, staff and service capabilities, and records documentation and insufficient emphasis on patient outcomes.

--HHS proposes to establish surveyor qualifications and a credentialing system for four areas of expertise. In our opinion, one of these areas--patient care and services--is so broad that few individuals are likely to have the requisite knowledge and skills to cover the wide range of activities included in this area.

### IMPROVEMENTS IN EVALUATION TECHNIQUES

HHS is developing guidelines and other aids to assist State personnel--both Survey Agency and Medicaid Agency--in carrying out their oversight responsibilities. Some relate to the evaluation process in general, while others deal with determining compliance with specific requirements. Most are in the planning or developmental stage. A brief discussion of each follows.

#### Survey guidelines

HHS plans to revise the current Interpretive Guidelines and Survey Procedures to coincide with the requirements contained in the proposed conditions of participation as adopted and also to develop new survey forms. The guidelines and forms will be designed to direct the surveyors' attention toward more outcome, patient-focused evaluation of compliance, rather than "paper compliance." Certain aspects of the revised form were discussed in recent public hearings; however, much of this work will be deferred until the requirements to be included in the conditions of participation have been established.

#### Inspection of care guidelines

The IOC guidelines issued in 1972 for use by State Medicaid Agencies are being revised and updated. The new guidelines will include a section dealing with PCMS, which would be required under the proposed conditions. Portions of the guidelines have been drafted. HHS has also developed and is field testing an IOC training course. This would be a counterpart to the surveyor training course.

#### Patient Care Management System

HHS is working to identify the basic data elements which should be included in patient assessments to assure that the assessments are comprehensive--i.e., completely address the medical, physical, and psychological needs of

the patient. The Department has received input from various sources, including potential users and interested organizations, but has yet to reach a consensus as to what these data elements should be. After these differences are resolved, HHS will require that States establish standard patient assessment forms which include the specified data elements.

The Department believes that the assessment forms will enable surveyors to objectively determine the quality of patient care because information will be focused on the patients and their needs. HHS believes that these instruments can also reduce conflicting results by State Survey and Medicaid Agencies since representatives of both agencies will be directed to the same document.

#### Pharmaceutical services

The proposed conditions include tolerance limits for drug administration errors, drug wastage, and unaccounted-for controlled drugs. 1/ HHS has field tested a methodology which State surveyors would use to determine whether these limits were exceeded. Final results of these field tests are expected in early 1981. The Department also field tested a methodology which surveyors would use to evaluate the pharmacist's medication review. The Department expects to implement the survey methodology by mid-1981.

#### Life safety

The Department has developed and adopted a Fire Safety Evaluation System, which it believes will reduce the number of questionable, personal judgments being made by surveyors when facilities do not meet requirements of the Life Safety Code. The Department has trained about 250 surveyors to apply this system and has developed guidelines and training aids.

#### POSSIBLE CHANGES IN SURVEY REQUIREMENTS

In March 1980, 2/ HHS issued a notice of public hearings to discuss changes it was considering in the survey and

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1/Drugs listed as being subject to the Comprehensive Drug Abuse Prevention Act of 1970 (Public Law 91-513). (See 21 CFR, part 1308.)

2/Federal Register, 45 FR 14900, March 7, 1980. The proposed changes involve title 42 of the Code of Federal Regulations (part 405, subpart S, and part 442, subpart C).

certification process. The changes under consideration are intended to make procedures for surveying and monitoring compliance (1) more effective in improving the quality of care, (2) less costly, (3) less confusing to the consumer, and (4) less burdensome to the industry. HHS does not plan to make any final decisions on these proposals until early 1981. Several of the proposed changes involve survey of long-term care. These proposals are as follows.

Better coordination of  
federally funded reviews

HHS is concerned about the conflicting findings on the quality of facilities' services by State Survey Agencies and the State Medicaid Agencies or PSROs. 1/ The Department attributes this problem to a variety of causes, including failure of the groups to exchange reports and discuss differences, use of different criteria, and lack of specific criteria in regulations used by IOC (i.e., Medicaid Agency) reviewers. The changes being considered for the survey and IOC processes include

- requiring the State Survey Agency and the State Medicaid Agency or PSRO to exchange and use each other's reports, including reconciling differences in findings;
- amending Medicaid IOC regulations to add greater specificity to the criteria, particularly regarding care planning, rehabilitative services, patient activities, and dietetic services--these criteria would be consistent with provisions in the conditions of participation--and
- requiring both State agencies to use the same criteria to evaluate a patient service.

Combine survey and inspection

Some States have integrated, in varying degrees, the survey and IOC functions. HHS believes that this integration can reduce cost as well as improve the effectiveness of quality assurance activities. At present the States have

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1/The inconsistencies between the State survey findings for ICFs and the findings of the HHS validation surveys and/or of the State Medicaid Agencies were highlighted in our August 16, 1977, report to the Secretary (HRD-77-129).

the option not to integrate these functions. The Department favors legislation granting the Secretary authority to require this integration. The proposed changes being considered are to:

- Reduce the IOC requirement from an in-depth evaluation of all Medicaid patients to a screening review. In-depth reviews would be limited to those patients where screening identified possible problems.
- Use the survey form for that portion of the IOC report identifying deficiencies in a facility's services.
- Designate the State Survey Agency as the organization which is to make the surveys/inspections.

#### Simplify utilization review

HHS believes that utilization review in nursing homes has evolved into basically a paper compliance activity and is not cost effective. Utilization review in SNFs is required by statute. In ICFs, utilization review is not specifically required by statute; however, "utilization control" is required. The proposed changes being considered are

- simplifying requirements in regulations for utilization review in SNFs and ICFs and
- eliminating the requirement for SNFs that an annual medical care evaluation (MCE) study be performed.

#### Uniform level of rating provider compliance

At present, surveyors are making "met" and "not met" determinations for three tiers of requirements--condition of participation, standard, and element--on SNFs and two tiers--standard and element--on ICFs. Any deficiencies noted at the element level are identified on the survey form, and the facility must establish a plan of correction regardless of the significance of the deficiency. Compliance with requirements by some Medicare and Medicaid providers are not reported below the standard level. The Department believes that rating at the element level is inequitable because it makes the nursing homes look bad in comparison to other providers, such as Home Health Agencies, which generally are rated at the standard level. HHS also believes that it often

forces facilities to develop plans of correction on minor deficiencies at the element level. HHS, therefore, is proposing the following changes:

- Standards of comparable weight would be established in terms of health and safety standards. These standards would reflect the statutory regulations and critical requirements for each type of provider.
- Standards would not be subdivided into elements.
- Deficiencies would be cited at the standard level, and an acceptable plan of correction would be required on standards not met.
- A repeat pattern of standards not met could result in termination from the Medicare and/or Medicaid programs. 1/

If HHS elects not to cite facilities for deficiencies and require corrective action plans below the standard level, we believe that the survey forms should continue to include the subrequirements (e.g., elements) and surveyors should be required to indicate whether they are met. We also believe that the State Survey Agency should be required to report deficiencies found at the element level to the Department so that this information can be entered into MMACS. In our opinion, HHS needs this information to determine which parts of the rather broad requirement stated in the standard are not being met. The current survey forms and the forms used to report deficiencies to HHS include this information down to element level, and HHS can readily determine what specific requirements in a standard are not being met through inquiry of MMACS. We believe that including elements of standards on the survey form also assists in evaluating the performance of individual surveyors and the State Survey Agencies.

#### Surveyor qualifications requirements

HHS is concerned that some States may be taking advantage of a loophole in current guidelines for State Survey Agencies by hiring as surveyors persons who do not have the desired background in health or health-related fields. Some States have also been lax in having their surveyors attend the basic health facility surveyor training course conducted by HHS.

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1/This is generally required under current HHS regulations.  
(See 42 CFR 405.1902 and 442.105.)

The Department is also concerned that surveyors skilled in a limited area can be responsible for surveying components that are outside the realm of their training.

According to HHS, each surveyor's knowledge and experience affects his or her interpretation of Federal regulations and this is one reason why there can be considerable variation in review results. HHS stated that a GAO report <sup>1/</sup> identified variations in the application of regulations by State surveyor personnel as a major problem. The Department believes that using surveyors meeting specific qualifications will increase the validity and reliability of survey findings because interpretations of standards will stem from a basic level of knowledge and skills of the surveyor in each survey area. HHS, therefore, proposed the following:

- Developing regulations setting forth surveyor qualifications at the entry level according to skills and knowledge required to survey in four major areas: Life Safety Code, administration and physical environment, patient care and services, and laboratory.
- Establishing a system to certify surveyors as qualified and continuing education program requirements for each of the four survey disciplines.
- Allowing individuals to qualify in more than one of the four survey disciplines.

We believe that one category of surveyor for which qualifications would be established may be unrealistically broad. The proposal indicates that one category of surveyor would be responsible for evaluating all patient care and services. These services would include physician, nursing, dietetics, rehabilitation, pharmaceutical, social services, and patient activities.

#### Flexible survey cycles

Surveys of providers were originally performed on a cycle of 1 year, 18 months, or 2 years, depending on the number and nature of deficiencies noted in the previous survey. In about 1970, HHS revised regulations to require annual surveys of SNFs because States were issuing 1-year

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<sup>1/</sup>"The Medicare Hospital Certification System Needs Reform" (HRD-79-37, May 14, 1979).



licenses to these facilities. In 1972, the Social Security Act was amended <sup>1/</sup> to specify that provider agreements would not exceed 1 year. According to HHS, the amendment was intended to facilitate terminating providers who had deficiencies--i.e., the provider could be terminated by not renewing its provider agreement. The Department has found that the time, documentation, and effort required to deny a provider a renewal of the agreement is generally the same as to terminate an existing agreement and therefore the intent of the amendment has not been realized.

In HHS' opinion, the belief that there is a clear relationship between annual surveys and compliance has not been supported by program experience. The Department believes that mandatory annual surveys have increased paperwork at all levels, caused scheduling problems for State Survey Agencies, resulted in nonproductive visits to good providers, and given equal treatment to good and bad providers. HHS believes that the survey cycle for a provider should be based on the provider's past performance and current compliance. By using a flexible cycle, State Survey Agencies could better allocate resources to focus on problem or marginal providers, including consulting with them to upgrade the quality of care being furnished. HHS, therefore, proposes, for long-term care facilities, allowing the survey cycle to vary from 3 to 24 months based on current compliance and past performance.

#### Change staffing report requirements

Current regulations require SNFs to report to the State Survey Agency the average numbers and types of personnel on each tour of duty at least 1 week of the quarter. The reporting week is selected by the State Survey Agency. HHS believes that, while the reports are useful in monitoring providers who have demonstrated marginal staffing compliance or who have been granted a special waiver, there is little justification for requiring the report of all providers every quarter. HHS, therefore, is proposing to modify the regulation to require the reports only when a provider

--historically or currently meets staffing requirements on a marginal basis,

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<sup>1/</sup>Public Law 92-603, October 30, 1972.

- has been granted special staffing waivers, 1/ and
- has given the State Survey Agency reason to question its continuing compliance with staffing requirements.

#### Other proposals

Proposals were made on two other matters applicable to nursing homes:

- Permitting patients and their families to participate in the survey process.
- Revising a regulation which requires a resurvey of providers with deficiencies within 90 days. The revised regulation would permit the surveyor to resurvey at the most appropriate time, which could be in excess of 90 days based on the provider's plan of corrective action.

#### CONCLUSIONS

A primary purpose of State oversight is to make each nursing home aware of any requirements it is not meeting and to assist the facility in taking prompt and adequate corrective action. For the Medicaid program, oversight also includes determining whether each participating nursing home's services are adequate to meet the needs of each recipient. Oversight therefore plays a key role in assuring that requirements are met and that services are adequate.

Past oversight efforts have been widely criticized, particularly (1) the tendency of State personnel to emphasize "paper compliance" rather than patient outcomes in making their reviews and (2) conflicts in findings of deficiencies among the various oversight organizations. HHS has recognized these problems and is taking or considering various actions designed to improve the quality of oversight and to increase the coordination among the oversight organizations.

Most of the proposed corrective actions are still in the study or developmental stage. In our opinion, however, the proposed actions generally are directed at areas of the oversight process that need improvement. We believe that some of

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1/Waiver of the requirement that SNFs have a registered nurse on duty during the day shift 7 days a week.

the proposed actions, if implemented, should reduce discrepancies in inspection results and help to shift emphasis from "paper compliance" to outcome-oriented appraisals. However, we also believe that HHS should reconsider proposals that might reduce the amount of detailed information it currently receives on facility compliance with individual requirements within standards.

RECOMMENDATION TO  
THE SECRETARY OF HHS

Regarding proposals to improve general oversight and enforcement of compliance with requirements in the conditions of participation, we recommend that the Secretary direct the Administrator of HCFA to continue requiring State agencies to determine and report on compliance with individual requirements within a standard, should the Department elect not to cite facilities for noncompliance with requirements below the standard level.

CLAUDE PEPPER, FLA.  
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**U.S. House of Representatives**  
**Select Committee on Aging**  
**Washington, D.C. 20515**

TELEPHONE: (202) 225-9278

April 21, 1980

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Honorable Elmer B. Staats  
Comptroller General of the United States  
General Accounting Office  
441 G Street, S.W.  
Washington, D.C. 20548

Dear Mr. Staats:

Your assistance in a matter of some importance to the House Select Committee on Aging would be appreciated.

For some time, our Committee has been investigating problems of drug abuse and adverse reactions of drugs involving patients in nursing homes. The purpose of this letter is to request the testimony of the General Accounting Office at hearings on this subject to be conducted by our Committee on May 7, 1980.

I understand that GAO has just completed a report which deals with the problems of assuring proper drug treatment in nursing homes. I am hopeful that we can arrange for you to release this important work at our hearings.

In addition, I would appreciate your having your staff examine the proposed draft of conditions of participation soon to be promulgated in the Federal Register by HEW. The proposed revision is not required by any act of Congress but springs from an Administration initiative called "Operation Common Sense." The purpose of the new draft regulations is to simplify and clarify standards, to focus on patient care, achieve more effective compliance and to promote cost containment while maintaining quality of care. Specifically, we would appreciate knowing the following:

- (1) What language has been lost from the January 1974 Conditions of Participation as promulgated in the Federal Register and the new proposed draft?
- (2) What language has been added?
- (3) Are these changes in conflict with any law or regulation?
- (4) What will be the effect of the deleted language?
- (5) What will be the probable effect of the additional standards or conditions?
- (6) To what extent could the proposed regulations result in reduced protections for nursing home patients?

(7) Are the regulations being simplified and made more readable from GAO's point of view?

(8) Will the standards likely result in saving taxpayers dollars at either the state or federal level? What ballpark figure do you project for such savings? What changes are responsible for these savings?

(9) Will these new regulations significantly shift enforcement attention from "paper compliance" to greater emphasis on patient care?

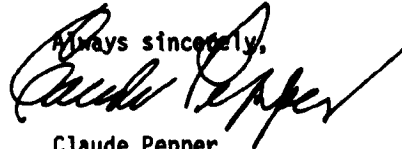
For purposes of the May 7 hearing, I would appreciate having GAO's analysis of the section of the proposed new regulations which relates to Pharmaceuticals. We would appreciate having GAO's analysis of the remaining sections of the draft regulations for a hearing to be called possibly in mid-June.

We would be most grateful for your favorable consideration of this request.

With kindest regards, and

Believe me,

Always sincerely,



Claude Pepper  
Chairman

CP:vhs

Enclosure

COMPARISON OF CURRENT AND JULY 1980 PROPOSEDNURSING HOME REGULATIONS

HHS has divided the proposed nursing home regulations into five subparts--general provisions, administration, patient care services, physical environment and safety, and patient rights--having a total of 20 sections. General provisions, the first subpart, states the purpose of the conditions and includes certain definitions but does not include any conditions of participation. The remaining four subparts--administration, patient care services, physical environment and safety, and patient rights--contain 18 conditions of participation. This appendix compares provisions in each of the 20 sections to provisions contained in the current SNF conditions of participation and ICF standards and in other HHS/HCFA regulations 1/ pertaining to nursing homes. Where changes are identified as affecting only ICFs, similar requirements are already in effect for SNFs. All citations of SNF, ICF, and other HHS regulations are in title 42 (Public Health) of the Code of Federal Regulations.

SUMMARY OF CHANGES BY  
CONDITION OF PARTICIPATION

Numerous changes have been proposed in requirements, particularly for the ICF program. This section highlights the additions and deletions by condition of participation, 2/ and the second section of this appendix contains more detailed information on the changes.

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1/Primarily the Medicaid regulations for utilization control.  
(Title 42, Code of Federal Regulations, part 456)

2/Four conditions of participation essentially have no changes in requirements. These are: compliance with Federal laws, compliance with State and local laws, medical direction, and rehabilitative services.

Governing body and management

## Increased requirements:

ICF: Facility policies, procedures, and guidelines;  
personnel and personnel qualifications.

ICF and SNF: Patient visiting hours and personnel  
training.

## Reduced requirements:

SNF: Reporting of staffing and retention of  
consultants.

Medical records

## Increased requirements:

ICF: Maintenance of records, including qualifica-  
tions of supervisor or consultant.

ICF and SNF: Types of records required.

Utilization review for SNFs

## Reduced requirements:

SNF: Elimination of certain studies.

Patient care management

## Increased requirements:

ICF and SNF: Institute systems (PCMS) meeting HHS  
standards.

Physician services

## Increased requirements:

ICF: Frequency of physician visits and provision  
of dental services.

ICF and SNF: Physician orders, establishment of  
standard operating procedures,  
provision of podiatric services.

Nursing services

## Increased requirements:

ICF: Personnel requirements and observation of patients.

ICF and SNF: Administration of medications and use of "pool" nurses.

## Reduced requirements:

ICF: Minimum 4-hour weekly consultation times for registered nurses.

Food and nutrition services

## Increased requirements:

ICF: Qualifications of supervisor and dietitian, physical plant, services provided.

ICF and SNF: Training requirements, duties of personnel, maintenance of records, food supplies.

Pharmaceutical services

## Increased requirements:

ICF: Drug procedures and supervision of services.

ICF and SNF: Responsibilities of key personnel, acceptable performance standards, maintenance of records.

## Reduced requirements:

SNF: Deletion of certain requirements for registered pharmacists.

Laboratory and radiological services

## Increased requirements:

ICF: Provision of services to patients and documentation of results.

Social services

## Increased requirements:

ICF: Qualifications of director or consultant.



Patient activities

## Increased requirements:

ICF: Qualifications of director or consultant.

Physical environment

## Increased requirements:

ICF: Limitations on beds per room and requirements for lighting, noise, temperatures, and pest control.

ICF and SNF: Patient call systems, water temperatures, furnishings and interiors, emergency utilities, maintenance of patient care equipment.

Safety

## Increased requirements:

ICF: Facilities may be required to meet more recent fire code.

ICF and SNF: Fire safety training, including frequency.

## Reduced requirements:

ICF and SNF: Increased waiver periods for noncompliance with fire code requirements for construction types and features.

Patient rights

## Increased requirements:

ICF and SNF: Access to patients and patient records, resident councils, patient access to telephones and officials of State and Federal agencies and interest groups.

DETAILED COMPARISON OF CHANGESGeneral provisions (Subpart A)Purpose (483.01)

This section contains an introductory statement, which explains that the subsequent sections present requirements for participation by SNFs and ICFs in the Medicare and

Medicaid programs and that these requirements will be used as the basis for survey activities by Federal and State surveyors.

#### Definitions (483.02)

This section would replace the definitions section of the current SNF regulations (405.1101). Additions to this section include definitions of chemical restraints, physical restraints, involuntary transfer, and drug administration error. Also added is a definition of a physician, which includes physician-directed physicians' assistants and nurse practitioners where permitted by State law.

Deleted from this section but transferred to the appropriate proposed conditions of participation are qualifications criteria for the administrator and for various nursing home positions, such as medical records practitioner, occupational therapist, patient activities coordinator, physical therapist, and social worker.

Deleted but not transferred to the pharmaceutical services condition of participation are definitions of drug administration, drug dispensing, and approved drugs and biologicals.

The current ICF regulations generally do not include definitions and, therefore, the entire section constitutes an addition to ICF requirements.

#### Administration (Subpart B)

##### Compliance with Federal laws (483.10)

The current SNF regulations combine compliance with Federal, State, and local laws in one condition of participation (405.1120). The State and local laws are dealt with separately in the revised conditions (see section 483.11). The current SNF regulations require compliance with Federal laws relating to fire and safety, sanitation, communicable and reportable diseases, post mortem procedures, and other relevant health and safety requirements. No specific laws are cited in the current regulations. The proposed conditions cite specific laws as well as HHS regulations implementing the laws. The laws cited include the Civil Rights Act of 1964, Rehabilitation Act of 1973, Age Discrimination Act of 1975, and uncompensated care and community services provisions of the Hill-Burton Act.

The current ICF regulations require compliance with Federal laws, regulations, and codes pertaining to health and safety, including drugs, sanitation, communicable and reportable diseases, and post mortem procedures (442.315).

The laws cited in the proposed conditions do not deal with the subjects contained in the current SNF and ICF regulations and, therefore, are additions to the nursing home regulations. These additions do not constitute new requirements, however, because they already were required by Federal statute or other HHS regulations.

Compliance with State and local laws (483.11)

This section covers the balance of provisions that are currently included in the SNF regulations requiring compliance with Federal, State, and local laws (405.1120) and in the ICF regulations requiring compliance with health and safety laws (442.315). The proposed requirements basically are the same as shown in the current SNF and ICF regulations.

Governing body and management (483.12)

Governing body and management is currently a SNF condition of participation (405.1121), and many of the provisions of the proposed condition are included in the current SNF regulation. Some of the proposed provisions are also covered by various requirements in the current ICF regulation.

The proposed conditions include more explicit requirements under some standards and additional requirements under other standards. The following are the most significant changes.

More explicit language:

- Authority and responsibilities of SNF and ICF administrators.
- Provisions for transfer agreements for ICF patients. 1/
- Content of written personnel policies and procedures for SNF and ICF employees.

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1/The proposed provisions for transfer agreements are similar to those in current SNF standards, which are set out in a separate condition of participation (405.1133).

**Additional requirements:**

- The governing body of ICFs must adopt written guidelines.
- The written guidelines for SNFs and ICFs must include a statement of the mission and objectives of the facility.
- The governing body of ICFs must prepare an institutional plan which is reviewed and updated annually.
- ICFs must have written personnel policies and procedures, which must include certain rights, responsibilities, and entitlements.
- ICFs must maintain personnel records meeting certain minimum standards.
- ICFs must have written policies governing control of communicable diseases in employees, a safe and sanitary environment for patients and personnel, and reporting and review of accidents involving patients and personnel.
- ICF employees must receive periodic health examinations.
- SNFs and ICFs must provide daily visiting hours encompassing at least a 12-hour period.
- New employees of SNFs and ICFs who provide direct patient care and who are not licensed, registered, or certified must receive at least 30 hours of training from licensed personnel within the first 30 days of employment.
- ICFs must disclose ownership of the facility. 1/

The current SNF regulations on governing body and management include a standard for patient rights (405.1121(k)). The proposed conditions would elevate patient rights to condition of participation status (483.50).

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1/This is currently required by HHS regulations (42 CFR Part 455) but was not included in ICF standards.

A possible reduction in requirements for SNFs and ICFs could result from proposed revisions in requirements for consultant service (483.12(j)). The proposed conditions specify that, when the nursing home does not employ personnel meeting qualifications in medical records, food and nutrition services, social services, and patient activities, the facility must employ a qualified consultant who makes regularly scheduled visits of a sufficient duration and frequency to ensure that the less qualified staff are rendering services in accordance with requirements set out in those conditions of participation. The proposed conditions also specify that, after 1 year's consultation for a particular service, the consultations may be discontinued if the facility administrator believes that the less qualified staff member directing the service is meeting the requirements in the conditions of participation for that service. The current SNF and ICF regulations in effect require continuing consultation as long as the facility does not employ personnel meeting the qualifications. <sup>1/</sup> According to the HHS introduction to the proposed conditions of participation, the Department is concerned that it has inadvertently created a consultant subset in the long-term care industry. The HHS introductory statement continues:

"Originally, consultants were seen as backup resources for full-time staff who lacked required education, training, and experience. What has resulted instead is continued use of unqualified staff and a near total dependency on the consultant for professional judgement and the performance of routine activities that the facilities should have the in-house capability to perform. We would like to reverse this trend in the interest of both cost containment and quality care."

Also deleted from the SNF regulations is a requirement that the facility submit quarterly staffing pattern data to the State Survey Agency (405.1121(b)). HHS recently held a series of public hearings in which one proposal discussed was to limit this reporting requirement to those facilities which have demonstrated marginal staffing compliance or which

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<sup>1/</sup>ICF regulations do not require a consultant for medical records.

have been granted a special waiver from the SNF regulations requiring a registered nurse 7 days a week. 1/

Medical records (483.13)

The proposed conditions of participation generally include all requirements in the current SNF (405.1132) and ICF (442.310 and 442.318) regulations. The additional requirements in the proposed conditions include:

- ICFs must have a director of medical records, and this individual must meet certain qualifications or be supervised by a consultant meeting these qualifications.
- SNFs and ICFs must maintain a master patient register, an admission and discharge register, and a daily census.
- SNFs and ICFs must maintain, separate from medical records, administrative records which include an inventory of the patients' personal effects, legal correspondence and documents relating to the patients' affairs, and personal or sensitive information not needed in the medical record.

The proposed conditions also revised the statement of qualifications for a medical records consultant from those currently stated in SNF regulations (405.1101(1)). The proposed conditions require that the person designated as director of medical records must

1. Be eligible to be certified as a registered record administrator or an accredited record technician or
2. Have training, experience, and demonstrated competency appropriate to the scope and complexity of services performed. This person must receive consultation from a medical record consultant who is an registered record administrator or an accredited record technician and has management experience or specialized training in long-term care consulting.

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1/The hearings were held in the 10 cities where HHS has regional offices during the period April to June 1980.

In the current SNF regulations, qualifications for option one were similar to those shown above. Option two, however, required that the incumbent be a graduate of an accredited school of medical record science (405.1101(1)). The current ICF regulations do not include any requirements for medical records personnel or the use of a consultant.

#### Utilization review (483.14)

The proposed conditions require that facilities have a written utilization review plan that (1) provides for review of each Medicare and Medicaid patient's needs for services that are provided him and (2) meet common utilization review plan requirements. As criteria for the latter, the proposed conditions cite portions of HHS regulations for utilization control applicable to the Medicaid SNF and ICF programs. The regulations cited require periodic review of the continuing need for care of those who have been patients for an extended duration.

Portions of the current utilization control regulations for SNFs, however, are not included in the proposed conditions. These regulations require periodic medical care evaluation studies (456.341 to 345). The MCEs are also required by current SNF regulations (405.1137(c)). HHS stated in the introduction to the proposed revised conditions that MCEs--which are intended to identify and examine patterns of care provided in a facility--were being eliminated as a requirement because the process is more applicable to the acute care setting and did not work well in the long-term care setting. HHS also stated that a Rand study <sup>1/</sup> concluded that there are definite limitations in applying MCE methodology in the long-term care setting.

#### Patient care services (Subpart C)

##### Patient care management (483.20)

This condition of participation requires SNFs and ICFs to establish a Patient Care Management System. According to HHS, PCMS consolidates the care planning requirements of five existing SNF conditions of participation--nursing services, social services, dietetic services, rehabilitative

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<sup>1/</sup>Chapter 6 of a Rand report on titled "The PSRO and the Nursing Home: Vol. I, An Assessment of PSRO Long Term Care Review," August 1979.

- The facility must notify patients of surveys and assist them in meeting with surveyors.
- Facilities must have at least one private phone for patient use and allow patients to install phones in their rooms.
- Patients' representatives must be given access to patient records after death.
- Patients must be permitted to review their records and to authorize others to have access to these records.

The HHS comments accompanying the proposed conditions included the following statements regarding patient rights:

**Accessibility:**

"As part of this expansion of Patients' Rights, we have proposed a standard for a stronger provision on accessibility. This will ensure access at all times to nursing home ombudsmen and legal advocates and reinforces their mandate under the 1977 Amendments to the Older Americans Act. However, since the patient has the right to see or refuse to see anyone, it is the patient who will ultimately determine just how accessible he or she will be."

**Other comments:**

"Other Provisions include the patients' right to form Residents' Councils, to be fully informed regarding all decisions affecting them, to privacy, and to have personal property. Standards will permit patient involvement in planning the care regimen. Patients should also be permitted to do as much for themselves as possible to forestall being cast in a dependent or helpless role."

The proposed conditions do not include standards regarding patients' personal funds. This matter is included in current SNF (405.1121(k)(6)) and ICF (442.311(e)) regulations. HHS comments accompanying the proposed conditions included the following statement regarding patient funds:



often than annually. The facility must use an assessment form which includes minimum core data specified by HCFA (483.20(c)).

- b. Development of a comprehensive care plan within 1 week of completion of the comprehensive assessment. The plan must be updated whenever significant changes in the patient's condition are identified and before each scheduled visit of the attending physician. 1/ The plan of care must specify the problems identified in the assessment, goals for the patient which are time limited and measurable, and the necessary care and services which must be provided to meet the goals. The plan also must show the team members responsible for providing the care and services and the required frequency of their visits (483.20(d)).
- c. Development of a discharge plan when the attending physician documents in the medical record that the patient has discharge potential. The plan must identify the direction, services, and assistance the patient will need from health, social, or welfare community agencies after discharge. At the time of discharge, the facility is to give the person or agencies responsible for the patient's postdischarge care an appropriate summary of information to insure optimal continuity of care (483.20(e)).
- d. Periodic evaluation of the patient's progress toward goals in order to identify the patient's current health needs. This evaluation is to include a determination of the reasons for any unachieved goals and an identification of new health needs for which goals need to be formulated in the care planning process (483.20(d)(4)).

The conditions specify that the interdisciplinary team must include (1) the patient's attending physician, (2) the nurse who has primary responsibility for the patient's nursing care, (3) health professionals providing rehabilitation

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1/According to another standard (483.21(c)(3)), the interval between physician visits cannot exceed 60 days on SNF patients and 120 days on ICF patients.

services to the patient, and (4) representatives from the facility's food and nutrition service, social service, and patient activities program. The standard also requires that the team include other facility personnel as needed and the patient and the patient's family when appropriate (483.20(b)(3)).

The conditions designate the facility's director of nursing as having primary responsibility for operation of PCMS. The director of nursing is responsible for orienting and training personnel for their roles in the operation of the system, monitoring the adequacy of patient records, and ensuring that each patient's care and discharge plan are properly executed. The director is also responsible for assigning one or more trained and qualified nurses to be responsible for the patient's care, developing preliminary care plans, and performing assessments. Finally, the director must coordinate all interdisciplinary team activities and ensure that health professionals participate, as needed, in patient care management activities.

We compared the requirements in this proposed condition of participation to requirements in (1) the current SNF and ICF regulations and (2) HHS regulations for utilization control in the Medicaid program (42 CFR, part 456). The following is a summary of the changes in standards that would result if the proposed conditions are adopted. Those requirements followed by an asterisk (\*) are currently included in Medicaid utilization control regulations.

**Patient assessments:**

- Defines the scope of patient assessments. \*
- Requires that ICF patients receive assessments. \*
- Requires that both ICF and SNF patients receive periodic reassessments.
- Requires SNF and ICF to use an assessment form which meets HCFA specifications.

--Establishes specific maximum time periods for performing assessments and reassessments for SNF and ICF patients. 1/

--Includes health professionals other than physicians in the assessment process and identifies professionals required to participate.

Plan of care:

--More clearly identifies parties responsible for input to the plan of care.

--Sets a maximum time interval for updating the plan of care on SNF patients. \* 2/

--Specifies the general types of information that should be included in plans of care for SNF and ICF patients. \*

Discharge plan:

--Requires development of discharge plans on ICF patients. \*

--Requires that the interdisciplinary team participate in development of the discharge plan for SNF and ICF patients.

Care evaluation:

--Clearly states that SNFs and ICFs must periodically determine the patient's progress toward goals and the reasons why goals were not achieved.

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1/Utilization control regulations specify that assessments must be made of SNF and ICF patients before admission or before authorization of payment to the facility.

2/Current ICF standards require that plans of care be updated at least quarterly (442.341). Under the proposed conditions, the maximum period would be increased to 120 days.

**Responsibility for coordinating care:**

- Specifies that one staff position (i.e., director of nursing) will be held responsible for coordinating patient care activities, including assessments, care and discharge plans, and execution of the plans.

**Corrective action by facilities:**

- Requires SNFs and ICFs to correct in a timely manner any deficiencies in the quality of their care and services identified by the State Survey Agency, the State Medicaid Agency, or PSROs.

**Physician services (483.21)**

This proposed condition of participation includes many of the provisions in the current SNF regulations (405.1123). The proposed conditions increase the requirements over those cited in the current ICF regulations (442.346). However, some of these requirements for ICFs are presently in Medicaid utilization control regulations. The following shows the additional requirements in the proposed conditions. Those followed by an asterisk (\*) are generally included in current utilization control regulations.

- At the time of admission, ICFs must obtain patient status information from a physician, including current medical findings, diagnosis, orders for immediate care, and the patient's discharge and rehabilitation potential. \*
- If medical orders are unobtainable from an attending physician on patient admission to a SNF or ICF, the medical director (SNF) or an emergency physician may give temporary orders.
- The attending physician must conduct a medical evaluation of ICF patients' immediate long-term care needs, based on a medical history and physical examination conducted within 48 hours of admissions. Exceptions to the 48-hour rule are allowed if a comparable examination was completed within 15 days of admission or the physician documents in the medical record that no significant changes have occurred since the last examination. \*

- The attending physician must review the ICF patient's plan of care as often as necessary, update the medical record, and make written comments on the patient's condition (e.g., progress notes) as often as necessary. \*
- Attending physicians may give telephone orders only to licensed staff members at SNFs and ICFs and must countersign them within 5 days. 1/
- A maximum time is established between physician visits for ICF patients.
- Attending physicians must adhere to established policies governing physician practices at SNFs and ICFs.
- Attending physicians for SNF and ICF patients must certify the necessity of patient services every 60 days. \*
- Attending physicians of SNF and ICF patients must record an intended visit schedule in the patient's medical record.
- ICFs must have written procedures that provide for having a physician available to furnish medical care in an emergency.
- ICFs must provide for certain dental services, including maintaining a list of dentists who will treat patients, arranging for transportation to the dentist if needed, and using a dentist in an advisory and staff training role. 2/

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1/The only comparable current SNF requirement involves drug orders, which requires countersigning of orders for controlled drugs within 48 hours (405.1124(h)). Current ICF regulations specify that verbal drug orders should be countersigned "in a manner consistent with good medical practice" (442.334).

2/These requirements are included in current SNF standards under a separate condition of participation--dental services (405.1129).

--SNFs and ICFs must provide for certain podiatric services, including maintaining a list of podiatrists who will treat patients, arranging for transportation to the podiatrist if needed, and using a podiatrist in an advisory and staff training role.

Medicaid utilization control regulations for ICFs include requirements that the attending physician provide medical information at the time of admission, make a medical evaluation of the patient, prepare a written medical plan of care, and periodically review the plan (456.370-380). 1/ The major change in the proposed conditions regarding attending physician input on ICF patients is that specific time limits have been set for providing the medical information and making the medical evaluation. Medicaid utilization control regulations also require attending physicians of SNF (456.260) and ICF (456.360) patients to certify the necessity of patient services every 60 days.

The proposed conditions also require that physicians visit ICF patients at least every 30 days for the first 90 days after admission and at least every 120 days thereafter. Current ICF regulations (442.346) specify only that the physician visit the patient at least every 60 days unless that frequency is considered unnecessary and reasons for that decision are recorded in the patient's medical record. The current regulations do not require that these justifications be independently reviewed and approved.

The proposed conditions require that physicians visit SNF patients at least every 30 days for the first 90 days after admission and at least every 60 days thereafter. The current SNF regulations are similar. They provide that after the first 90 days, the frequency of visits can be decreased from every 30 days to every 60 days if the physician justifies this action in the patient's medical record. The current SNF regulations also require that the physician submit the justification to the State Medicaid Agency, if the patient is a Medicaid recipient, and that the facility's utilization review committee review the justification. If either organization does not concur, the 30-day schedule must be reinstated (405.1123(b)).

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1/The current regulation specifies that the plan be reviewed at least every 90 days. The proposed conditions specify that physicians may space visits up to 120 days apart.

The proposed conditions do not require the attending physicians of SNF or ICF patients to justify the visit frequencies they select and do not require any independent review and approval action. The HHS introductory comments accompanying the proposed conditions included the following statement regarding physician visits:

"We have revised the physician visit schedule so that the attending physician (or physician's assistant or nurse practitioner employed and directed by the physician) will review the patient's plan of care, update the medical regimen, and evaluate the patient's condition as often as necessary. At least once every 30 days for the first 90 days, the physician will visit the patient to assure that the transition to the SNF or ICF is relatively non-traumatic and that the plan of care is appropriate and being implemented properly.

"Subsequent to the 90th day, the physician will schedule his visits in accordance with individual professional determination of the patient's needs, not to exceed 60 days for SNF patients or 120 days for ICF patients. The professional staffing of the facility and the availability of the physician by telephone should ensure adequate care during the intervals between physician visits. The rationale behind this change is simple: one must question the predication of visits on a time interval rather than on patient need. The proposed change is patient-centered with patient needs specifying the visit schedule. The outside limits are a necessity for enforcement purposes. We expect, as a result of this change, a firm commitment by the attending physician to a schedule that has been based on professional judgement."

The proposed conditions also broaden the definition of physician to include physician-directed physician assistants and nurse practitioners in those States having statutes permitting this practice.

Medical direction (483.22)

This proposed condition applies only to SNFs, as does the current HHS regulation on this subject (405.1122). The only significant change in the proposed conditions is that the medical director will establish standard operating procedures for physician practices in the facility. <sup>1/</sup> The HHS comments accompanying the proposed conditions included the following regarding medical direction.

"The role of the Medical Director in SNFs has been strengthened to include establishing standard operating procedures for physician practices in the facility. These procedures will govern such issues as patient visit schedules and coverage during emergencies and in the absence of the attending physician. The attending physician will be expected to formalize acceptance of these procedures and work closely with the Medical Director for the benefit of the patient."

As with the current SNF regulations for medical direction, the proposed condition will permit waivers of the requirement in accordance with other HHS regulations (405.1911)(b)). Under these regulations, the Secretary may waive the requirement for a full-time or part-time medical director for appropriate periods where the State Survey Agency documents that (1) the facility has made and continues to make a good-faith effort to comply and (2) the facility is located in an area where the supply of physicians is not sufficient to permit compliance with this requirement without seriously reducing the availability of physician services within the area.

Nursing services (483.23)

The proposed conditions are comparable to the current SNF regulations for nursing services (405.1124). ICF requirements relating to nursing services are scattered throughout the current regulations. In cases where current ICF requirements are comparable to proposed conditions, the latter generally are more explicit. Some of the requirements in the proposed conditions represent new requirements for ICFs.

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<sup>1/</sup>The proposed conditions specify that, in ICFs, these procedures shall be developed by the administrator and director of nursing.



**More explicit ICF requirements:**

- Utilization of nursing personnel, including assignments and work scheduling.
- Responsibilities of the director of nursing. 1/
- Drug administration procedures, including verifying conformance with physicians' orders.

**New ICF requirements:**

- Nursing personnel must be trained in rehabilitative nursing.
- Nursing personnel must observe food and fluid intake of patients and record in the medical record and report to the physician or dietitian any deviations from normal. 2/

Three requirements in the proposed conditions are new to both SNFs and ICFs. The proposed conditions specify that patients must be allowed to self-administer medications unless prohibited in writing by the attending physician. The current SNF regulations are silent on this matter, and the current ICF regulations permit self-administration only when authorized by the attending physician (442.337). The proposed conditions also specify that verbal drug orders must be countersigned by the attending physician within 5 days. 3/ The only requirement in current SNF regulations is that verbal orders for controlled drugs (i.e., schedule II) must be signed within

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1/Current ICF regulations refer to this position as a health services supervisor (442.339). The position may be held by either a registered nurse or by a licensed practical or vocational nurse. Under the proposed conditions, the position is designated as director of nursing and the incumbent will have the same responsibilities as a director of nursing in a SNF. The qualifications for the director of nursing position in an ICF will remain the same.

2/This is implied in current ICF regulations for patients on special diets (442.332).

3/The proposed physician services conditions require physicians to countersign all verbal orders within 5 days (483.21(c)).

48 hours (405.1124). Current ICF regulations specify that the facility must have the physician sign medication orders "in a manner consistent with good medical practice" (442.334). The proposed conditions also specify the capacities in which pool nursing personnel can be used. The current SNF and ICF regulations are silent on this point.

One change in the proposed conditions could be considered a reduction in ICF requirements or could have that effect. Under both the proposed conditions and the current ICF regulations, the director of nursing (formerly health services supervisor) must be either a registered nurse or a licensed practical or vocational nurse. If the position is not filled by a registered nurse, the facility must have a contract with such a nurse to consult with the licensed practical or vocational nurse. However, the proposed conditions specify "at least weekly consultation," while current ICF regulations specify that these consultations be "at regular intervals, but not less than 4 hours each week."

The proposed conditions retain the requirement in the current SNF regulations which specifies that a registered nurse be on duty 7 days a week on the day shift (405.1124(c)). Also retained are the same provisions under which this requirement may be waived by the Secretary. Generally a waiver can be granted if the facility has a full-time registered nurse on duty 40 hours a week and the facility (1) is located in a rural area with a shortage of skilled nursing services, (2) is, and has been, making a good-faith effort to secure registered nurse services for more than 40 hours per week, and (3) either has concurrence from attending physicians that patients' needs are being met with current registered nurse staffing or suitable arrangements have been made to meet needs specified by attending physicians on days when the full-time registered nurse is not on duty (see 405.1911(a)).

The HHS comments accompanying the proposed conditions stated that consideration was given to several other nursing services requirements but that no action was being taken at this time. The requirements considered but not acted on, and HHS' comments are:

**Ban nursing pools:**

"Although most commenters deplored the use of temporary pool personnel, they agreed that they perform a useful service in emergencies. We have not prohibited their use, therefore, but will not permit them to fill the position of charge nurse on the day shift or director of nursing services."

**Use of medication aides:**

"With regard to the use of medication aides rather than licensed personnel in the distribution of medications, we have found that there is no national consensus. While many States require that only licensed personnel perform this function, a significant number permit specially trained medication aides under the direction of a licensed nurse to distribute medications. Consequently, we will defer to State law in this matter. We feel that the central issue is not who actually administers the medication, but who is on-site and trained to recognize and attend to drug reactions. Since this proposed rule explicitly holds the director of nursing services accountable for drug administration, we expect that the distribution will be under the supervision of a licensed nurse. Furthermore, with the advent of unit dose dispensing it seems less efficient to use licensed personnel for the dispensing function."

**Nursing staffing standards:**

"Some States have chosen to employ such standards but to our knowledge there has been no systematic evaluation of their effectiveness, impact on quality, problems of over-staffing, or cost/benefit analysis of any of these approaches. In the absence of any evidence, we have chosen not to require specific staffing ratios at this time. However, we would appreciate knowing more about the experiences of those States which require specifics in staffing as well as any documentation of the relative impact of such standards."

Concurrently, we are planning to undertake a study on the subject, and will contact States to provide us with their assessment of the effectiveness of their staffing requirements."

Food and nutrition services (483.24)

The proposed conditions are generally comparable to the current SNF regulations for dietetic services (405.1125). The proposed conditions include more explicit language as well as new requirements for both SNFs and ICFs.

More explicit requirements:

- Storage and preparation of food in ICFs.
- Kitchen location and design in SNFs.

New requirements:

- States specific qualifications requirements for dietetic services supervisor in ICFs.
- The full-time dietetic services supervisor (or qualified consultant) at both SNFs and ICFs must be a member of the PCMS interdisciplinary team and participate in patient care, including patient assessments and developing plans of care. 1/
- Dietetic services supervisors at SNFs and ICFs who qualify through a State-approved course or through military training must take 15 hours of continuing education annually.
- ICFs must employ sufficient supportive personnel trained in the preparation and service of food.
- Menus at SNFs and ICFs must be planned at least 1 week in advance.
- SNFs must retain a record of each menu served for 30 days.

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1/The current SNF (405.1125) and ICF (442.332) regulations indicate that the dietetic representative becomes involved only when the attending physician orders special diets.

- SNFs and ICFs must retain records of all food purchased for 30 days.
- ICFs must use a current diet manual to plan, order, and prepare diets.
- ICFs must offer appropriate substitutes of similar nutritive value if a patient refuses food.
- ICFs must provide evening snacks where not prohibited by diet restrictions.
- SNFs and ICFs must ensure the availability of religious preference diets.
- SNFs and ICFs must retain a 3-day supply of staple foods at all times. 1/
- ICFs must meet certain requirements regarding kitchen location and design at ICFs.

The proposed conditions require that the dietetic service for both SNFs and ICFs be under the supervision of a full-time dietetic service supervisor. The dietetic service supervisor must be

1. A qualified dietitian; or
2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or
3. A graduate of a State-approved course that provided 90 or more hours of classroom instruction in food service supervision and must have experience as a supervisor in a health care institution and maintain 15 hours of continuing education annually; or
4. Trained and experienced in food service supervision and management in a military service equivalent in content to the requirements specified in 2 or 3 above and maintain 15 hours of continuing education annually.

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1/HHS comments accompanying the proposed conditions stated this requirement was added because of "nationwide concern over tragic episodes which occurred during recent extremes in weather."

The proposed conditions define a qualified dietitian as:

"A qualified dietitian must be registered, or eligible for registration, as determined by the Commission on Dietetic Registration. In addition, this person must have at least 1 year of supervisory experience in the food and nutrition service of a health care facility and participate annually in continuing education."

The proposed conditions also specify that, if the dietetic services supervisor is not a qualified dietitian, the incumbent must receive consultation from a qualified dietitian for at least 1 year. The current SNF regulations for the dietetic service supervisor position (405.1101(e)) are similar to those proposed, except that the 15-hour annual continuing education program cited in options 3 and 4 above is not required. The requirements for a qualified dietitian (405.1101(f)) are also comparable to those proposed.

The current ICF regulations state only that the facility "must have a staff member trained or experienced in food management or nutrition" who is responsible for planning menus and supervising the meal preparation and service to ensure that the menu plan is followed (442.332).

#### Pharmaceutical services (483.25)

The proposed conditions are comparable to the current SNF regulations for pharmaceutical services (405.1127). The proposed conditions include some new requirements for both SNFs and ICFs.

More explicit requirements:

--Recordkeeping for controlled drugs at ICFs.

New requirements:

--ICFs must have a pharmaceutical services committee.

--ICFs must have procedures for storing and disposing of drugs and biologicals.

--Tolerance limits (for compliance) have been established on unaccounted for controlled drugs for both SNFs and ICFs.

- Tolerance limits (for compliance) have been established on drug administration, errors for both SNFs and ICFs.
- Tolerance limits (for compliance) have been established on drug discard rates for both SNFs and ICFs.
- The director of nursing and the pharmacist are equally responsible for supervision of the pharmaceutical services at SNFs (and ICFs). 1/
- Pharmacists at each ICF must review the drug regimen of each patient at least monthly. 2/
- At both SNFs and ICFs, a record of drug regimen reviews must be prepared by the pharmacist and maintained in the facility.
- ICFs must have drug integrity and labeling procedures.

The proposed conditions also state that "Drug regimen review activities must be integrated, as necessary, into patient care planning \* \* \*." (483.25(h)). What is not clear in the above statement is whether the pharmacist is expected to take an active role in patient assessments and developing plans of care because the pharmacist is not a required member of the PCMS interdisciplinary team.

The proposed conditions omit a requirement specified in current SNF conditions regarding use of drugs and biologicals. The current SNF regulations specify that "Only approved drugs and biologicals are used in the facility \* \* \*" (405.1127(b)).

Approved drugs and biologicals are defined in current SNF regulations as:

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1/Current SNF regulations make the pharmacist alone responsible.

2/Current ICF regulations specify that a registered nurse make this review monthly (442.336).

"Only such drugs and biologicals as are:

(1) In the case of Medicare:

- (i) Included (or approved for inclusion) in the United States Pharmacopoeia, National Formulary, or United States Homeopathic Pharmacopoeia; or
- (ii) Included (or approved for inclusion) in AMA Drug Evaluations or Accepted Dental Therapeutics, except for any drugs and biologicals unfavorably evaluated therein; or
- (iii) Not included (nor approved for inclusion) in the compendia listed in paragraphs (b)(1)(i) and (b)(1)(ii) of this section, may be considered approved if such drugs:
  - (A) Were furnished to the patient during his prior hospitalization, and
  - (B) Were approved for use during a prior hospitalization by the hospital's pharmacy and drug therapeutics committee (or equivalent), and
  - (C) Are required for the continuing treatment of the patient in the facility.

(2) In the case of Medicaid, those drugs approved by the State Title XIX agency."

HHS officials told us this requirement was dropped because it was considered a program coverage issue rather than a standard of care. In the Department's opinion, the welfare of the patient is assured by the fact that drugs must be approved for marketing by the Food and Drug Administration.

The proposed conditions do not include a definition of a pharmacist. The current SNF regulations include a qualifications statement which requires that the pharmacist:



1. Be licensed as a pharmacist by the State in which he is practicing.
2. Have training or experience in the specialized functions of institutional pharmacy, such as residencies in hospital pharmacy, seminars on institutional pharmacy, and related training programs (405.1101(p)).

HHS, in its comments accompanying the proposed conditions, said the following about changes in pharmaceutical services requirements.

**Medication reviews:**

"We are extending the role of the pharmacy consultant to monthly reviews of drug therapy in ICFs as well as in SNFs. Since there is little difference in drug utilization patterns in both facilities, it makes sense to use the same review procedure for both. Research has shown that the clinical pharmacist does make an impact in SNFs and a similar outcome may be expected in ICFs. In addition, the consultant registered nurse who was formerly performing the drug regimen reviews in an ICF will now be available to take an active part in patient care management activities."

**Responsibility of director of nursing:**

"Under the revised Pharmaceutical Services section, the pharmacist and the director of nursing are jointly responsible for developing a safe and accurate system of drug distribution."

**Drug integrity and labeling:**

"This section addresses requirements for stock orders, drug integrity, and labeling in order to ensure that therapy does not continue beyond an appropriate period and that the drugs used are of good quality and properly labeled."

"Limit" standards:

"This revision also includes proposed 'limit' standards which are intended to reduce the amount of unaccounted for schedule drugs, drug wastage, and errors in administration within a facility. For example, limits are established for unaccounted for schedule drugs. There is a 5 percent limit on drug administration errors and a 4 percent limit on drugs which may be discarded. These are new criteria and are based primarily on expert regulations, as well as a review of the literature in studies conducted in hospitals and longterm care facilities. The Department welcomes comments on whether such limits should be established at all, their appropriateness, and any data that would suggest more appropriate levels.

"Concurrent with these proposals, we are funding a study to determine the feasibility of documenting and surveying for standards expressed in such terms. Should the study find that these criteria are not reasonable and cannot accurately be verified through the survey process, the requirements of the 1974 regulations will be reinstated in the final version of this rule."

Laboratory and radiological services (483.26)

The requirements in the proposed conditions are essentially the same as those in the current SNF regulations for these services (405.1128). The current ICF regulations have no comparable requirements. 1/ Therefore, the increased requirements for ICFs include:

- The facility must make these services available to patients.
- The facility must meet HHS standards if the services are provided in-house or have an agreement with a provider which meets Federal, State, and local laws.

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1/Current ICF regulations specify that facilities must maintain effective arrangements with outside resources for promptly providing medical and remedial services required by a resident but not regularly provided within the ICF (442.317).

- Physicians must note orders for these services in the patient's medical record.
- All test results must be authenticated, dated, and made a part of the record.
- The facility must help the patient arrange for transportation to obtain the required service.
- If the facility stores and transfuses blood or blood products, it must meet appropriate standards established by HHS for hospitals.

Social service (483.27)

The requirements in the proposed conditions are comparable to those in the current SNF (405.1130) and ICF (442.344) regulations for social services. The current and proposed social services requirements are rather rudimentary--(1) a facility can elect to either provide the services in-house or have written procedures for referring patients to qualified outside resources and (2) if the facility elects to provide these services in-house, a social services director must be responsible for arranging and integrating social services with other elements of the care plan.

The proposed conditions also state the qualifications required for the social services director. The required qualifications appear to be a slight upgrading of the current SNF regulations and the first definitive statement for ICFs. The qualifications stated in the proposed conditions are:

1. The person designated as social services director must have
  - a. A master of social work degree; or
  - b. A graduate degree in social or behavioral sciences with a specialty in gerontology; or
  - c. A bachelor of social work degree from a college or university with an undergraduate social work program accredited by the Council on Social Work Education; or

- d. A bachelor of arts or bachelor of science degree in social or behavioral sciences with 1 year of experience in providing social services in a long-term care facility; or
  - e. An associate of arts degree in social or behavioral sciences with 2 years of experience in the provision of social services in a long-term care facility.
2. If the person designated as social services director does not meet the requirements of section 1 a or 1 b above, he or she must receive consultation 1/ from a social services consultant who meets these requirements and has at least 1 year of experience in providing social services in a long-term facility.

The current SNF requirements for social services director (or consultant) are:

- Is licensed, if applicable, by the State in which practicing.
- Is a graduate of a school of social work accredited or approved by the Council on Social Work Education.
- Has 1 year of social work experience in a health care setting (405.1101(s)).

The only qualifications requirement in current ICF regulations is that the social services director must be "qualified by training or experience" to provide the services (442.344(c)).

#### Patient activities (483.28)

The requirements in the proposed conditions are comparable to those in the current SNF (405.1131) and ICF (442.345) regulations for patient activities. The only change of substance is that the proposed conditions require that the patient's activities plan be developed in consultation with the patient and the plan be reviewed with the patient at least quarterly. This requirement is included in current ICF regulations, but current SNF regulations are silent on the issue.

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1/Must be at least 1 year in duration.

The proposed conditions, which designate the primary position as patient activities director, specify that the position can be filled by any of the following:

1. Therapeutic recreation specialist.
2. Occupational therapist.
3. Occupational therapy assistant.
4. A person who has social services qualifications 1 (a) or (b) (see p. 91).
5. A person who
  - a. Has completed a course approved by the State or by the Secretary that provides at least 36 classroom hours in patient activities coordination; and
  - b. Has 2 years of full-time experience in a patient activities program in a health care setting.
6. Patient activities directors not meeting any of the above qualifications options but who
  - a. Receive regularly scheduled consultation 1/ from an individual who meets one of the requirements of 1 through 4 above and who has at least 1 year of experience as director of a long-term care activities program.

The requirements for this position in the current SNF regulations are defined as

1. Is a qualified therapeutic recreation specialist; or
2. Is a qualified occupational therapist or occupational therapy assistant; or
3. Has 2 years of experience in a social or recreational program within the last 5 years, 1 year of which was full time in a patient activities program in a health care setting (405.1101(o)).

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1/Must be at least 1 year in duration.

As indicated above, the proposed conditions add one additional discipline--social services--to the list of individuals qualified to direct patient activities. The proposed conditions also appear to relax requirements to some degree in that option 6 above permits facilities to use personnel having no formal training or experience whereas current SNF regulations require that the position be filled by someone having at least some experience in social or recreational programs.

The qualifications for a therapeutic recreation specialist, occupational therapist, and occupational therapy assistant are defined in both the proposed conditions and the current SNF regulations. The following are the qualifications stated in the proposed conditions.

**Therapeutic recreation specialist:**

1. a. Has completed a full 4-year course in an accredited college or university with a major study appropriate to the field of therapeutic recreation, or has 3 years of experience in the principles, methods, and techniques of recreation; and
- b. Is eligible for registration as a therapeutic recreation specialist under the requirements set by the National Therapeutic Recreation Society (branch of the National Recreation and Park Association).

**Occupational therapist:**

1. a. Is eligible for certification as an occupational therapist by the American Occupational Therapy Association; and
- b. Is a graduate of an occupational therapist educational program accredited jointly by the American Occupational Therapy Association and the Committee on Allied Health Education and Accreditation of the American Medical Association; or

2. Has equivalent training and experience.

Occupational therapy assistant:

1. a. Is eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association; and
  - b. Is a graduate of an occupational therapy assistant program accredited by the American Occupational Therapy Association; or
2. Has equivalent training and experience.

The current SNF regulations also state qualifications for a therapeutic recreation specialist (405.1101(v)), occupational therapist (405.1101(m)), and occupational therapy assistant (405.1101(n)). The requirements for therapeutic recreation specialist appear to have been upgraded because the current SNF regulations do not include formal education or experience requirements. The qualifications requirements stated in the proposed conditions for occupational therapist and occupational therapy assistant are generally comparable to those stated in current SNF regulations.

The current ICF regulations specify only that the staff member responsible for the patient activities program be "qualified by training or experience in directing group activity" (442.345(b)).

Rehabilitative services (483.29)

The requirements in the proposed conditions are comparable to those in the current SNF (405.1126) and ICF (442.343) regulations for rehabilitative services. The only significant new requirement for both SNFs and ICFs is that therapists must submit reports of the patient's progress to the attending physician within 2 weeks after initial therapy and at least every 30 days thereafter as necessary. 1/

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1/Current SNF regulations require that therapists and attending physicians reevaluate the rehabilitation plan at least every 30 days and that a patient progress report be transmitted to the physician within 2 weeks of therapy initiation.

Both the current SNF and ICF regulations specify that prescribed therapy must be administered by a qualified therapist or by qualified assistants or other supportive personnel supervised by the qualified therapist. The current SNF regulations define the qualifications for various types of qualified therapists, and the current ICF regulations are cross-referenced to those definitions. The proposed standards include the following as meeting the definition of qualified therapist.

**Speech-language pathologist:**

1. Is eligible for a certificate of clinical competence in speech-language pathology granted by the American Speech-Language-Hearing Association in effect on January 17, 1974; or
2. Meets the educational requirements for certification, and has accumulated or is accumulating the supervised clinical experience required for certification.

**Audiologist:**

1. Is eligible for a certificate of clinical competence in audiology granted by the American Speech-Language-Hearing Association, in effect on January 17, 1974; or
2. Meets the educational requirements for certification and has accumulated or is accumulating the supervised clinical experience required for certification.

**Physical therapist:**

1. a. Is a graduate of a program in physical therapy approved by the American Physical Therapy Association or by the Council on Medical Education of the American Medical Association; and
- b. Has 2 years of experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, offered until December 31, 1977; and



- c. Was licensed or registered before January 1, 1966, and had 15 years of full-time experience as a physical therapist before January 1, 1970; or
2. Has graduated from a State-approved 4-year college program in physical therapy before January 1, 1966.

Physical therapist assistant:

1. Is a graduate of a 2-year college-level program approved by the American Physical Therapy Association; or
2. Has equivalent training and experience.

Other qualified occupations:

Meets the qualifications of an occupational therapist or occupational therapy assistant as defined in the proposed standards for patient activities.

Physical environment and safety (Subpart D)

Physical environment (483.40)

The provisions in the proposed conditions are comparable to those in the current SNF regulations (405.1134). The current SNF regulations include a standard for life safety from fire (405.1134(a)). In the proposed conditions, these requirements are transferred to section 483.45 (see p. 99). The proposed physical environment condition also includes requirements for infection control. Infection control is a separate condition of participation in current SNF regulations (405.1135). Current ICF regulations contain many of the requirements stated in the proposed conditions. New requirements for SNFs or ICFs would include the following.

--There must not be more than 12 beds per room in ICFs caring primarily for the mentally ill and retarded. 1/

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1/Can be waived under certain circumstances.

- Each nursing station in SNFs and ICFs must be equipped to register patients' calls through a communication system from patient areas, including patient rooms, toilet, and bathing facilities. In a SNF, each patient's bed must have a call signal that registers at the nursing station. 1/
- ICFs must have an effective, safe, and continuing pest control system.
- ICFs must meet specific requirements for lighting, noise levels, and building temperatures.
- SNFs and ICFs must provide furnishing and interior decorations which promote a homelike atmosphere. Patients must be permitted and encouraged to have personal possessions in their rooms that do not interfere with their care, treatment, or well-being or that of other patients.
- SNFs and ICFs must maintain and service patient care equipment in accordance with manufacturers' recommendations.
- SNFs and ICFs must ensure that temperature of hot water for bathing and handwashing does not exceed 120 degrees Fahrenheit (48.8 Celsius).
- SNFs and ICFs must have a qualified person to maintain their heating, ventilating, and air-conditioning system and provide emergency service. If the facility does not employ a qualified 2/ person, it must have a written agreement with an outside source to provide normal maintenance and emergency service.
- The facility must have a contingency plan to ensure a supply of power, heat, and water. 3/

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1/A signal system is generally required in current SNF regulations (405.1134(d)).

2/Qualifications are not defined in the proposed standards.

3/HHS comments accompanying the proposed conditions stated this requirement was added to "reflect nationwide concern over tragic episodes which occurred during recent extremes in weather."

Safety (483.45)

The proposed conditions are comparable to the current SNF (405.1134(a), 405.1136) and ICF (442.313, 321-323) regulations. The most significant changes are the following:

- SNFs and ICFs must meet the provisions of the 1973 edition of the Life Safety Code of the National Fire Protection Association unless, on May 31, 1976, the facility was in compliance with the 1967 code (with or without waivers) and continues to remain in compliance with that edition of the code. 1/
- ICFs having nonflammable gases must meet National Fire Protection Association codes for those gases.
- All facility employees must attend, at least annually, a fire safety training program conducted by a qualified outside organization or agency.

The current SNF and ICF regulations provide for waivers for appropriate periods of certain fire safety requirements, including construction types and construction features. The proposed conditions allow waivers of 5 years on construction types and 2 years on construction features--with the provision that waivers be reevaluated upon modification, renovation, alteration, or any other change of the feature waived. The HHS comments accompanying the proposed conditions included the following regarding increasing waiver periods:

"With rare exceptions, neither of these construction categories change once evaluated. Granting only one-year waivers has compounded paperwork for surveyors and facilities, since a yearly justification was necessary. We are proposing that construction type waivers be granted for

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1/Current SNF and ICF standards require compliance with the 1967 National Fire Protection Association Code. Amendments to the Social Security Act in December 1975 generally required SNFs to meet the 1973 edition with the above cited exceptions; however, section 915 of the Omnibus Reconciliation Act of 1980 (Public Law 96-499) repealed the requirement and authorized the Secretary of HHS to determine in regulations when SNFs are required to meet the provisions of revised editions of the Life Safety Code.

5 years and construction feature waivers for 2 years. Of course, any changes in building construction or renovations will trigger complete re-evaluation."

Patient rights (Subpart E)

Patients' rights (483.50)

A substantial number of new requirements are added to patient rights in the proposed conditions. The patient rights requirements in current SNF regulations generally are included in the governing body and management condition of participation (405.1121(k)) and in ICF regulations under residents' bill of rights standards (442.311). In addition to establishing new requirements, the proposed conditions are also more explicit regarding some requirements already stated in SNF and ICF regulations.

More explicit requirements for SNFs and ICFs include:

- Patient's role in planning his or her care.
- Assuring patient privacy.
- Records on patients' personal property.
- Controls over use of chemical restraints (particularly SNF).
- Informing patients of charges for services.
- Procedures for handling involuntary transfers, including appropriate notice to affected patients.

New requirements for SNFs and ICFs include:

- Federally funded ombudsmen and patients' representatives must be given access to patients.
- Addresses and telephone numbers of HHS, the State Survey Agency, the State ombudsmen, and the Area Agency on Aging must be posted.
- Patients must be allowed to form a residents' council, and the facility must provide assistance to the council.

- The facility must notify patients of surveys and assist them in meeting with surveyors.
- Facilities must have at least one private phone for patient use and allow patients to install phones in their rooms.
- Patients' representatives must be given access to patient records after death.
- Patients must be permitted to review their records and to authorize others to have access to these records.

The HHS comments accompanying the proposed conditions included the following statements regarding patient rights:

**Accessibility:**

"As part of this expansion of Patients' Rights, we have proposed a standard for a stronger provision on accessibility. This will ensure access at all times to nursing home ombudsmen and legal advocates and reinforces their mandate under the 1977 Amendments to the Older Americans Act. However, since the patient has the right to see or refuse to see anyone, it is the patient who will ultimately determine just how accessible he or she will be."

**Other comments:**

"Other Provisions include the patients' right to form Residents' Councils, to be fully informed regarding all decisions affecting them, to privacy, and to have personal property. Standards will permit patient involvement in planning the care regimen. Patients should also be permitted to do as much for themselves as possible to forestall being cast in a dependent or helpless role."

The proposed conditions do not include standards regarding patients' personal funds. This matter is included in current SNF (405.1121(k)(6)) and ICF (442.311(e)) regulations. HHS comments accompanying the proposed conditions included the following statement regarding patient funds:

"Section 21(a) of PUB.L. 95-142, the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, requires long-term care facilities to establish and maintain a complete accounting system of patients' funds which prevents commingling of patient and facility monies. These regulations will be forthcoming as a final rule. We intend to include a standard on the protection of patients' personal funds in Subpart E--Patients' Rights. Furthermore, Section 21(b) of PUB.L. 95-142, a companion regulation on Permissible Charges to Patients Funds will soon be published as a proposed rule. The provisions of this regulation will ultimately be incorporated into patients' rights."

The regulations regarding accounting for patient funds were published in July 1980 and will become effective after review and approval by the Office of Management and Budget.

HHS ESTIMATE OF COST TO MEET  
JULY 1980 PROPOSED REQUIREMENTS

<u>Requirement category and assumptions made</u>	<u>Annual cost</u> (millions)
<b>Patient rights:</b>	
1. Permit 12-hour visiting days.  No additional staffing required. No specific estimate was computed. The potential cost is probably less than \$5 million.	\$ 5.00
2. Comply with procedures on use of restraints.  Slight increase in observation and documentation time. Estimate is taken amount.	1.00
3. Comply with procedures for involuntary transfers.  Estimate is taken amount.	1.00
4. Support resident councils.  About 30 percent of facilities already have councils. The other 70 percent can support councils by providing one employee for about 2 hours per week.	<u>8.80</u>
Subtotal: patient rights	<u>\$15.80</u>

<u>Requirement category and assumptions made</u>	<u>Annual cost</u>
	(millions)

Patient care management:

1. Patient assessments.

Scenario No. 1:

One assessment per year on all patients who stay more than 45 days (54 percent of SNF, 65 percent of ICF) assuming 100-percent bed occupancy and no turnover. About 1 million assessments annually--\$19.5 million.

Scenario No. 2:

One assessment per patient per year based on estimated turnover rates and assuming full occupancy. About 2.5 million assessments annually--\$48.8 million.

Average of two scenarios

\$19.5 million (No. 1) + \$48.8 million  
(No. 2) = \$68.3 million divided by 2 = \$34.15

Note 1: Both scenarios are based on the assumption that 10 percent of patients will receive full team assessments and 90 percent will receive core team assessments. For full team assessments, it was assumed that the attending physician will make a special visit and other members of the team would each spend 1 hour. Estimated cost per assessment was about \$57. For core team assessments, it was assumed that the attending physician would not have to make a special visit and that 30 minutes would be spent by each nursing team member and 15 minutes by each nonnursing team member. Estimated cost per assessment was about \$15. (See p. 26 for discussion of full team and core team assessments.)

Note 2: Scenario No. 1 includes both Medicare and Medicaid SNF patients as well as ICF patients. Scenario No. 2 does not include Medicare SNF patients because statistics show the average stay is 24 days and assessments are required only if the patient's stay will exceed 45 days.



<u>Requirement category and assumptions made</u>	<u>Annual cost</u> (millions)
2. Patient assessment forms.	\$ 1.00
Cost to States to develop stand- ard patient assessment forms meeting HHS requirements. Estimate is token amount.	
Subtotal: patient care management	<u>\$35.15</u>
Physician involvement:	
1. Increased volume of visits to ICF patients.	1.00
Physicians must visit patients every 30 days for first 90 days. This increased volume will be offset in later periods because physicians will increase time between visits from 60 days to 120 days. Estimate is token amount.	
2. Development of standard operating proce- dures for attending physicians.	<u>1.00</u>
No cost in SNFs because medical directors will prepare procedures as part of normal duties. Estimate is for time required for adminis- trator and director of nursing in ICFs to develop procedures. Estimate is token amount.	
Subtotal: physician involvement	<u>\$2.00</u>

<u>Requirement category and assumptions made</u>	<u>Annual cost</u> (millions)
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## Manpower:

1. Additional cost to ICFs to employ a qualified patient activities director. \$ 7.30

About 50 percent of the ICFs have a fully qualified incumbent. About 25 percent have unqualified incumbents who will upgrade themselves at their own expense and who will not receive additional pay after doing so. About 25 percent will hire new qualified persons at higher rates than paid to incumbents. All directors work 20 hours per week. The calculated cost is based on the pay differential between the salary for a nonqualified incumbent and the salary that will be paid to a qualified person at the 25 percent of facilities which will hire new employees.

2. Additional cost to ICFs to employ a qualified dietetic service supervisor. 9.30

About 60 percent of the ICFs have a fully qualified incumbent. About 20 percent have unqualified incumbents who will upgrade themselves at their own expense and who will not receive additional pay after doing so. About 20 percent will hire new qualified persons at higher rates than paid to incumbents. The calculated cost is based on the pay differential between the salary for a nonqualified incumbent and the salary that will be paid to a qualified person at the 20 percent of facilities which will hire new employees.

<u>Requirement category and assumptions made</u>	<u>Annual cost</u> (millions)
3. Additional cost to SNFs and ICFs to provide 30 hours initial training to novice nurses aides and orderlies.	<u>\$10.00</u>
<p>There are about 425,000 nurses aide positions in all facilities and the turnover rate is 50 percent per year. Only fully inexperienced aides receive the full 30 hours training, and the balance require only orientation. Ten percent of new hires are experienced aides. About 70 percent of all facilities currently provide training because of State regulations or self-imposed policies. About 8 hours of the students' 30-hour training time will be away from direct care and about 19 hours of the instructors' time will be away from normal duties. The cost is based on the nondirect care time for novice aides and orderlies hired at only those facilities not now providing initial training (30 percent) and the instructors' time at those facilities. The estimate assumes that the instructor at each of these facilities will have to provide only one 30-hour training session per year.</p>	
Subtotal: manpower	<u>\$26.60</u>
TOTAL ESTIMATED COST	<u>\$79.55</u>

NURSING HOME INDUSTRY ESTIMATE OF COST  
TO MEET JULY 1980 PROPOSED REQUIREMENTS

Condition/Standard	SIF		ICF		TOTAL COST	
	Start-up Costs In Year 1	Recurring Annual Costs	Start-up Costs In Year 1	Recurring Annual Costs	Start-up Costs In Year 1	Recurring Annual Costs
483.20 Patient Care Management						
Initial Assessment	\$ 12,047,000	\$ 12,047,000	\$ 6,509,000	\$ 6,509,000	\$ 18,556,000	\$ 18,556,000
Limited Assessment	9,303,000	9,303,000	3,181,000	3,181,000	12,484,000	12,484,000
Annual Assessment	6,385,000	6,385,000	3,459,000	3,459,000	9,844,000	9,844,000
Training of Staff	6,241,000*	2,571,000*	7,376,000**	3,018,000**	13,617,000	5,599,000
DOR trainer	2,442,000**	1,724,000**	3,372,000**	2,389,000**	5,814,000	4,104,000
Subtotal	36,418,000	32,039,000	23,018,000	18,518,000	60,236,000	60,648,000
483.50 Patients' Rights						
Std.(f) Resident Council	2,327,000**	2,327,000**	3,214,000**	3,214,000**	5,541,000	5,541,000
Std.(h) Involuntary Transfers	2,357,000**	2,357,000**	3,256,000**	3,256,000**	5,613,000	5,613,000
Subtotal	4,684,000	4,684,000	6,470,000	6,470,000	11,154,000	11,154,000
483.12 Governing Body and Management						
Std.(f) Visiting Hours and Facility	77,651,000**	77,651,000**	107,232,000**	107,232,000**	184,883,000	184,883,000
Std.(g) Staff Development	38,889,000***	16,667,000***	31,018,000***	13,636,000***	70,707,000	30,303,000
Nurse's aide time	20,265,000**	20,265,000**	27,985,000**	27,985,000**	48,250,000	48,250,000
Training staff's time	99,154,000	36,932,000	69,083,000	41,621,000	118,957,000	78,553,000
Subtotal - Staff Development	N.A.	N.A.	337,000	136,000	337,000	136,000
Training - 36 hour course	N.A.	N.A.	2,787,000	2,787,000	2,787,000	2,787,000
Upgrading wages	N.A.	N.A.	1,495,000	999,000	1,495,000	999,000
Consultant	N.A.	N.A.	4,619,000	3,420,000	4,619,000	3,420,000
Subtotal	N.A.	N.A.	11,179,000	11,179,000	11,179,000	11,179,000
483.27 Social Services Director						
Consultant	N.A.	N.A.	249,000	366,000**	249,000	631,000
Initial training - 90 hour course	265,000**	265,000**	8,083,000	8,083,000	8,083,000	8,083,000
Continuing education - 15 hours	N.A.	N.A.	40,915,000	40,915,000	40,915,000	40,915,000
Upgrading wages	N.A.	N.A.	3,834,000	3,834,000	3,834,000	3,834,000
Full-time hiring	N.A.	N.A.	53,447,000	53,198,000	53,712,000	53,463,000
Biweekly consultant	265,000	265,000				
Subtotal	265,000	265,000	10,110,000	10,110,000	10,110,000	10,110,000
483.25 Pharmaceutical Services						
Consultant	N.A.	N.A.	6,053,000	6,053,000	6,053,000	6,053,000
Pharmaceutical Service Committee	20,248,000**	20,248,000**	27,962,000**	27,962,000**	48,210,000	48,210,000
Drug administration	20,248,000	20,248,000	44,125,000	44,125,000	64,373,000	64,373,000
Subtotal	N.A.	N.A.	13,966,000	13,966,000	13,966,000	13,966,000
483.13 Medical Records						
Consultant	240,000**	240,000**	331,000**	331,000**	571,000	571,000
Staff development	29,867,000	29,867,000			62,730,000	62,730,000
Subtotal	29,867,000	29,867,000				
483.23 Nursing Services (3)						
TOTAL COST	\$228,527,000	\$201,917,000	\$367,863,000	\$332,923,000	\$586,390,000	\$534,840,000

\* Allocated on the basis of number of beds; SIF 468, ICF 544.  
 \*\* Allocated on the basis of number of facilities; SIF 424, ICF 588.  
 \*\*\* Allocated on the basis of type of facility; SIF 558, ICF 458.  
 N.A. Not Applicable.

HHS COST ESTIMATE TO MEET PROPOSED  
JANUARY 1981 PATIENTS' RIGHTS REQUIREMENTS

<u>Requirement category and assumptions made</u>	<u>Annual cost</u>
	(millions)
1. Provide 10-hour visiting days	\$ 9.3
<p>One-half of the facilities surveyed employed receptionists. One-fourth of the facilities surveyed had less than 10-hour visiting days; the average time was 6.5 hours. Incremental costs were based on these latter facilities with receptionists hiring staff to cover the additional visiting time--3.5 hours. (1,825 facilities x 3.5 hours/day x \$4/hour x 365 days/year = \$9.3 million)</p>	
2. Comply with standards on use of restraints	5.4
<p>Standards call for release of physically restrained patients every 2 hours for at least 10 minutes. Fifty percent of all abusive or aggressive patients will require physical restraint.</p>	
3. Comply with standards for involuntary transfers	.3
<p>Estimate is a token amount based on additional clerical time to type transfer notices.</p>	
4. Support resident councils	<u>4.8</u>
<p>One-half of the facilities surveyed have resident councils. The other one-half can support councils by providing one employee for about 2 hours each week.</p>	
Total	<u>\$19.8</u>

COMPARISON OF PATIENTS' RIGHTS PROVISIONSHHS PROPOSALS VS. STATE LAWS AND REGULATIONSVisiting Hours

HHS July 1980 proposed regulation: Visiting hours must encompass at least a 12-hour period sometime between 7:00 a.m. and 10:00 p.m. and not include time devoted to patient feeding, bathing, and treatment. The patient's representatives and ombudsman/advocate representatives must have access to the patient at all times. Under certain circumstances, the patient's family may have access to the patient outside regular visiting hours.

HHS January 1981 proposed regulation: The facility must have daily visiting hours which encompass at least a 10-hour period. Ombudsman representatives and two persons designated by the patient must have access to the patient at all times.

Florida statute: Facility visiting hours shall be flexible, taking into consideration special circumstances such as, but not limited to, out-of-town visitors and working relatives and friends.

Connecticut regulation: Visiting hours shall be as liberal as may be consistent with good resident care.

Oklahoma proposed regulation: No provisions. A 1980 statute provides that public agency, legal service program, or community organization representatives shall be permitted patient access at reasonable hours, which shall be 10:00 a.m. to 8:00 p.m.

Resident Councils

HHS July 1980 proposed regulation: The facility must permit the formation of a resident council by interested patients, provide space for meetings, and provide assistance in attending meetings.

HHS January 1981 proposed regulation: No change.

Florida statute: Patients have a right to join with other patients or individuals within or outside the facility to work for improvements in patient care, free from restraint, interference, coercion, discrimination, or reprisal.

Connecticut statute: Patients may organize, maintain, and participate in a patient-run resident council, as a means of fostering communication between residents and staff, encouraging resident independence and addressing the basic rights of nursing home patients and residents, free from administrative interference and reprisal.

Oklahoma proposed regulation: Each facility shall establish a residents' advisory council which shall review procedures for implementing residents' rights, facility responsibilities and make recommendations for changes or additions which will strengthen the facility's policies and procedures as the affect residents' rights and facility responsibilities.

### Restraints

HHS July 1980 proposed regulation: The facility may not subject any patient to physical or chemical restraints for purposes of discipline or convenience except when an emergency exists in which failure to use restraints is likely to endanger the health or safety of the patient or others; and only upon the written order of a physician. The physician's written order must specify a period of time and document necessity. The facility may not reimpose restraints except upon the written order of a physician who has personally observed the patient since the previous restraint order was imposed. The nursing staff must observe a chemically restrained patient at least every 4 hours to assess possible side effects; and a physically restrained patient at least every 30 minutes to assess possible adverse effects and attend to the patient's physical needs.

HHS January 1981 proposed regulation: The facility may not subject any patient to physical restraints for purposes of discipline or convenience or in such a manner as to cause injury. A patient may be physically restrained only upon the written order of a physician who must document the reason and periodically review the need for the order. A physically restrained patient must be

observed every hour. Except while sleeping, physical restraints must be removed at least 10 minutes out of every 2 hours to allow the patient an opportunity to move and exercise.

Drugs may not had used to limit physical or mental capability beyond that which is reasonably necessary to treat the patient. When drugs are used to protect the patient from harm to himself or others, the physician must order the drug in writing; document the reason; and periodically review the need for the order. The patient must be observed for a duration and frequency that is consistent with the patient's health status, the drug, its dosage, and route of administration.

Florida statute: Patients have the right to be free from physical and chemical restraints, except those authorized in writing by a physician for a specified and limited period of time or as are necessitated by an emergency. In an emergency, restraint may only be applied by a qualified nurse who shall set forth in writing the circumstances requiring the use of restraint, and; in the case of use of a chemical restraint, a physician shall be consulted immediately thereafter. Restraints shall not be used in lieu of staff supervision or merely for staff convenience, for punishment, or for reasons other than patient protection or safety.

Connecticut statute: Each patient shall be free from chemical and physical restraints except as authorized in writing by a physician or when necessary to protect the patient from injury to himself or to others.

Oklahoma proposed regulation: Restraint, the restrictive placement or application of restrictive devices to prevent a resident from endangering himself or others while awake, shall be used only on written order of a physician, except in an emergency. In an emergency, the use of restraints must be confirmed by a physician's written order within 12 hrs. after application of restraints. A restraints order written by a physician shall be valid for a maximum period of 3 days. No person may be restrained unless there is an attendant constantly on duty on the same floor and within reasonable hearing distance (100 ft. maximum). Frequent observation of the patient will be conducted by the attendant at intervals no greater than 30 minutes.



State law prohibits the use of chemical restraints unless authorized in writing by a physician except in an emergency. Consultation with a physician is required within 24 hours in the case of an emergency.

### Involuntary Transfers

HHS July 1980 proposed regulation: A facility may not involuntarily transfer a patient except when (1) the patient's physician determines that failure to transfer the patient will threaten the health and safety of the patient or others, and documents that determination, (2) the nonpayment of allowable fees has occurred, or (3) the findings of a medical necessity review determine that the patient no longer requires the level of care provided.

The facility must notify the patient, or the patient's representative and attending physician at least 15 days before an involuntary intrafacility transfer and at least 30 days before any other involuntary transfer. This notice must be in writing and contain the reasons for the proposed transfer; the effective date of the proposed transfer, and the location to which the facility proposes to transfer the patient.

HHS January 1981 proposed regulations: A facility may not involuntarily transfer a patient except when (1) the patient's physician determines that failure to transfer the patient will threaten the health and safety of the patient or others, and documents that determination, (2) nonpayment of allowable fees has occurred, (3) the findings of a medical necessity review determine that the patient no longer requires the level of care provided or when the facility documents it can no longer meet a patient's needs, or (4) in an intrafacility transfer situation, when the facility wishes to fully utilize its room capacity by assigning persons of the same sex to fill vacant beds.

The facility must notify the patient, or the patient's representative and attending physician at least 5 days before an involuntary intrafacility transfer and at least 30 days before any other involuntary transfer. This notice must be in writing and contain the reasons for the proposed transfer; the effective date of the proposed transfer; the location, if known, to which the facility proposes to transfer the patient.

Florida statute: Patients have the right to be transferred or discharged only for medical reasons or for the welfare of other patients, and the right to be given reasonable advance notice of no less than 30 days of any involuntary transfer or discharge, except in the case of an emergency as determined by a licensed professional on the staff of the nursing home, or in the case of conflicting rules and regulations which govern Title XVIII or Title XIX of the Social Security Act. For nonpayment of a bill for care received, the patient shall be given 15 days' advance notice. A facility certified to provide services under Title XIX of the Social Security Act shall not transfer or discharge patients solely because the source of payment for care changes from private to public funds or from public to private funds, unless the facility, as documented in the patient's medical record, makes a reasonable effort to arrange for appropriate continued care in the community or through another nursing home.

Connecticut statute: Each patient will be transferred or discharged only for medical reasons, or for his welfare or that of other patients, as documented in his medical record; or in the case of a private patient, for his nonpayment or arrearage of more than 15 days of the per diem room rates established by the nursing home pursuant to approval by the commission on hospitals and health care for his stay, except as prohibited by the Social Security Act. In the case of an involuntary transfer or discharge, the patient or his guardian, relative or sponsoring agency, and the patient's personal physician--if the discharge plan is prepared by the medical director of the nursing home facility--is given at least 30 days written notice to ensure orderly transfer or discharge.

Oklahoma proposed regulation: Involuntary transfer or discharge of a resident may be initiated by a facility only for medical reasons as documented by the attending physician, for the resident's safety or for the safety of other residents as documented by the attending physician and the supervising nurse, or for the nonpayment of charges for the resident's care as documented by the business records of the facility.

Written notice shall be provided 10 days in advance of the transfer or discharge date to the resident, the resident's next of kin or guardian, if any, to the party responsible for payment of charges for the resident's care, if different from any of the foregoing, and to the

State. The 10 day requirement shall not apply when an emergency transfer is mandated by the resident's health care needs or when the transfer or discharge is necessary for the physical safety of other residents.

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