HOME CARE II

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

PROFESSIONAL CERTIFICATION

for Home Care & Hospice Executives

Sponsored by Home Care University, an affiliate of The National Association for Home Care

HOMECARE UNIVERSITY

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

PROFESSIONAL CERTIFICATION

for Home Care & Hospice Executives

Sponsored by Home Care University, an affiliate of The National Association for Home Care

HOMECARE UNIVERSITY

HOME CARE AIDE ASSOCIATION OF AMERICA

THE HOME CARE AIDE ASSOCIATION OF AMERICA IS AN AFFILIATE OF THE NATIONAL ASSOCIATION FOR HOME CARE, LOCATED AT 519 C STREET, NE, WASHINGTON, DC 20002-5809.

HCAA Cert.

National Uniformity for Paraprofessional Title, Qualifications, and Supervision

The paraprofessional home care worker is a key component of both acute and long-term home care programs. Two elements are essential to the success of the paraprofessional: appropriate training and supervision. Supervision should include a strong worker support system. The paraprofessionals' support system includes competent administrative leadership and the potential for interaction and sharing of experience among workers.

The Home Care Aide Association of America (HCAAA) developed these standards for home care paraprofessional titles, qualifications, and supervision as a conceptual model for paraprofessional services. A uniform system must be agreed on before policymakers will provide adequate funding to cover the costs of implementing increased training and supervision. Adoption of this approach will result in greater uniformity and accountability, improved quality in home care services and public policy decisions, and enhanced consumer understanding. It will allow the industry to improve current home care services funded by the Older Americans Act, Medicare, Medicaid, the Social Services Block Grant (Title XX), insurance programs, and consumers. Most important, it will enable the industry to develop a comprehensive long-term care policy.

This position paper is based on the premise that uniform titles, qualifications, training, and supervisory standards for the paraprofessional in home care must be agreed on and that the financial resources to meet the standards must be made available simultaneously with the imposition of those standards. These standards should apply to all paraprofessional home care services regardless of payment source. The policies outlined in this paper are not intended to supersede, preempt, or otherwise affect existing state scope of practice laws regarding the provision of care in the home.

The core services around which a long-term care strategy should be forged are those cost-effective services that are performed by home care paraprofessionals. NAHC and other organizations have called this work category homemaker-home health aide. This worker is a paraprofessional with training and competence in both home management and personal care skills. Individuals perform these tasks under a variety of titles, each with different training requirements, standards of supervision, and funding sources, for example, the home health aide within the Medicare model and the homemaker under Title XX. This lack of uniformity in title, function, and standards for training and supervision for the home care paraprofessional has resulted in considerable fragmentation and no clear perspective on the continuum of long-term care services provided by this important segment of the home care community.

Without uniform standards and definitions, long-term care policymakers will be pressured to accept what exists, rather than to promote an improved classification system.

Uniform Title

To facilitate long-term care planning and legislation, the HCAAA Advisory Board has proposed the use of a generic title for paraprofessionals in home care. It will cover many manifestations and leave room for the growth and development of classifications and specializations as they become appropriate. That title is *home care aide*. The term encompasses the essential components of the job. Care is being provided in the home by someone who has received training and is working under professional supervision with the goal of assisting the client with independent living. HCAAA's Advisory Board is proud to advocate the term *home care aide*.

Levels of Preparation and Responsibilities for the Three Classifications of Home Care Aide

To prevent or delay institutionalization, clients will need a range of services that extend from basic housekeeping to complex personal care. The home care aide must be prepared to adapt to client differences. The three classifications of home care aide defined below address a range of client needs and the attendant needs for training and supervision. HCAAA proposes that experienced home care aides bypass training if they are able to demon-

strate their ability to perform required tasks through a competency evaluation. Any long-term home care program must provide funding for this training and supervision to meet client needs.

Delineating three classifications of home care aide will provide the flexibility needed to design a system that maintains appropriate standards for appropriate levels of care. It is inefficient to discourage provision of these services if the only available personnel are overqualified and more costly than needed. It is essential that those clients who need environmental services or minimal personal care services must receive help from people who are fully qualified to meet their needs.

The environmental and personal care needs of the client can be met by the same person. The Class III home care aide is prepared and competent to perform tasks of the Class I and Class II home care aide, as well as tasks for which he or she has had more advanced training. Similarly, the Class II home care aide can perform the duties of both home care aide Classes I and II. No home care aide is to perform tasks with clients (1) for which he or she has not received appropriate training or (2) without proper supervision.

It is also important to note that this classification system allows individuals to work their way up a career ladder or path. Such verification of the value of this role will enhance job satisfaction and thus improve patient care.

The following descriptions of Home Care Aide I, II, and III address these issues.

Home Care Aide I

The home care aide I (HCA I) assists with environmental services such as housekeeping and homemaking services to preserve a safe, sanitary home and enhance family life. The HCA I should encourage the client and/or family to assume as much responsibility as possible for care and environment in accordance with the plan of care. The HCA I is *not* to provide any personal care.

Examples of duties: housekeeping; shopping; laundry; essential errands; basic meal preparation and meal planning (not for special diets); maintaining a safe environment; observing, monitoring and reporting on a client's condition; and teaching of those tasks to the client that will increase client independence and that the HCA I is qualified to teach.

Training: The following training units, based on the National HomeCaring Council's "A Model Curriculum and Teaching Guide for the Instruction of the Homemaker-Home Health Aide," should be completed before assignment.

SECTION I. Orientation to Home Care Aide* Services, 4.5 hrs.

SECTION II. Understanding and Working with Various Client Populations
Unit A. Communication, 2 hrs.
Unit B. Understanding Basic Human Needs, 2.5 hrs.

SECTION III. Practical Knowledge and Skills in Home Management
Unit A. Maintaining a Clean, Safe and Healthy Environment, 4.5 hrs.
Unit D. Portion on Infectious Diseases and Infection Control, 1.5 hrs.

SECTION IV. Practical Knowledge and Skills in Personal Care
Unit G. Emergency Procedures, 1 hr.
SUBTOTAL 16 hrs.

*The model curriculum refers to homemaker-home health aide duties; it is anticipated that future versions of the curriculum will refer to home care aides to reflect the change in title recommended by HCAAA and NAHC.

The following units should be completed within six months of the first assignment or prior to the HCA I working in any situation where the content of a unit would be appropriate to the home care aide's duties:

SECTION II. Understanding and Working with Various Client Populations
Unit C. Understanding and Working with Children, 3 hrs.
Unit D. Understanding and Working with Older Clients, 4 hours
Unit E. Understanding and Working with Clients Who are Ill, 2 hrs.
Unit F. Understanding and Working with Clients with Disabilities, 2.5 hrs.
Unit G. Mental Health and Illness, 2 hrs.
Unit H. Understanding Dying and Death, 1 hr.

SECTION III. Practical Knowledge and Skills in Home Management, 7 hrs.
(all remaining hours in Section III except 1-1/2 hours of modified diets—see HCA II)

SECTION V. Application of Knowledge and Skills—The Practicum, 2.5 hrs.
SUBTOTAL 24 hrs.
SIX MONTH TOTAL 40 hrs.

Supervision: Supervision of the HCA I shall occur at least every 62 days in at least one home while the HCA I is on duty. Supervision may be performed by staff such as nurses, social workers, and home economists. An experienced HCA III may also supervise a HCA I if the HCA III has received additional training in supervision and is under

the direct supervision of a professional.

Inservice: The HCA I shall be required to complete at least six hours of inservice training per year on topics relevant to appropriate clients and duties and meet applicable state laws.

Home Care Aide II

The home care aide II (HCA II) assists the client and/or family with home management activities and with non-medically directed personal care. The HCA II is *not* to perform duties under a medically directed plan of care and is not to be assigned duties related to assistance with medications or wound care.

Examples of Duties: All the duties of a HCA I plus: assistance with ambulation, bathing, hair care/grooming, dressing, toileting, transfer activities, special diets, activities of daily living, and appropriate client teaching consistent with training.

Training: The HCA II is to complete all the training units required of the HCA I (40 hours) prior to any assignment to a client involving the provision of care.

The following additional units are to be completed within six months of the first assignment as HCA II. However, no HCA II shall be assigned to provide services for which the HCA II has not been trained and for which the HCA II has not demonstrated competency.

SECTION III. Practical Knowledge and Skills in Home Management
Unit B. Modified Diets, 1.5 hrs.

SECTION IV. Practical Knowledge and Skills in Personal Care
Unit A. Body Systems, Disorders, and Diseases, 3 hrs.
Unit B. Observing Body Functions, 3 hrs.
Unit C. Care of the Client in Bed, 8.5 hrs.
Unit D. Care of the Client not in Bed, 1.5 hrs.

SECTION V. Application of Knowledge and Skills—The Practicum
Unit F. Supervised Application of Knowledge and Skills, 2.5 hrs.
Additional Training (beyond HCA I requirement), 20 hrs.
TOTAL TRAINING REQUIRED within six months of first assignment is 60 hrs.

Supervision: Supervision of the HCA II shall occur at least every 62 days in at least one home while the HCA II is on duty. Supervision must be performed by appropriate professionals.

Inservice: The HCA II shall be required to complete at least 10 hours of inservice education per year that are relevant to appropriate clients and duties and meet applicable state laws.

Home Care Aide III

The home care aide III (HCA III) works under a medically supervised plan of care to assist the client and/or family with household management and personal care.

Examples of Duties: All duties of the HCA I and HCA II plus those delineated under a medically directed plan of care. These would include: nonsterile wound care, assistance with self-administered medications, assistance with prescribed exercises and rehabilitation activities, simple procedures, help with assistive devices, and appropriate client instruction consistent with training.

Training: The HCA III will complete 75 hours of training and pass a competency evaluation. Training beyond the HCA I and HCA II requirements must be completed within the first six months of assignment as an HCA III. However, no HCA III shall be assigned to provide services for which he or she has not been trained and has not demonstrated competency.

Units to be completed beyond the requirements for HCA II are:

SECTION IV. Practical Knowledge and Skills in Personal Care
Unit E. Observations about Medications, 1 hr.
Unit F. Rehabilitation, 2 hrs.
Unit G. Health Procedures, 2 hrs.
1. Dry, nonsterile Technique Dressing
2. Simple Procedures

SECTION V. Application of Knowledge and Skills—The Practicum.
Supervised Application of Knowledge and Skills, 10 hrs.
Additional training (beyond HCA II requirement), 15 hrs.
TOTAL 75 hrs.

Supervision: Supervision of the HCA III shall occur at least every 62 days in at least one home while the HCA III is on duty. Supervision must be performed by appropriate professionals such as nurses.

Inservice: The HCA III shall be required, at a minimum, to meet current HCFA inservice requirements for home care aides under the Medicare program.

Special Needs

As this field continues to advance, special needs must be addressed. Specifically trained paraprofessionals are the ones to address these needs. As these needs evolve, new types of aides will be developed with specialized training and supervision requirements. Possible examples of future specialty areas include pediatric HCAs, mental health HCAs, HIV HCAs, and HCAs who are trained to help individuals with Alzheimer's and developmental disabilities.

With basic uniformity and consistent definitions, redefinitions and progress in the field of paraprofessional home care services will be facilitated and this crucial role in home care developed to its utmost.

BASIC STATISTICS ABOUT HOME CARE

Home care in the United States is a diverse and dynamic service industry. More than 20,000 providers deliver home care services to some 8 million individuals who require such services because of acute illness, long-term health conditions, permanent disability, or terminal illness. Annual expenditures for home care were $40 billion in 1997 and are expected to total $42 billion in 1998.[1]

1. **HOME CARE PROVIDERS**
   The first home care agencies were established in the 1880s. Their number grew to some 1,100 by 1963 and to more than 20,000 currently. Home health agencies, home care aide organizations, and hospices are known collectively as "home care organizations."

   a. Medicare-certified Agencies
      Home care agencies of various types have been providing high-quality, inhome services to Americans for more than a century. However, Medicare's enactment in 1965 greatly accelerated the industry's growth. Medicare made home care services, primarily skilled nursing and therapy of a curative or restorative nature, available to the elderly. In 1973, these services were extended to certain disabled younger Americans. Between 1967 and 1985, the number of agencies certified to participate in the Medicare program more than tripled, from 1,753 to 5,983. In the mid-1980s, the number of Medicare-certified home care agencies leveled off at around 5,900 as a result of increasing Medicare paperwork and unreliable payment policies. These problems led to a lawsuit brought against the Health Care Financing Administration (HCFA) in 1987 by a coalition of Members of the US Congress led by Reps. Harley Staggers (D-WV) and Claude Pepper (D-FL), consumer groups, and the National Association for Home Care (NAHC). The successful conclusion of this lawsuit gave NAHC the opportunity to participate in rewriting the Medicare home care payment policies. Following these revisions, annual outlays for Medicare's home health benefit increased significantly and the number of Medicare-certified home health agencies rose to more than 10,000. More recently, the number declined to 9,655 and continues to decrease. NAHC believes the recent decline in agencies is the direct result of changes in Medicare home health reimbursement enacted as part of the Balanced Budget Act of 1997 (BBA).

      The number of hospital-based and freestanding proprietary agencies has grown faster than any other type of certified agency since the coverage clarifications. Freestanding proprietary agencies now comprise 46% and hospital-based agencies 27% of all certified agencies. This differs markedly from the industry composition in the early 1980s, when public health agencies dominated the ranks of certified agencies and proprietary and hospital-based agencies combined accounted for only one-fourth of the total. Table 1 shows the changes over time in types of agencies participating in Medicare.

Table 1. Number of Medicare-certified Home Care Agencies, by Auspice, for Selected Years, 1967-1998

	FREESTANDING AGENCIES						FACILITY-BASED AGENCIES			
Year	VNA	COMB	PUB	PROP	PNP	OTH	HOSP	REHAB	SNF	TOTAL
1967	549	93	939	0	0	39	133	0	0	1,753
1975	525	46	1,228	47	0	109	273	9	5	2,242
1980	515	63	1,260	186	484	40	359	8	9	2,924
1985	514	59	1,205	1,943	832	4	1,277	20	129	5,983
1990	474	47	985	1,884	710	0	1,486	8	101	5,695
1991	476	41	941	1,970	701	0	1,537	9	105	5,780
1992	530	52	1,083	1,962	637	28	1,623	3	86	6,004
1993	594	46	1,196	2,146	558	41	1,809	1	106	6,497
1994	586	45	1,146	2,892	597	48	2,081	3	123	7,521
1995	575	40	1,182	3,951	667	65	2,470	4	166	9,120
1996	576	34	1,177	4,658	695	58	2,634	4	191	10,027
1997	553	33	1,149	5,024	715	65	2,698	3	204	10,444
1998*	508	32	1,131	4,418	678	66	2,631	3	188	9,655

Source: HCFA, Center for Information Systems, Health Standards and Quality Bureau.
VNA: Visiting Nurse Associations are freestanding, voluntary, nonprofit organizations governed by a board of directors and usually financed by tax-deductible contributions as well as by earnings.
COMB: Combination agencies are combined government and voluntary agencies. These agencies are sometimes included with counts for VNAs.
PUB: Public agencies are government agencies operated by a state, county, city, or other unit of local government having a major responsibility for preventing disease and for community health education.
PROP: Proprietary agencies are freestanding, for-profit home care agencies.
*Data for 1998 were obtained on September 30. Actual FY counts are expected to differ.
PNP: Private not-for-profit agencies are freestanding and privately developed, governed, and owned nonprofit home care agencies. These agencies were not counted separately prior to 1980.
OTH: Other freestanding agencies that do not fit one of the categories for freestanding agencies listed above.
HOSP: Hospital-based agencies are operating units or departments of a hospital. Agencies that have working arrangements with a hospital, or perhaps are even owned by a hospital but operated as separate entities, are classified as freestanding agencies under one of the categories listed above.
REHAB: Refers to agencies based in rehabilitation facilities.
SNF: Refers to agencies based in skilled nursing facilities.

b. Medicare-certified Hospices

Medicare added hospice benefits in October 1983, 10 years after the first hospice was established in the United States. Hospices provide palliative medical care and supportive social, emotional, and spiritual services to the terminally ill and their families. The number of Medicare-certified hospices has grown from 31 in January 1984 to 2,287 in September 1998 (for a separate fact sheet with detailed information on hospices, please contact the Hospice Association of America, 202/546-4759).

c. Non-Medicare-certified Agencies

The noncertified home care agencies, home care aide organizations, and hospices that remain outside Medicare do so for a variety of reasons. Some do not provide the kinds of service that Medicare covers. For example, home care aide organizations that do not provide skilled nursing care are not eligible to participate in Medicare.

2. HOME CARE EXPENDITURES AND UTILIZATION

a. National Expenditures

HCFA projects the national expenditure for health care will total $1,147 billion in 1998.[2] In the past few years, growth in health care spending has slowed. Health spending grew at an average annual rate of 5.3% in 1997 and 1998, maintaining a slowed growth trend begun in 1996. In part, this slowdown in the rate of spending for health care has been attributed to the growing influence of managed care as a payment mechanism and to the relatively low inflation rates for the economy as a whole. For the early part of the next decade (2001-2007), HCFA projects an average annual national health spending growth rate of 7.5%.

Table 2 provides the estimated 1996 national expenditures for personal health care by type. Personal health care is a subset of total health spending and includes spending for health care goods and services used by individuals. Of the $907 billion attributed to personal health care spending in 1996, 62% was for hospital care and physician services and only a small fraction (3%) was spent on home care.

Total home care spending is difficult to estimate due to limitations of data sources. Home care spending was estimated to total $40 billion in 1997. Based on the prior year's trends, NAHC estimates total spending for home care of $42 billion in 1998. However, some spending for home care services is not included in the national health accounts data, for example, payments made by consumers to independent providers and payments to hospital-based agencies by sources other than Medicare and Medicaid.

Table 2. Personal Health Care Expenditures, 1996

	Percent
Total personal health care	100
Hospital care	40
Physicians' services	22
Nursing home care	9
Drugs and other medical nondurables	10
Other professional services	6
Dentists' services	5
Home care	3
Other personal health care	3
Vision products and other medical durables	2

Source: Levit, K.R. et al, "National Health Spending Trends in 1996," Health Affairs (January/February 1998): 35-51.

b. Health Care Prices

Information on the average cost to consumers of home care by visit type was collected through the National Medical Expenditure Survey (NMES) in 1987. These figures were updated by NAHC using the Medicare rates of growth in per-visit charges. Table 3 shows that on average a home care visit cost $48 in 1987 and $75 in 1997. HCFA estimates the 1997 average benefit payment per Medicare home health visit at $67.

Table 3. Average Cost Per Home Care Visit, 1987 and 1997

	1987	1997[a]
Average	**$48**	**$75**
Nurse	62	96
Therapist	57	89
Home care aide	34	53
Homemaker	33	51
Other[b]	56	87

Sources: Altman, B., and Walden, D. "Home Health Care: Use, Expenditures and Sources of Payment." National Medical Expenditure Survey Research Findings 15, Publication No. 93-0040, Agency for Health Care Policy and Research (AHCPR), Rockville, MD: Public Health Service, 1993.
Notes: **a** Updated by the average annual rate of increase of Medicare per-visit charges, which was 4.5% between 1987 and 1996 (HCFA, Office of Information Services).
b Includes social workers and other professionals.

c. Medicare Home Health

Medicare is the largest single payor of home care services. In 1996, Medicare spending accounted for nearly 40% of total home care expenditures. Other public funding sources for home care include Medicaid, the Older Americans Act, Title XX Social Services Block Grants, the Veterans' Administration, and Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). Private insurance comprised only a small portion of home care payments. Close to one-fourth of home care service is financed through out-of-pocket payments (see Table 4).

Table 4. Sources of Payment for Home Care 1996

Source of Payment	Percent
Total	100.0
Medicare	38.7
Medicaid	27.2
Private insurance	12.2
Out-of-pocket	20.5
Other and unknown	1.3

Source: Agency for Health Care Policy and Research, Center for Cost and Financing Studies, National Medical Expenditure Survey data (aligned to National Health Accounts Data), December1997.
Note: Figures may not add to 100.0% due to rounding

Prior to BBA enactment the home health benefit represented a small but growing portion of Medicare spending -- less than 9% of total benefit payments in 1997. However, since BBA implementation, home health has experienced a dramatic downturn, and in 1998 made up only 6.2% of total Medicare outlays (see Table 5). About 42% of the estimated $210 billion 1998 Medicare benefit payments will go to hospitals and approximately 15% to physicians. Hospice payments will account for one percent of the total Medicare benefit payments in 1998.

Table 5. Medicare Benefit Payments, 1998 and 1999

	1998 (estimated)		1999 (projected)	
	Amount (millions)	Percent of Total	Amount (millions)	Percent of Total
Total Medicare Benefit Payments*	**$210,136**	**100.0**	**$222,002**	**100.0**
Part A				
Hospital care	88,236	42.0	88,310	39.8
Skilled nursing facility	13,408	6.4	13,835	6.2
Home health agency**	12,790	6.1	6,171	2.8
Hospice	2,080	1.0	2,181	1.0
Managed Care	17,807	8.5	20,493	9.2
Total	**$134,321**	**64.0**	**$130,990**	**59.0**
Part B				
Physician	31,595	15.0	32,967	14.8
Durable Medical Equipment	4,246	2.0	4,214	1.9
Carrier Lab	4,779	2.3	4,306	1.9
Hospital	10,625	5.1	11,082	5.0
Home Health **	273	0.1	8,420	3.8
Intermediary Lab	1,683	0.8	1,765	0.8
Other Intermediary	4,228	2.0	4,744	2.1
Managed Care	14,132	6.7	18,793	8.5
Total	**$75,815**	**36.1**	**$91,012**	**41.0**

Source: HCFA, Office of the Actuary, unpublished estimates for the President's fiscal year 2000 budget (December 1998).
* Medicare Part A totals do not include peer review organizations (PROs). Figures may not add to totals due to rounding.
** Home health outlays do not include the transfer of funds between the trust funds.

In 1997, HCFA estimated 38.5 million aged and disabled persons were enrolled in the Medicare program. An estimated 3.4 million enrollees received fee-for-service home health services in 1997, representing a greater than 40% rise from the number of home health recipients in 1990. Table 6 shows the growth over time in the Medicare home health benefit. For the period 1990-1997, Medicare home health expenditures increased from $3.9 billion to an estimated $17.2 billion. Most of the rise in spending occurred as a result of the increase in visits, which increased from 70 million in 1990 to an estimated 270 million in 1997. Growth in the Medicare home health benefit between 1990 and 1996 can be attributed to specific court decisions, legislative expansions of the benefit, and to a number of sociodemographic trends, which had fostered growth in the program from the beginning.

Table 6. Medicare Fee-for-Service Home Health Outlays, Clients and Visits for Selected Years, 1967-1997

Year	Outlays ($ millions)	Clients (1000s)	Visits (1000s)
1967	$ 46	n/a	n/a
1980	662	957	22,428
1985	1,773	1,589	39,742
1990	3,860	1,940	69,532
1991	5,566	2,223	99,183
1992	7,724	2,523	132,494
1993	10,198	2,868	168,029
1994	13,269	3,175	220,495
1995	15,976	3,457	266,261
1996	17,266	3,583	283,936
1997	17,241	3,370	269,919

Source: HCFA, Office of the Actuary and Bureau of Data Management and Strategy.
Note: The 1990 to 1997 data was updated June 1998.

The BBA (PL 105-33) introduced a new per-beneficiary limit, designed to reduce growth in Medicare home health expenditures, that restricts payments to agencies under Medicare to the lowest of the agency's actual, allowable costs, its aggregate per-visit cost limits, or its aggregate per-beneficiary annual limit. The Lewin Group estimated that 90% of agencies would have costs that exceed BBA limits in 1998 by an average of 32% without a change in Medicare practice patterns.3 These reductions have resulted in agency closures throughout the country (contact NAHC for more information).

Medicare hospice expenditures have grown from $112 million in 1987 to an estimated $2.2 billion in 1998. An estimated 338,273 beneficiaries received hospice services under Medicare in 1996 (see Hospice Facts & Statistics for more detailed information).

d. Medicaid Home Care

As in the case of Medicare, home health services represent a relatively small part of total Medicaid payments. Table 7 shows that close to half of the $117 billion in Medicaid benefit payments in fiscal year (FY) 96 went for hospital and skilled nursing facility services. Home care services comprised 9% of the payments. Hospice is an optional Medicaid service that is currently offered by 42 states. Payments for hospice services were estimated at $319 million in FY96.

Table 7. Medicaid Expenditures, by Type of Service, Fiscal Years 1994, 1995, and 1996

	Fiscal Year		
	1994	1995	1996
	In billions		
Total Vendor Payments	$108.3	$120.1	$117.1
	Percent of total		
Nursing facility services	25.0	24.2	24.2
Inpatient services	26.1	24.0	22.3
General hospitals	24.2	21.9	20.6
Mental hospitals	1.9	2.1	1.7
Other care	8.6	10.0	8.6
Intermediate care facility (MR) services[a]	7.7	8.6	7.1
Prescribed drugs	8.2	8.1	8.5
Home health services[b]	6.5	7.8	9.0
Physician services	6.6	6.1	5.7
Outpatient hospital services	5.9	5.5	5.3
Clinic services	3.5	3.6	3.6
Laboratory and radiological services	1.1	1.0	0.9
Early and periodic screening	0.9	1.0	1.2

Source: Health Care Financing Administration, Division of Medical Statistics. Data are from the Form HCFA-2082.
Notes: **a** "MR" indicates facilities for persons with mental retardation.
b Includes home health, personal care, and home and community-based waiver payments.

Table 8 shows the growth in the Medicaid home health benefit since FY75. Between FY96 and FY97, expenditures increased from $10.6 billion to $12.2 billion, an increase of 15%.

Table 8. Medicaid Home Health Expenditures and Recipients, for Selected Years, 1975-1997

Fiscal Year	Vendor Payments ($millions)	Recipients (1000s)
1975	70	343
1980	332	392
1985	1,120	535
1990	3,404	719
1991	4,101	812
1992	4,888	926
1993	5,601	1,067
1994	7,049	1,376
1995	9,406	1,639
1996	10,583	1,633
1997	12,237	1,861

Source: HCFA, Division of Medicaid Statistics. Data are derived from Form HCFA-2082.

e. Managed Care

Health care services in the United States are increasingly financed through managed care organizations. A managed care organization, including health maintenance organizations, typically finances health care services through a negotiated prepaid rate to health care providers. A fully capitated contract specifies a lump sum payment per enrollee to cover all care provided through the plan, but there are many variations. In contrast, traditional health insurance pays providers based on the number of services delivered with few limitations on which providers would be paid, a payment arrangement commonly termed fee-for-service

Managed care is most prevalent in the employer-based health insurance market. Three out of four workers with health insurance received health insurance through a managed care plan in 1995.[4] Managed care enrollment has increased among Medicaid enrollees, particularly in states that have federal waivers to convert their Medicaid program to a managed care program. As of June 30, 1996, 40% of all Medicaid beneficiaries were enrolled in managed care.[5] Medicare managed care has increased at a slower pace. As of August 1997, about 14% of Medicare beneficiaries were part of Medicare managed care.[6]

The increasingly competitive health care market has created incentives for home care agencies to enter managed care provider networks. However, little is known about the extent to which home care agencies have entered into managed care arrangements. A preliminary study conducted for HCFA compared patient outcomes and total expenditures for Medicare home health clients who received services through Medicare managed care and a group who received services through fee-for-service Medicare home health. The authors found the managed care clients used less home health resources but also had less favorable outcomes on average than their Medicare fee-for-service counterparts, suggesting the need for further research on the relationship between volume of home care services and outcomes.[7]

3. **HOME CARE RECIPIENTS**

Based on a need for assistance in performing basic life activities known as activities of daily living or

instrumental activities of daily living, research from the Disability Statistics Rehabilitation Research and Training Center indicates that as of 1994, approximately 16% of the US population aged 65 and over and approximately 2.5% of US population ages 18-64 could benefit from home care services.[8] Most receive services from so-called informal caregivers-family members, friends or others who provide services on an unpaid basis.

The NMES findings indicate that 5.9 million individuals, roughly 2.5% of the US population, received formal home care services in 1987. Of these recipients, nearly half were older than 65, and the amount of home care they used tended to increase with age. About 40% of the home care recipients had functional limitations in one or more activities of daily living. Age and functional disability are likely predictors of the need for home care services. By projecting the NMES estimate forward based on Census Bureau population projections, NAHC estimates that 8 million people received home care services in 1998.

A more recent survey, conducted by the National Center for Health Statistics (NCHS), profiled persons discharged from home health agencies in 1995-96 and collected information on client diagnoses.[2] Table 9 shows two-thirds of discharges were over age 65 and 64% were women. Table 10 shows that 22% of home health patients discharged from home health agencies in 1995-96 had conditions related to diseases of the circulatory system as their primary diagnosis. People with heart disease, including congestive heart failure, made up about half of this group. Cancer, diabetes, and hypertension were also frequent admission diagnoses for home health patients.

Table 9. Percent of Home Health Discharges by Age, Sex, Race, and Marital Status, 1995-96

Characteristic	Percent	Characteristic	Percent	Characteristic	Percent
Age		Gender		Marital Status at Discharge	
under 45 Years	19.5	Male	36.5	Married	37.0
45-54 years	5.9	Female	63.5	Widowed	24.6
55-64 years	8.4			Divorced or separated	5.0
65-69 years	10.8	Race		Single or never married	18.4
70-74 years	13.2	White	62.8		
75-79 years	12.4	Black	7.4	Unknown	15.0
80-84 years	14.2	Other	2.6		
85 years and older	15.4	Unknown	27.2		
Unknown	*				

Source: National Center for Health Statistics (NCHS) Advance Data No. 297. April 16, 1998.
Note: Percentages based on a national sample representing 7,775,700 home health patients discharged from October 1995 to September 1996.
*Figure does not meet standard of reliability or precision

Table 10. Percent of Home Health Discharges by First-listed and All-listed Diagnoses at Admission, According to Type of Care Received: United States 1995-96

	Primary Diagnosis	All-listed Diagnoses

Admissions Diagnosis	ICD-9-CM Code	All Discharges	Percent	All Discharges	Percent
Total		8,168,900	100.0	21,953,900	100.0
Infectious and parasitic diseases	001-139	166,400	*1.9	385,700	1.7
Human immunodeficiency virus (HIV) disease	042	*36,700	*	*57,200	*
Neoplasms	140-239	948,200	8.6	1,661,300	5.8
Malignant neoplasms	140-208,230-234	923,000	8.3	1,560,600	5.4
Malignant neoplasm of trachea, bronchus, and lung	162,197.0,197.3	27,000	*0.5	213,800	0.5
Malignant neoplasm of breast	174-175,198.81	*175,600	*	*233,300	*1.0
Malignant neoplasm of prostate	185	34,600	*	*82,700	*0.3
Endocrine, nutritional, and metabolic diseases, and immunity disorders	240-279	456,200	5.8	1,912,300	8.9
Diabetes mellitus	250	333,400	4.3	1,256,600	5.9
Diseases of the blood and blood forming organs	280-289	*130,500	*1.7	488,500	2.3
Mental disorders	290-319	138,800	1.7	728,400	3.4
Diseases of the nervous system and sense organs	320-389	271,700	3.3	870,800	4.0
Diseases of the circulatory system	390-459	1,776,900	22.4	5,779,300	26.7
Essential hypertension	401	260,700	3.3	1,717,400	8.0
Heart disease	391-392.0, 393-398, 402, 404, 410-416, 420-429	999,100	12.5	2,884,400	13.3
Diseases of the respiratory system	460-519	639,200	8.0	1,369,200	6.2
Diseases of the digestive system	520-579	314,100	4.0	973,700	4.5
Diseases of the genitourinary system	580-629	181,300	2.2	711,100	3.3
Diseases of the skin					

and subcutaneous tissue	680-709	190,100	2.4	421,800	2.0
Diseases of the musculoskeletal system and connective tissue	710-739	629,200	8.1	1,617,600	7.6
Symptoms, signs, and ill-defined conditions	780-799	578,000	7.4	1,853,900	8.6
Injury and poisoning	800-999	974,400	12.5	1,343,800	6.3
Supplementary classification	V01-V82	565,500	7.3	1,420,200	6.7
All other diagnoses	630-676, 740-759, 760-779	174,900	2.2	416,500	2.0
Unknown or no diagnosis		*	*	...	...

Note: Percentages based on a national sample representing 7,775,700 home health patients discharged from October 1995 to September 1996.
*Figure does not meet standard of reliability or precision.

Medicare home health utilization by principal diagnosis is similar to the NCHS data. In the HCFA data, diseases of the circulatory system also accounted for almost 30% of the Medicare beneficiaries admitted to home care in 1996. Medicare home health patients with neoplasms comprised 6.8% of all the program's home care admissions; endocrine, nutritional and metabolic diseases, and immunity disorders accounted for 9.1%. Diseases of the respiratory system made up 8.1%; diseases of the musculoskeletal system comprised 10.2%; and injury and poisoning accounted for 10.5%.

Many hospital patients are discharged to home care services for continued rehabilitative care. As hospital stays shortened in the early 1980s, the percentage of Medicare patients discharged to home health care increased from 9.1% in 1981 to 17.9% in 1985. More recently, the Medicare Payment Advisory Commission (MedPAC) estimated that 16% of Medicare hospital patients used home health care within 30 days of discharge in FY96. Table 11 shows the diagnostic-related groups with the most discharges to home health care following a hospitalization.

Table 11. Diagnoses With Highest Number of Beneficiaries Using Home Health Care Within One Day of Discharge from an Acute Care Hospital, Fiscal Year 1996

DRG	Description	Discharges to Home Health Care: Total	Discharges to Home Health Care: Percent	Percent of Post-Acute Cases Discharged to Home Health Care	Percent of Home Health Care Cases
127	Heart failure and shock	59,510	9.5%	49.4%	6.9%
209	Major joint and limb reattachment procedure of lower extremity	51,086	15.0	22.9	5.9
89	Simple pneumonia and pleurisy, age >17 with CC	31,750	8.3	36.9	3.7
106	Coronary bypass with cardiac catheterization	29,148	29.4	71.8	3.4
88	Chronic obstructive pulmonary disease	28,709	8.6	52.4	3.3
148	Major small and large bowel procedures with CC	27,489	20.7	55.3	3.2
14	Specific cerebrovascular disorders except transient ischemic attack	27,455	8.8	17.4	3.2
107	Coronary bypass without cardiac catheterization	18,338	28.8	75.8	2.1
121	Circulatory disorders with AMI and cardiovascular complication	17,266	13.6	50.9	2.0
478	Other vascular procedures with CC	13,931	11.8	48.0	1.6

Source: Medicare Payment Advisory Commission analysis of MedPAR data from the Health Care Financing Administration. (June 1998)
Notes: Cases where the patient died or was transferred to another acute care hospital are excluded from the calculations. Post-acute care use does not include home health episodes that began before a patient was hospitalized or rehabilitation facility and long-term care hospital stays that began in fiscal year 1996 but ended in fiscal year 1997.
DRG=diagnosis-related group. CC=complication and/or comorbidity. AMI=acute myocardial infarction.

4. CAREGIVERS

a. Informal Caregivers

Estimates indicate that almost three-quarters of elderly persons with severe disabilities receiving home care services in 1989 relied solely on family members or other unpaid help.[10] Eight of 10 of these informal caregivers provide unpaid assistance for an average of four hours a day, seven days a week. Three-quarters of informal caregivers are female, and nearly one-third are over age 65. A 1996 telephone survey of US households estimated there were 22 million US households with at least one member who provided some level of unpaid assistance to a spouse, relative, or other person older than age 50.[11]

b. Formal Caregivers

Formal caregivers include professionals and paraprofessionals who provide inhome health care

and personal care services, and are compensated for the services they provide. The Bureau of Labor Statistics (BLS) and HCFA provide data on these employees. However, agency definitions and methods of counting are different. BLS provides an occupational classification for "home health care services," which excludes hospital-based and public agency workers. Its method of counting is "number of employees." HCFA limits its statistics to employees of certified home health agencies. Furthermore, its survey presents data on full-time equivalents (FTEs).

In Table 12, BLS estimates that more than 500,000 persons were employed in home health care agencies, with the exclusions described above. HCFA recorded 372,453 FTEs employed in Medicare-certified agencies as of September 1998. The HCFA FTE counts show a decline of 43,000 FTEs since December 1997. Using either method, the largest numbers of employees are home care aides and registered nurses.

Table 12. Numbers of Home Health Care Workers, 1996 and Medicare-certified Agency FTEs, 1998

Type of Employee	Number of Employees[a]	Number of FTEs[b]
RNs	134,443	132,796
LPNs	47,651	27,775
Physical Therapists	11,236	13,619
Home Care Aides	318,124	124,218
Occupational Therapists	4,344	3,574
Speech Pathologists	3,304	1,985
Social Workers	8,995	6,895
Other	137,303	61,591
Totals	665,400	372,453

Sources: a U.S. Department of Labor, Bureau of Labor Statistics, National Industry-Occupation Employment Matrix, data for 1996. Excludes hospital-based and public agencies.
b Unpublished data on FTEs in Medicare-certified home health agencies as of September 1998 from the HCFA Center for Information Systems, Health Standards and Quality Bureau.

The 1996 number of employees data by job category presented in Table 12 is based on the Current Population Survey, which is conducted every three years. However, BLS also collects monthly information on employment for all workers, which includes home care services. BLS monthly statistics present data at an aggregate level combining all job titles. Table 13 shows the calendar year home care services employment for 1993-1997, based on BLS monthly statistics. During the period 1993-1997, home care employment grew from 510,000 employees to 713,000 employees-a 7.9% average annual rate of growth. However, in 1998 total home care employment declined by 7.2%.[12]

Table 13. Home Health Care Services Total Employment, 1993-1998

Year	Total Number of Employees
1993	510,000
1994	596,000
1995	656,000
1996	695,000
1997	713,000
1998	662,000

Sources: US Department of Labor, Bureau of Labor Statistics: Establishment Data, 1999. BLS online.
Note: Excludes hospital-based and public home care agency employees. All numbers are as of December of the corresponding year.

c. Productivity

Home care agencies frequently ask for information on employee productivity based on the average number of visits provided. Several studies of nursing productivity reveal that nurses deliver an average of five visits per day (see Table 14). Nurses who specialize in pediatric care average 2.4 visits per day, while IV nurses average as many as other nurses.

Table 14. Comparative Findings of Home Care Nurse Productivity

Study	Patients per Day
Spoelstra[a], 1996	5.0
Caie-Lawrence[b], 1990	5.0
C.S. Hedtke[c], 1992	4.8
1. Pediatric RNs	2.4
2. IV RNs	4.9
NAHC[d], 1997	
1. RNs	4.5
2. LPNs	5.0

Sources: **a** Spoelstra S. "Productivity of Registered Nurses in Home Health Care: A Nationwide Survey." CARING Magazine, 1996.
b Caie-Lawrence J.A. Time Study of Home Care Nurses Poster Presentation, Sixth National Nursing Symposium-Home Health Care, May 17, 1990; Ann Arbor, MI.
c Hedtke C.S. "How do home care nurses spend their time?" Journal of Nursing Administration, 1992; 22(1):18-22.
d National Association for Home Care Home Care and Hospice Productivity Survey, 1997.

In 1996, NAHC surveyed its member home care and hospice agencies about their staff productivity.[13] The survey was nonrandom, and therefore results are not statistically reliable as estimates of home care agency productivity in general. The productivity averages by discipline are presented in Table 15. These findings were limited to salaried and hourly employees making home care visits from January to March 1996. Data for hospice staff were reported separately. The productivity measure is based on a formula and definition developed by the home care

industry and published in the Uniform Data Set for Home Care and Hospice.[14]

Table 15. Staff Productivity in Home Care

	Number of Visits per 8-Hour Day				
	Mean	Median	25th percentile	75th percentile	Number of Agencies
Home Care Aide III*	5.2	5.0	4.2	5.8	255
Practical Nurse (LPN)	5.0	5.0	3.7	6.1	96
Registered Nurse (RN)	4.5	4.4	3.5	5.2	253
Occupational Therapist	4.9	4.5	3.7	5.5	80
Physical Therapist	6.0	5.3	4.4	7.0	126
Speech Pathologist	4.6	4.0	3.2	5.4	57
Social Worker (MSW)	3.0	2.4	1.8	3.5	89

Source: Home Care & Hospice Staff Productivity, NAHC, 1997.
Notes: The mean and median are both measures of central tendency. The median represents the point where half the agencies were higher and half were lower. The mean is the sum of each agency's productivity divided by the number of agencies providing information.
*A home care aide III is trained to provide medically directed services.

d. Compensation

Starting in 1996, NAHC has worked with the Hospital and Healthcare Compensation Service (HCS) to conduct an annual survey of compensation in the home care and hospice industry. This agreement avoids duplication of effort in data collection by combining the efforts of both organizations. Summary results for the 1998 HCS survey are shown in Table 16 and Table 17. As in past surveys, compensation is reported for the median salary, rather than mean salary, to reduce the likelihood that very high or very low salaries would skew results.

Table 16. Average Compensation of Home Health Agency Executives, October 1998

	Salary Range by Percentile		
	25th	Median	75th
Executive Director/CEO	$50,986	$59,586	$73,564
Chief Operating Officer/Program Director	50,021	57,211	73,077
Top Level Financial Executive	44,720	57,200	71,687
Director of Nurses/Clinical Services	42,137	47,700	53,988
Director of Social Work and Counseling	36,300	41,600	49,525
Utilization Review/Quality Assurance Manager	40,500	45,000	50,960

Source: Homecare Salary & Benefits Report 1998-1999, NAHC/HCS, October 1998.

Table 17. Average Compensation of Home Health Agency Caregivers, October 1998

	Per-Hour Rates by Percentile			Per-Visit Rates by Percentile		
	25th	Median	75th	25th	Median	75th
Registered Nurse	$16.89	$18.22	$20.00	$24.00	$28.98	$33.00
Licensed Practical Nurse	11.84	13.00	14.41	16.12	18.00	22.00
Occupational Therapist	21.04	23.54	26.74	41.40	46.00	50.00
Physical Therapist	23.39	26.51	29.86	40.22	45.39	50.00
Respiratory Therapist	13.87	15.61	17.53	31.90	35.00	41.50
Speech/Language Pathologist	19.54	21.74	25.97	42.00	46.07	50.21
Medical Social Worker	15.46	17.41	19.78	38.00	45.00	50.00
Home Care Aide III	7.85	8.76	9.28	11.59	12.00	13.50

Source: Homecare Salary & Benefits Report, 1998-1999, NAHC/HCS, October 1998.

5. COST EFFECTIVENESS

In many cases, home care is a cost-effective service, not only for individuals recuperating from a hospital stay but also for those who, because of a functional or cognitive disability, are unable to take care of themselves. Table 18 compares the average Medicare charges on a per-day basis for hospital and skilled nursing facility to the average Medicare charge for a home health visit. The following section lists some examples of cost-effective home care. However, it should be noted that cost-effectiveness is not the only rationale for home care. In fact, the best argument for home care is that it is a humane and compassionate way to deliver health care and supportive services. Home care reinforces and supplements the care provided by family members and friends and maintains the recipient's dignity and independence, qualities that are all too often lost even in the best institutions. Furthermore, home care allows patients to take an active role in their care, becoming members of a multidisciplinary health care team.[15] Several research studies conducted in the past several years have

compared inpatient care to home care costs for a specific group of patients. The cost savings data for six of these studies are summarized in Table 19. The information has been aggregated at a monthly level for purposes of comparison.

Table 18. Comparison of Hospital, SNF, and Home Health Medicare Charges, 1995-1997

	1995	1996	1997
Hospital charges per day	$1,909	$2,071	$2,121
Skilled nursing facility charges per day	401	443	454
Home health charges per visit	84	86	88

Sources: The 1995 and 1996 hospital and SNF Medicare charge data are from the Annual Statistical Supplement, 1997, to the Social Security Bulletin, Social Security Administration (December 1997). Home care information from HCFA, Office of Information Services.
Note: Additional years are projected using consumer price index forecasts from the Bureau of Labor Statistics' web site and "The Economic and Budget Outlook: Fiscal Years 1999-2008" Congressional Budget Office web site (January 1998).

Table 19. Cost of Inpatient Care Compared to Home Care, Selected Conditions

Conditions	Per-patient Per-month Hospital Costs	Per-patient Per-month Home Care Costs	Per-patient Per-month Dollar Savings
Low birth weight[a]	$26,190	$330	$25,860
Ventilator-dependent adults[b]	21,570	7,050	14,520
Oxygen-dependent children[c]	12,090	5,250	6,840
Chemotherapy for children with cancer[d]	69,870	55,950	13,920
Congestive heart failure among the elderly[e]	1,758	1,605	153
Intravenous antibiotic therapy for cellulitis, osteomyelitis, others[f]	12,510	4,650	7,860

Sources:
a Casiro, OG, McKenzie, ME, McFayden, L, Shapiro, C, Seshia MMK, MacDonald, N, Moffat, M, and Cheang, MS. "Earlier Discharge with Community-based Intervention for Low Birth Weight Infants: A Randomized Trial." Pediatrics, 1993, 92(1), 128-134.
b Bach, JR, Intinola, P, Alba, AS, and Holland, IE. "The Ventilator-assisted Individual: Cost Analysis of Institutionalization vs. Rehabilitation and In-home Management." Chest, 1992, 101(1), 26-30.
c Field, AI, Rosenblatt, A, Pollack, MM, and Kaufman, J. "Home Care Cost-Effectiveness for Respiratory Technology-dependent Children." American Journal of Diseases of Children, 1991, 145, 729-733.
d Close, P, Burkey, E, Kazak, A, Danz, P, and Lange, B. "A Prospective Controlled Evaluation of Home Chemotherapy for Children with Cancer." Pediatrics, 1995, 95(6), 896-900. Note: The study found that the daily charges for chemotherapy were $2,329±627 in the hospital and $1,865±833 at home. These charges were multiplied by 30 days reflecting the above per-patient per-month costs.
e Rich, MW, Beckham, V, Wittenberg, C, Leven, C, Freedland, K, and Carney, RM. "A Multidisciplinary Intervention to

Prevent the Readmission of Elderly Patients with Congestive Heart Failure." The New England Journal of Medicine. 1995, 333(18), 1190-1195.
f William, DN, et al. "Safety, Efficacy, and Cost Savings in an Outpatient Intravenous Antibiotic Program." Clinical Therapy 1993, 15, 169-179, cited in Williams, D. "Reducing Costs and Hospital Stay for Pneumonia with Home Intravenous Cefotaxime Treatment: Results with a Computerized Ambulatory Drug Delivery System." The American Journal of Medicine. 1994, 97(2A), 50-55.
Note: The estimated hospital cost/day/patient is $417 and the estimated savings/day/patient is $262. These costs were multipled by 30 days, reflecting the above patient per-month costs.

Several additional studies of home care cost effectiveness are summarized in the following paragraphs.

a. Psychiatric Care
An inhome crisis intervention program developed for psychiatric patients in Connecticut was effective in reducing hospital admissions, lengths of stay, and readmissions. A two-year analysis of more than 600 patients showed that 80.7% of patients referred for hospital care could be treated at home instead. When inpatient admissions were necessary, the average length of stay was reduced from 11.97 days to 7.48 days by adding elements of the inhome care program; and patients who received home care services were less likely to be readmitted for hospital care (11.8% of home care patients were readmitted compared to 45.9% of patients who did not receive home care services).[16]

b. Terminally Ill Veterans
A home care program for terminally ill veterans reduced hospital per-capita costs by $971. In the six-month study, patients receiving home care used 5.9 fewer hospital days than those in the control group. No differences were found in patient survival, activities of daily living, cognitive functioning, or morale. However, patient and caregiver satisfaction with care was significantly better among the patients receiving home care.[17]

c. Patients with COPD
An innovative home care program for patients with chronic obstructive pulmonary disease (COPD) that was tested in Connecticut found significant cost savings. The overall goal of the program was to provide more comprehensive home care services to COPD patients who previously required frequent hospitalizations. Monthly costs for hospitalizations, emergency room visits, and home care fell from $2,836 per patient before the intervention to $2,508 per patient-a net savings of $328 per patient per month.[18]

d. Patients with Congestive Heart Failure
The impact of intensive home care monitoring on the morbidity rates of elderly patients with congestive heart failure was the focus of another study. The study found that with intensive home care surveillance, the total hospitalization rate dropped from 3.2 admissions per year to 1.2 admissions per year and the length of stay decreased from 26 days per year to 6 days per year. Cardiovascular admissions declined from 2.9 admissions per year to 0.8 admissions per year, and length of stay decreased from 23 days per year to four days per year. An inhome program also resulted in significant functional status improvement in elderly patients with congestive heart failure.[19]

Endnotes

1. Health Care Financing Administration, Office of the Actuary, National Health Statistics Group, unpublished data on hospital-based and non-hospital-based home health expenditures, 1960-1997. NAHC based its 1998 projection on the 4.8% average annual rate of growth in freestanding home health expenditures from 1996-1998.
2. Smith, S., M. Freeland, S. Heffler, D. McKusick, et al., "The Next Ten Years of Health Spending: What Does the Future Hold?" Health Affairs 17, no. 5 (1998).

3. The Lewin Group, "An Impact Analysis for Home Health Agencies of the Medicare Home Health Interim Payment System of the 1997 Balanced Budget Act." Washington, DC: National Association for Home Care. (August 11, 1998).
4. Jensen, Gail A., M.A. Morrisey, S. Gaffney, and D.K. Liston. "The New Dominance of Managed Care: Insurance Trends in the 1990s." Health Affairs 16, no. 1 (January/February 1997):136.
5. Health Care Financing Administration. "Managed Care in Medicare and Medicaid." Fact Sheet. (February 20, 1998).
6. Ibid.
7. Shaughnessy, P.W., R.E. Schlenker, D.F. Hittle, et al., A Study of Home Health Care Quality and Cost Under Capitated and Fee-For-Service Payment Systems, Vol. 1: Summary (Denver: Center for Health Policy Research, 1994).
8. US Department of Education, National Institute on Disability and Rehabilitation Research, Disability Statistics Rehabilitation Research and Training Center, University of California, San Francisco. "Disability Statistics Abstract," Number 17, November 1996.
9. Haupt, Barbara J. National Center for Health Statistics, "An Overview of Home Health and Hospice Care Patients: 1996 National Home and Hospice Care Survey," Advance Data, no. 297 (April 16, 1998).
10. US Bipartisan Commission on Comprehensive Health Care. The Pepper Commission Final Report: A Call for Action. S.Prt. 101-114. Washington, DC: Government Printing Office, 1990.
11. National Alliance for Caregiving and the American Association for Retired Persons, Family Caregiving in the US: Findings from a National Survey, Washington, DC: Author (1997).
12. Bureau of Labor Statistics, online (1/11/99).
13. National Association for Home Care, Home Care and Hospice Staff Productivity, Washington, DC: Author, 1997.
14. The Uniform Data Set for Home Care and Hospice, Washington, DC: NAHC Research Department.
15. Sheldon, P., and M. Bender, "High-Technology in Home Care," Community Health Nursing and Home Health Nursing, 3 (1994): 507-519.
16. Pigott, H.E., and L. Trott. "Translating Research into Practice: The Implementation of an In-home Crisis Intervention Triage and Treatment Service in the Private Sector," American Journal of Health Quality 8, no. 3 (1993): 138-144.
17. Hughes, S.L., J. Cummings, F. Weaver, L. Manheim, B. Braun, and K. Conrad. "A Randomized Trial of the Cost Effectiveness of VA Hospital-based Home Care for the Terminally Ill," Health Services Research 6 (1992): 801-817.
18. Haggerty, M.C., R. Stockdale-Woolley, and S. Nair. "Respi-Care: An Innovative Home Care Program for the Patient with Chronic Obstructive Pulmonary Disease," Chest 3 (1991): 607-612.
19. Kornowski, R., D. Zeeli, M. Averbuch, A. Finkelstein, et al. "Intensive Home-care Surveillance Prevents Hospitalization and Improved Morbidity Rates Among Elderly Patients with Severe Congestive Heart Failure," American Heart Journal 4 (1995): 762-766.

News and Info | Consumer Info

Return to the HomeCare Online Center!

We love receiving comments and suggestions for improvement!
Send them to webmaster@nahc.org

1997 Regulatory Blueprint for Action

I. Survey and Certification

SUPPORT REQUIRED QUALITY IMPROVEMENT PROGRAM

ISSUE: The current Conditions of Participation (CoP) require quarterly clinical record reviews and an annual agency evaluation but not an overall patient-centered quality management program. The Health Care Financing Administration (HCFA) proposes including requirements for an internal quality improvement management system based on a standard patient assessment and outcomes monitoring.

The current evaluation of HHAs, although improved with home visits by surveyors, does not adequately assess the quality of care delivered. HCFA proposes that HHAs be required to use standard patient assessment items and outcome measures to provide data by which quality can be assessed. HCFA also proposes that if reliable and valid patient outcomes data were available they could focus surveys as follows: 1) new agencies, 2) complaints, 3) agencies where the data indicate a problem, and 4) random surveys of the remaining agencies.

RECOMMENDATION: Support requirements for quality improvement based on patient outcomes. Such a requirement should allow flexibility in design of the quality management program. Specific data requirements should not be finalized until the results of the current HCFA demonstration project are evaluated to ensure implementation of effective and efficient regulations.

1. Broad parameters of quality improvement requirements should be specified but providers should be allowed to design their own quality management program.
2. Evaluation of an HHA's quality is more appropriate through patient outcome measures. However, the following conditions must be met in implementing an outcome measurement system.
    a. Indicators that are reliable and valid.
    b. Number of outcome measures limited to those that most accurately predict quality.

   c. Method for case-mix adjustment.
   d. Standard assessment items limited to those items needed for outcomes measurement and case-mix adjustment (agencies may develop their own assessment tool which will include the required assessment items plus additional assessment items desired for care planning purposes).
   e. A system that is simple and has clinical utility for all patients, not just Medicare.
   f. Mechanism for HCFA to validate agency data.
   g. Ongoing evaluation of the entire system so that changes can be made as needed.
3. The percentage of random surveys should be phased in so that a high proportion of agencies receive surveys initially while the system is new and decrease as it is shown that the data is sufficient to identify agencies that have quality problems, e.g., first year 75%, second year 50%, third year 25%, etc.

RATIONALE: The ideal quality management system is based on what happens to the patients served. HCFA has funded research to develop outcome indicators for home health care. The current HCFA demonstration project must be completed before an outcomes based system can be used with confidence. Because of the variety of factors that can affect outcomes that are not controlled by the HHA, it is important to have adequate adjustments (e.g., case-mix adjustment) to compensate for these factors. Quality assessment should not rely solely on outcome measures; limited structure and process measures are appropriate.

Such a quality system will have the tendency to involve massive data collection unless controlled. Every effort must be made to keep data collection and paperwork burden to a minimum so that resources can be used for patient care rather than paperwork.

[TOP]

SUPPORT PROPOSED QUALITY ASSESSMENT/PERFORMANCE IMPROVEMENT PROGRAM FOR HOSPICE WITH CERTAIN CONDITIONS

ISSUE: The proposed hospice conditions of participation are expected to require hospices to develop, implement, maintain, and evaluate an effective, data driven quality assessment and performance improvement program. HCFA has indicated its intent to require hospices to either develop their own or use currently available systems of measures to track patient outcomes in such areas as pain management, quality of life, skin integrity, and patient satisfaction. The requirement will include retaining the information in a data base that permits analysis over time. HCFA has also indicated that it will not be initiating any research and demonstration projects to develop systems of measures for the hospice industry, but in the future it may require that hospices report performance data into a national data base.

RECOMMENDATION: HAA agrees that agencies should be responsible for ongoing quality assessment/program improvement (QA/PI) programs based on patient outcomes. Such requirements should recognize that there does not yet exist a valid and reliable data set of performance measures for use in hospice care and allow flexibility in design of individual hospice QA/PI programs.

1. Broad parameters of quality improvement requirements should be specific but providers should be allowed to identify, prioritize, and phase in specific systems of measures to capture outcomes that they believe are essential to their provision of optimal hospice care.
2. The following conditions must be met in implementing any outcome measurement system for hospices:
   a. Reliable and valid indicators.
   b. Number of outcome measures limited to those that most accurately predict quality.

c. Method for case-mix adjustment.
d. Standard assessment limited to those items needed for outcomes measurement and case-mix adjustment (agencies may develop their own assessment tool and will use additional assessment items for care planning purposes).
e. A system that is simple and has clinical utility for all patients, not just Medicare.
f. Mechanism for HCFA to validate agency data.
g. Ongoing evaluation of the entire system so that changes can be made if it does not work properly.

3. HCFA should study the application of the home care outcome measures/OASIS to hospice care.

RATIONALE: The ideal QA/PI is based on what happens to the patients. However, currently there are no standard, valid, and reliable outcome measures for hospice. Hospices will need to create their own systems of measures or borrow from others because HCFA does not plan to initiate hospice-specific research and demonstration projects. There will be an insufficient level of confidence in the results until a methodology for evaluating outcomes measures is available. In addition, research and demonstration projects are not factored into the current per diem reimbursement structure. Therefore, hospices should be surveyed for initiating QA/PI programs based on currently available tools until such time as the industry has been able to develop hospice-specific systems of measures. Also, quality assessment should not rely solely on outcome measures; limited structure and process measures are appropriate.

The proposed quality system will have a tendency to involve massive data collection unless purposely controlled. Every effort must be made to keep data collection and the paperwork burden to a minimum so that resources can be used for patient care rather than paperwork.

[TOP]

CLARIFY SEPARATE ENTITY

ISSUE: In recent years, home care/hospice organizations have become more complex, multi-functional entities. The appearance of these complex organizations has made it increasingly difficult for surveyors to determine what part of the organization is the certified HHA or hospice and subject to the Conditions of Participation. Many of the instructions issued in the past are outdated and provide conflicting guidelines.

RECOMMENDATION: The bounds of an HHA/hospice that is part of a complex organization should be established by determining that the HHA/hospice is either a "legally separate entity" or is "a functionally separate entity." Functionally separate entities can be identified by application of the guidelines found in the HCFA document "Investigation and Decision-Making in the Survey Process". Once the surveyor determines whether the HHA/hospice is a legally or functionally separate entity, he or she should apply the survey process as follows:

Legally Separate Entity- the Medicare-certified HHA/hospice is a separate legal entity (e.g., corporation or partnership). When the HHA/hospice is legally separate from other parts of the organization, no further questions should be posed about the organizational boundaries. The HHA/hospice administrator or designee should direct the surveyor to those patients and records that receive HHA/hospice services. The survey process is then applied to the legal entity which has been identified as the HHA/hospice to determine compliance with the Conditions of Participation (CoP).

In an organization that has multiple legally separate entities, the Medicare surveyor has authority to apply the CoP only to that legal entity that has applied for Medicare certification or recertification. If, during the process of surveying a HHA/hospice, it becomes apparent that another separate legal entity in the

organization has created the public perception that its services are from the Medicare certified HHA/hospice, the surveyor should report the other entity to the appropriate authority which investigates fraudulent business practices.

or

Functionally Separate Entity-the Medi-care-certified HHA/hospice is a separate functional subdivision of an agency or organization. In order to determine if a HHA/hospice that is part of a complex agency or organization that provides more than one program or multiple services meets "organizationally separate entity" criteria, the agency representative must demonstrate that the HHA/hospice:

- has verbal and written descriptions that indicate separate programs so that the public can distinguish the Medicare home health/hospice program from other organizational entities, and
- has admission and care management processes and procedures that are distinct from those of the other entities of the organization.

Once the functionally separate entity is identified as the home health agency/hospice, the survey process may be applied to determine compliance with the Medicare CoP.

If, during the course of the Medicare survey, it is determined that the HHA/hospice has failed to maintain separateness of programs, admission and care management processes and procedures, other subdivisions of the organization may be subject to survey.

RATIONALE: Federal law defines a HHA as a "public or private organization or a subdivision of such an agency or organization" (42 USC S1395X). Hospice is defined as a "public agency or private organization or subdivision of either of these that is primarily engaged in providing care to terminally ill individuals" (42 CFR §418.3). "Subdivi-sion" is defined in the State Operations Manual (§2182) as a "component of a multi-function health agency. "There is no requirement that a _subdivision' be a separate legal entity from other parts of an organization. In order to comply with federal law (42 USC S1395X) and the definition of _subdivision' as in Section 2182 of the State Operations Manual, an organization simply must be able to delineate the home health agency from other "components of a multi-function health agency." This requirement is met when both HHAs and hospices have distinct admission and care management processes and a program description which differentiates the HHA or hospice from other organizational programs.

[TOP]

CONTINUE TO ALLOW HHAs TO PROVIDE SERVICES UNDER ARRANGEMENTS

ISSUE: The Medicare Conditions of Participation (CoP) require that an HHA must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization (42 CFR §484.14(a)). HCFA interprets service "directly through agency employees" as meaning providing the services "by employees in its entirety," which essentially inhibits contract arrangements even when needed for emergencies or staffing shortages. Additionally, HCFA currently allows home health agencies to determine which one of the "qualifying services" (nursing, PT, OT, ST, MSW, home health aide) they wish to provide directly by employees.

HCFA has indicated that they plan to change this regulation to require that HHAs provide directly, by employees, 50% of all professional services.

RECOMMENDATION: HHAs should be permitted to provide services under arrangement with individuals or other agencies or organizations. HCFA should enforce the regulations that are in the CoP entitled "Organizations, Services, and Administration" to ensure that HHAs: 1) do not merely serve as a billing agent for other parties; 2) exercise professional supervision and quality controls over the personnel providing "under arrangement" services, and 3) assure coordination of all personnel providing services.

HCFA should consider adding language similar to that appearing in HIM-11, §200.2 (Arrangements by Home Health Agencies), to the regulations in order to strengthen the requirements of HHAs to ensure quality of services provided under arrangement: "In permitting HHAs to furnish services under arrangements, it is not intended that the HHA merely serve as a billing mechanism for the other party. Accordingly for services provided under arrangements to be covered the agency must exercise professional responsibility for the arranged-for services."

RATIONALE: The current health care environment has resulted in an increase in managed care and numerous organizational relationships. In order to remain competitive for managed care contracts, HHAs often contract for services to control costs. Mergers, acquisitions, and joint ventures are taking place at a rapid pace. It is unknown at this time what impact these health care industry changes will have on home care, but flexibility in the provision of services will be critical to HHA survival.

Home care experience shows that subcontracting is necessary when: temporary staffing shortages exist; community demands result in increased referrals; and patients require the skills of specialty nurses and therapists.

HHAs should be permitted to continue to provide services "under arrangement" in order to control costs and meet patient care needs. It is unnecessary to require services be provided through employees in order to ensure quality. Existing quality and supervision regulations and guidelines, if enforced, can serve to ensure quality of care to Medicare beneficiaries.

[TOP]

CONTINUE FLEXIBILITY IN REQUIRED COVERED SERVICES PROVIDED BY HHAS

ISSUE: Currently, agencies are required to offer skilled nursing and any one of the other covered services (42 CFR §484.14(a)). It has been suggested that HCFA require all Medicare certified home health agencies provide all covered services (SN plus home health aide, PT, OT, ST, and MSW) as one way to make the home health benefit more responsive to beneficiary needs. The suggestion is seen as a means to ensure more standardization of the Medicare home health benefit, eliminate patient confusion caused by multiple providers, and ensure availability of all services for beneficiaries in need of home health care. This suggestion is thought to be a way to eliminate billing duplication and other problems created when two home health agencies must bill for home care services. However, such a requirement could create additional problems.

RECOMMENDATION: Retain the current requirements that home health agencies provide skilled nursing and at least one other covered service in order to be certified as a Medicare provider. Strengthen the requirement that HHAs may accept only those patients for whom they can provide the services needed by requiring providers to notify the patient and physician if services needed are not available and requiring providers to assist patients with locating and arranging for needed services.

If it is necessary for two home health agencies to provide services in order to meet the patient's needs, both agencies must meet the CoP. HCFA should strengthen regulations that require coordination between HHAs.

HCFA should develop a code to be used by the agencies on the UB-92 to denote that more than one HHA is providing and billing for services.

RATIONALE: Some patients and their physicians have a preference for services from certain HHAs. In addition, some home health agencies are not able to provide all covered services due to difficulties securing staff and appropriate supervisory personnel. These agencies will lose their Medicare certification if required to deliver all services in order to be certified as Medicare providers. This is particularly applicable in hard to serve rural and inner city areas. Thus, patients may be deprived of those Medicare services that the agencies are able to provide. Agencies should be allowed to continue to decide what other services to offer, taking into consideration such issues as community needs and availability of personnel.

The concerns identified can be adequately addressed by strengthening the requirements for acceptance of patients and coordination of care. HHAs can meet their responsibility by informing beneficiaries of the scope of services that are available from the HHA prior to initiation of care, coordinating services with other agencies for additional services, or assisting patients to make arrangements with health care facilities that offer the needed service.

[TOP]

INCREASE FLEXIBILITY IN THE APPLICATION OF THE CONDITIONS OF PARTICIPATION

ISSUE: HCFA requires the application of all of the Medicare Conditions of Participation (CoP) to all patients served by the Medicare-certified agency regardless of payor source or services. Only one of the CoP, the supervision of home health aides, has been written to provide flexibility in application based on intensity of service needs. These requirements increase the cost of services to all payors.

RECOMMENDATION: Allow HHAs flexibility in application of the CoP to payors other than Medicare:

- Apply plan of care (42 CFR §§484.18(a) and 484.18(b)), clinical record, and advance directive (§484.10(c)(2)(ii)) requirements only to medically unstable patients and patients in need of therapeutic services (§484.48). These would apply to all patients where Medicare is a payor.
- Apply medication monitoring (§484.18(c)) requirements only to those patients receiving nursing services, regardless of the payor.

RATIONALE: Certain CoP in their full application are excessive for the delivery of some services by home health agencies. If additional flexibility is built into the CoP, costs would be contained for delivery of services to patients in certified agencies. Also, quality would be increased because agencies would be less likely to establish unregulated separate entities to avoid the costs of compliance with unnecessary requirements.

Advance directives should not be required in the same manner for medically stable persons. Some examples are visits to new mothers receiving services as part of an early maternity hospital discharge program and persons who do not require skilled services but who wish to secure the services of an HHA nurse to visit monthly to check blood pressure, pulse and breath sounds.

Physicians should not have to review and sign the plan of care if a person needs long term care personal care services only, and does not require skilled services. State professional practice acts do not require physician orders for personal care services and recognize the licensed nurse as the person who should be responsible for aide activities.

If a physician orders only therapy, the home health agency should not be responsible for the patient's medication monitoring. This should be the responsibility of the physician and pharmacist.

Clinical records for persons who are medically stable, but are receiving nursing services to maintain general health compliance should not be required to contain a plan of care signed by a physician and summary reports sent to a physician, as they are excessive and unnecessary.

[TOP]

ABOLISH PRESCRIPTIVE AND BURDENSOME PROCEDURAL REQUIREMENTS RELATED TO ORAL ORDERS

ISSUE: The Medicare Home Health Conditions of Participation (CoP) at 42 CFR §484.18(c) and coverage rules at 42 CFR §409.43(d) require that all oral orders must be signed and dated by the registered nurse or therapist responsible for furnishing or supervising the ordered services. The Health Care Financing Administration's (HCFA) contends that this will ensure that oral orders received by agency personnel other than the professionals directly responsible for the patient's care will be reviewed by the responsible persons prior to implementation. In addition, §409.43(d) states that "oral orders must also be countersigned and dated by the physician before the HHA bills for the care."

HCFA's office of survey and certification and some Regional Home Health Intermediaries (RHHI) have interpreted this regulation as meaning that the same piece of paper that is prepared by the person receiving the oral orders must be reviewed and signed by the nurse or therapist and must be countersigned by the physician. This requirement contradicts the instructions in §234.7 (item 23) of the Medicare Home Health Agency Manual (HIM-11) for completing the 485 and can result in increased paperwork for providers and physicians and needless delays in submission of Medicare claims.

RECOMMENDATION: HCFA should reevaluate their current interpretation of regulations related to oral orders. Home health agencies should be permitted to establish their own procedures for confirming and documenting oral orders. Documentation that indicates the nurse or therapist responsible for providing or supervising the care has received the oral order should not be required on the form countersigned by the physician.

Require signed orders prior to billing to include only orders needed to support billed services. Do not cite agencies with deficiencies when they can demonstrate that they made a good faith effort to obtain the paperwork from the physician to validate oral orders.

RATIONALE: There are numerous ways that oral orders can be safely and effectively received and documented that would not require home health agencies to secure three signatures on the same piece of paper.

Webster defines "countersignature" as "a signature attesting the authenticity of a document already signed by another." The physician's "countersignature" is needed to confirm that the information, as documented and signed by the person who received the oral order, is correct. The purpose of the nurse or therapist's signature is to confirm that they have been informed of the oral orders. Since they did not receive the orders, they cannot attest to their authenticity. Therefore, it is not necessary that the same form or paper be signed by both the physician and the supervising/responsible nurse/therapist.

This rationale is further supported by HIM-11 §204.2E in which HCFA allows that: "the (oral) orders may be signed by the supervising registered nurse or qualified therapist after the services have been rendered, as long

as HHA personnel who receive the oral orders notify that nurse or therapist before the service is rendered."

HHAs cannot control the actions of physicians. Since HHAs cannot ensure that physicians will sign for the oral orders that they have issued, penalties should be limited. Therefore, HHAs that have, in good faith, accepted and carried out physicians' oral orders should only be required to demonstrate that they have taken appropriate steps to obtain the physician's signature on oral orders. Since the intent of the law is to ensure that services paid for by the Medicare program are ordered by a physician, denial of payment should not occur when agencies have not obtained the physician's signature for minor changes in the plan of care, but should occur only when the provider has not obtained signatures on those oral orders needed to support the services billed.

[TOP]

REVISE ORGANIZATIONAL STRUCTURE REQUIREMENTS

ISSUE: HCFA recently revised organizational and functional requirements for home health agency (HHA) alternate sites (branches, subunits, etc.) in a Program Memorandum dated April 3, 1996, to the Region Offices (RO). The revised requirements have raised new questions and do not adequately address the current health care environment with its complex organizational structures. Furthermore, this information was not disseminated to home health agencies via manual updates.

There has been some RO correspondence indicating the use of arbitrary guidelines requiring that a certain percentage of Medicare patients be served as a basis for determining intent to serve Medicare beneficiaries.

The site designation program memorandum issued by HCFA central and advisories issued by some of the ROs to State Survey Agencies reference quality of care concerns about alternate sites as the basis for criteria listed. However, the criteria differs from one region to another and is prescriptive and burdensome, with little guarantee of ensuring quality. Many agencies that have operated alternate sites and delivered quality services effectively and efficiently since the inception of the Medicare benefit do not meet the new criteria.

RECOMMENDATION: Establish a work group including representatives from the home care industry to assess the current health care system as it relates to home health provider organizational structure. Establish new organizational requirements and definitions for alternate sites that address Medicare program costs and ensure flexible yet effective administration and supervision of services. Initiate investigation of payment methodology that is fair and cost-efficient to the Medicare program. Denial of certification for failure to serve Medicare beneficiaries should be based on proven discrimination rather than arbitrary percentage of Medicare patients served.

RATIONALE: One of the goals of the HCFA Home Health Initiative was administrative simplification. This will not be achieved merely by re-interpreting old regulations that do not address the current environment. In this age of rapid contact via telephone, fax machines, and pagers, communication between various service sites is instantaneous. Modern transportation and mail services in addition to telecommunication promote effective sharing of administration, supervision, and services between sites. Current site definitions and rules have not keep pace with changes in the health care environment.

HHAs that serve either large geographic rural areas or densely populated metropolitan areas operate branch offices and subunits in order to provide a home base for personnel that is close to the patients that the agency serves, where patient records will be accessible, where supplies are available, and where personnel can meet to coordinate care with others who are serving the patient. This is a very efficient, cost-effective means of providing high quality service while avoiding duplication of administrative positions and functions.

Requiring a percentage of patients served to be Medicare beneficiaries is a flawed methodology since it does not prove discrimination and may only be reflective or the agency's success in working with other payors.

The practice of locating offices at sites where HHAs will receive the most favorable reimbursement is clearly a cost problem and should be resolved through changes in procedure related to cost limit methodology

[TOP]

MAKE PERSONNEL QUALIFICATIONS CONSISTENT AND REQUIRE CRIMINAL BACKGROUND CHECKS

ISSUE: Current regulations specify in the personnel qualifications (42 CFR §484.4) that social workers and occupational therapists and the assistants for each profession must have two years of related experience in their profession in order to meet the requirements for home health agencies. There are no experience requirements for nurses and in most cases physical therapists. Additionally, social workers are required to have a master's degree in social work and one year of health care experience, while regulations for other health provider settings, such as hospice, do not impose the same requirements. Many states have enacted laws requiring criminal background checks for aides but not for professional personnel.

RECOMMENDATION: Reduce or delete experience requirements for medical social workers, social work assistants, occupational therapists, and physical and occupational therapy assistants consistent with the nurse requirements.

Include a personnel requirement that agencies must assess staff competencies and provide orientation and training as needed.

Once an organized national system which is reasonable in cost and produces complete and timely information has been developed, require criminal background checks for all home visiting staff through a state registry or professional board prior to their first contact with patients.

RATIONALE: Because of the independent aspects of home visiting it is preferable to employ staff who already have experience in their profession. However, a rigid requirement does not allow for differences in education and work experiences. This requirement may contribute in part to the shortage of therapists and social workers for home care services. It also does not allow the agency flexibility to develop less experienced staff through HHA-sponsored orientation and preceptor programs.

The social services covered by Medicare include: assessment, referral to community resources, and counseling to resolve social or emotional problems that may be an impediment to the effective treatment of the patient's medical condition. These are responsibilities that are generally within the capabilities of bachelor's degree prepared social workers.

This recommendation would, in effect, allow personnel who meet state practice requirements to provide services in a Medicare certified home health agency.

[TOP]

FOCUS AIDE SUPERVISION ON INDIVIDUAL AIDES RATHER THAN EACH PATIENT

RECOMMENDATION:

1. HCFA core requirements should be consistent for aides working in all settings. Aide training and certification programs should address core content applicable to all aides as well as site of practice specific requirements and certification. These requirements should apply to Medicare as well as all Medicaid programs (e.g., PCA, waiver programs).
2. There should be three levels of certification with specific training and testing requirements for each level as proposed by the Home Care Aide Association of America's position paper entitled "National Uniformity for Paraprofessional Title, Qualifi-cations, and Supervision". The nurse aide and home health aide should be required to meet the level III requirements described in this paper.
3. Both training and competency evaluation should be required. If training is required, certified aides presently working in home care should be grandfathered.
4. Training programs should be approved by the state or by an approved accrediting organizations. Educational institutions and community organizations as well as providers may be approved to offer training and competency evaluation programs by these accrediting organizations.
5. One registry for aides practicing in all settings (home care, nursing homes and hospitals) should be established to maintain an up-to-date list of aides who are in good standing.
6. An organized system for criminal checks should be developed which is reasonable in cost and will provide up to date information in a timely manner.

RATIONALE: The basic job functions for home health aides and aides in other settings are the same with the differences being in application to a particular setting. A consistent training and certification program would prevent unnecessary duplication and allow easier mobility of home care/hospice workers. Aides would only have to complete the site-specific requirements when changing settings. Home health agencies/hospices would be able to accept with confidence a previous certification from an approved program.

There are different levels of home care/hospice workers with some only performing homemaker functions, so different levels of training and competency evaluation are indicated. Both training and testing should be required since testing can never cover every aspect of training. Requiring both training and testing for all aides will minimize the differences in quality of services and eliminate the financial inequity for those agencies that provide both versus agencies that only test. Consistency in training programs will also better prepare hospice home health aides to provide personal care services to nursing home residents enrolled in a hospice program.

Home care aides and nursing home aides should be tracked through the same registry since workers may move in and out of these settings. Criminal checks are needed but there currently is no systematic way to accomplish them effectively and in a timely manner.

[TOP]

REQUIRE REGION OFFICE REVIEW OF CHALLENGES TO DEFICIENCIES

ISSUE: Home health agencies and hospices are subject to Conditions of Participation (CoP) and regular surveys to participate in the Medicare program. Due to the complexity of Medicare regulations, interpretive guidelines, and limited surveyor training, inconsistent and highly subjective interpretations of these requirements continue. Also, HCFA has not published adequate criteria for differentiating condition level from standard level deficiencies.

The current HCFA instructions require that home health/hospice providers respond to a statement of deficiencies within 10 days. Providers are instructed to indicate their disagreement with a citation on the plan of correction form. If agencies submit both a corrective action and their disagreement, the disagreement is often ignored since the corrective action is included. If they submit only their disagreement, the plan of correction is considered unacceptable and the agency is at risk of termination. This essentially nullifies providers' ability to refute a deficiency citation. Ordinarily, the provider is expected to achieve compliance within 60 days of notice of the deficiency unless the seriousness warrants quicker corrective action.

RECOMMENDATION: HCFA should require that all challenges to a deficiency citation be reviewed by the Region Office and a response given to the HHA/hospice within 30 days. For standard level deficiencies and condition level deficiencies that pose no immediate threat to patients, the HHA/hospice would not have to submit the corrective action initially. If the Region Office upholds the deficiency the HHA/hospice would then be required to submit the corrective action and achieve compliance within 30 days. For deficiencies considered to pose a threat to patient safety, the HHA/hospice would be required to submit and begin corrective action in addition to their challenge to the citation. If the Region Office reversed the determination, then the HHA/hospice could abandon the corrective action plan. The Region Office determinations would need to be included in the file for public disclosure.

RATIONALE: Without an objective review of the providers' objections the agencies have no recourse but to accept the determination of a surveyor even if that determination is wrong. This may involve costly or time-consuming procedures that are not necessary.

[TOP]

PROMOTE EQUITABLE APPLICATION OF REGULATIONS IMPLEMENTING OBRA-87 SANCTIONS

ISSUE: The Omnibus Budget Reconcil-iation Act of 1987 (OBRA-87) authorized administrative and civil money sanctions against agencies which are not in compliance with the Conditions of Participation. The "intermediate sanctions" could be imposed in addition to or in lieu of termination from the Medicare program. HCFA developed a range of sanctions, specific procedures and conditions for imposing sanctions and the severity of each sanction as proposed rules published in the Federal Register notice of August 2, 1991. The proposed rules do not identify which conditions or standards of participation are more serious than others. In addition, the guidelines are vague regarding temporary management and civil money penalties.

Final regulations were expected in 1995, but have not yet been published. It is anticipated that, once published, the type and severity of sanctions will have a significant impact on agencies' operations. It is important that the sanctions and appeals process assure equitable application of the Omnibus Budget Reconciliation Act of 1987 (OBRA-87, P.L. 100-203) provisions and protect agencies from unwarranted penalties.

RECOMMENDATION: HCFA should include the following points in the regulations implementing OBRA-87 Sanctions:

1. Only condition level deficiencies that impact quality of care should warrant sanctions;
2. Differentiate condition level deficiencies as those which pose a threat to patients from standard level deficiencies.
3. Complaint surveys should be based on "significant" complaints which are those that affect patient health, safety, and rights (42 CFR §§484.10, 484.18, 484.30, 484.32, 484.34, and 484.36);

4. Personnel responsible for imposing sanctions should be trained and tested;
5. An objective structured system for imposing civil money penalties should be developed;
6. All surveys should conclude with an exit interview to allow the provider to clarify issues; and
7. The time frame should be amended to allow for more than five days between the last survey and imposition of sanctions.
8. All recommendations for sanctions should be subject to region office review prior to imposition.
9. Further study should be undertaken to determine how to relate payment and sanctions to quality of care.

RATIONALE: The imposition of administrative and financial sanctions against agencies raises many concerns. The types of sanctions, levels of civil money penalties, and the correlation between the sanctions and specific deficiencies will also be critical in assuring that the provisions are implemented appropriately and equitably. Specific guidelines for surveyors are essential to ensure equitable imposition of sanctions. Since existing quality assurance technology does not permit the measurement of refined gradations of quality, further studies are needed before relating quality to payment.

[TOP]

INCREASE TRAINING FOR HOME HEALTH AND HOSPICE SURVEYORS

ISSUE: State surveyors for Medicare certified providers generally survey all types of providers, i.e., nursing homes, home care agencies, hospices, and hospitals. Each of these providers is governed by a different set of complex regulations. The Health Care Financing Administration (HCFA) does not conduct routine in-depth surveyor training programs. Usually, state surveyors are trained by other state surveyors who may or may not have attended HCFA surveyor training. Recently, Operation Restore Trust (ORT) activities have placed surveyors in the position of reviewing records for coverage compliance and determining what documentation should be submitted to intermediaries for which they have received little training.

RECOMMENDATION: HCFA should follow-through on its stated plan to provide surveyor training on the Medicare Home Health and Hospice regulations. Training programs should:

- Be required for all surveyors.
- Be based on an established curriculum with specific learning goals.
- Include information on Medicare coverage of services information.
- Ensure consistent interpretation and application of the regulations.

Surveyors should have a healthcare background and their pay should be commensurate with area standards. In addition, state agencies should be required to show evidence of surveyor training for all new surveyors and provide ongoing continuing education to all surveyors.

HCFA should develop a formal procedure for sharing information between the FIs and state survey agencies (SA). SAs should report suspected coverage problems to the FIs and the FIs should report suspected quality problems to the SAs. SAs and FIs must be cross trained on basic coverage and regulatory principles, reporting procedures, and determining the bounds of their individual authority. Training should be ongoing in order that the level of knowledge stays current.

RATIONALE: Surveyors for the Medicare Home Health & Hospice Benefit should have full knowledge of the provisions and requirements of the benefit to avoid inappropriate requirements of hospice and home health providers and ensure the highest quality of care for patients. A healthcare background is essential for proper assessment of quality care. Underpaying surveyors limits a state's ability to recruit quality personnel.

[TOP]

MODIFY HOSPICE REGULATIONS FOR INPATIENT RESPITE CARE

ISSUE: The Health Care Financing Administration's (HCFA) regulations under the Medicare Hospice Benefit (MHB) requirements for both inpatient acute care and inpatient respite care are that a registered nurse (RN) be available 24-hours a day. This stipulation is understandable for inpatient acute care (e.g., hospitals) because of inherent and implied patient need. However, institutional respite care is provided as a means of relieving the family caregiver, not because a patient's condition requires skilled care in an institution. The 24-hour hospice requirement constitutes a higher standard than that required of routine skilled nursing facility (SNF) [42 CFR §483.28] or nursing facility (NF) care, which allows some SNFs and NFs to seek a waiver from the 24-hour RN requirement and allows an RN for the eight-hour day shift only, with licensed nurses for the balance of the shifts.

Hospices generally contract with SNFs and NFs for in-patient respite care. However, with the implementation of the new SNF/NF regulation under OBRA-87 which allows application for a waiver of the 24-hour RN staffing requirement for some SNFs/NFs, hospices that continue to contract with a facility that has such a waiver will automatically be out of compliance with the Medicare Hospice Benefit regulations.

RECOMMENDATION: Change the requirement in the MHB for nursing care under the inpatient respite care provision to mirror the less stringent requirements for skilled nursing facilities and nursing facilities in the Omnibus Budget Reconciliation Act of 1987 (OBRA-87). The 24-hour RN staffing requirement should be removed from the hospice Conditions of Participation for NF and SNF in-patient respite care.

RATIONALE: Under the current regulations, the only in-patient respite option hospices often have is to place the patient in a hospital which results in unnecessary utilization of a hospital bed and increased costs. Hospice caregivers require respite; hospice patients receiving the respite level of care do not necessarily require skilled care in an institution.

[TOP]

SURVEY FREQUENCY FOR MEDICARE HOSPICE PROVIDERS SHOULD BE BASED ON PERFORMANCE

ISSUE: Only 10% of Medicare hospice providers are surveyed each year. There is no legislative requirement for the frequency of surveys for providers of the Medicare Hospice Benefit (MHB). HCFA's failure to require survey hospice providers be surveyed on a regular basis can result in lack of compliance with regulations and poor quality of care.

RECOMMENDATION: Limited resources available for hospice surveys should be used to target quality issues by adopting the following survey frequency guidelines:

- New Medicare hospice agencies should be surveyed annually for at least the first two years of certification.
- Agencies with condition level deficiencies should be surveyed at least annually until they are deficiency free.
- Complaint surveys should be conducted following significant complaints. If deficiencies are found, annual surveys should be conducted until deficiency free.

- All hospices should be surveyed, at a minimum, every three years.

RATIONALE: When the MHB was created by the Congress, in order to assure quality of care and implement the benefit, HCFA was given the responsibility of creating regulations to be followed by providers of hospice services. As the next step of this responsibility, there needs to be regular surveys to ensure compliance with these regulations. Recipients of the MHB should be afforded the same protections provided to recipients of other Medicare benefits.

[TOP]

Legislation and Regulations | Regulatory Blueprint Table of Contents

Return to the HomeCare On-Line Center!

We love receiving comments and suggestions for improvement!
Send them to webmaster@nahc.org

CFR Part 409—Hospital Insurance Benefit

42 CFR Part 409—Subpart E—Home Health Services Under Hospital Insurance

409.40 Basis, purpose, and scope.

This subpart implements sections 1814(a)(2)(C), 1835(a)(2)(A), and 1861(m) of the Act with respect to the requirements that must be met for Medicare payment to be made for home health services furnished to eligible beneficiaries.

[59 FR 65493, Dec. 20, 1994]

409.41 Requirement for payment.

In order for home health services to qualify for payment under the Medicare program the following requirements must be met:

(a) The services must be furnished to an eligible beneficiary by, or under arrangements with, an HHA that—

(1) Meets the conditions of participation for HHAs at part 484 of this chapter; and

(2) Has in effect a Medicare provider agreement as described in part 489, subparts A, B, C, D, and E of this chapter.

(b) The physician certification and recertification requirements for home health services described in 424.22.

(c) All requirements contained in 409.42 through 409.47.

[59 FR 65494, Dec. 20, 1994]

409.42 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home health services, a beneficiary must meet each of the following requirements:

(a) Confined to the home. The beneficiary must be confined to the home or in an institution that is not a hospital, SNF or nursing facility as defined in section 1861(e)(1), 1819(a)(1) or 1919(a)(1) of the Act, respectively.

(b) Under the care of a physician. The beneficiary must be under the care of a physician who establishes the plan of care. A doctor of podiatric medicine may establish a plan of care only if that is consistent with the functions he or she is authorized to perform under State law.

(c) In need of skilled services. The beneficiary must need at least one of the following skilled services as certified by a physician in accordance with the physician certification and recertification requirements for home health services under 424.22 of this chapter.

(1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services found in 409.32. (Also see 409.33(a) and (b) for a description of examples of skilled nursing and rehabilitation services.)

(2) Physical therapy services that meet the requirements of 409.44(c).

(3) Speech-language pathology services that meet the requirements of 409.44(c).

(4) Continuing occupational therapy services that meet the requirements of 409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period.

(d) Under a plan of care. The beneficiary must be under a plan of care that meets the requirements for plans of care specified in 409.43.

(e) By whom the services must be furnished. The home health services must be furnished by, or under arrangements made by, a participating HHA.

[59 FR 65494, Dec. 20, 1994; 60 FR 39122, Aug. 1, 1995]

409.43 Plan of care requirements.

(a) Contents. The plan of care must contain those items listed in 484.18(a) of this chapter that specify the standards relating to a plan of care that an HHA must meet in order to participate in the Medicare program.

(b) Physician's orders. The physician's orders for services in the plan of care must specify the medical treatments to be furnished as well as the type of home health discipline that will furnish the ordered services and at what frequency the services will

be furnished. Orders for services to be provided "as needed" or "PRN" must be accompanied by a description of the beneficiary's medical signs and symptoms that would occasion the visit and a specific limit on the number of those visits to be made under the order before an additional physician order would have to be obtained. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished. If a range of visits is ordered, the upper limit of the range is considered the specific frequency.

(c) Physician signature. The plan of care must be signed and dated by a physician who meets the certification and recertification requirements of 424.22 of this chapter. The plan of care must be signed by the physician before the bill for services is submitted. Any changes in the plan must be signed and dated by the physician.

(d) Oral (verbal) orders. If any services are provided based on a physician's oral orders, the orders must be put in writing and be signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Oral orders may only be accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. The oral orders must also be countersigned and dated by the physician before the HHA bills for the care.

(e) Frequency of review. The plan of care must be reviewed by the physician (as specified in 409.42(b)) in consultation with agency professional personnel at least every 62 days. Each review of a beneficiary's plan of care must contain the signature of the physician who reviewed it and the date of review.

(f) Termination of the plan of care. The plan of care is considered to be terminated if the beneficiary does not receive at least one covered skilled nursing, physical therapy, speech-language pathology services, or occupational therapy visit in a 62-day period unless the physician documents that the interval without such care is appropriate to the treatment of the beneficiary's illness or injury.

[59 FR 65494, Dec. 20, 1994]

409.44 Skilled services requirements.

(a) General. The intermediary's decision on whether care is reasonable and necessary is based on information provided on the forms and in the medical record concerning the unique medical condition of the individual beneficiary. A coverage denial is not made solely on the basis of the reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care.

(b) Skilled nursing care.

(1) Skilled nursing care consists of those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse, as defined in 484.4 of this chapter, and meet the criteria for skilled nursing services specified in 409.32. See 409.33(a) and (b) for a description of skilled nursing services and examples of them.

(i) In determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice.

(ii) If the nature of a service is such that it can safely and effectively be performed by the average nonmedical person without direct supervision of a licensed nurse, the service cannot be regarded as a skilled nursing service.

(iii) The fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse.

(iv) If the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

(2) The skilled nursing care must be provided on a part-time or intermittent basis.

(3) The skilled nursing services must be reasonable and necessary for the treatment of the illness or injury.

(i) To be considered reasonable and necessary, the services must be consistent with the nature and severity of the beneficiary's illness or injury, his or her particular medical needs, and accepted standards of medical and nursing practice.

(ii) The skilled nursing care provided to the beneficiary must be reasonable within the context of the beneficiary's condition.

(iii) The determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time.

(c) Physical therapy, speech-language pathology services, and occupational therapy. To be covered, physical therapy, speech-language pathology services, and occupational therapy must satisfy the criteria in paragraphs (c)(1) through (4) of this section. Occupational therapy services initially qualify for home health coverage only if they are part of a plan of care that also includes intermittent skilled nursing care, physical therapy, or speech-language pathology services as follows:

(1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist) that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes.

(2) Physical and occupational therapy and speech-language pathology services must be reasonable and necessary. To be considered reasonable and necessary, the following conditions must be met:

(i) The services must be considered under accepted standards of medical practice to be a specific, safe, and effective treatment for the beneficiary's condition.

(ii) The services must be of such a level of complexity and sophistication or the condition of the beneficiary must be such that the services required can safely and effectively be performed only by a qualified physical therapist or by a qualified physical therapy assistant under the supervision of a qualified physical therapist, by a qualified speech-language pathologist, or by a qualified occupational therapist or a qualified occupational therapy assistant under the supervision of a qualified occupational therapist (as defined in 484.4 of this chapter). Services that do not require the performance or supervision of a physical therapist or an occupational therapist are not considered reasonable or necessary physical therapy or occupational therapy services, even if they are performed by or supervised by a physical therapist or occupational therapist. Services that do not require the skills of a speech-language pathologist are not considered to be reasonable and necessary speech-language pathology services even if they are performed by or supervised by a speech-language pathologist.

(iii) There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition, or the services must be necessary to establish a safe and effective maintenance program required in connection with a specific disease, or the skills of a therapist must be necessary to perform a safe and effective maintenance program. If the services are for the establishment of a maintenance program, they may include the design of the program, the instruction of the beneficiary, family, or home health aides, and the necessary infrequent reevaluations of the beneficiary and the program to the degree that the specialized knowledge and judgment

of a physical therapist, speech-language pathologist, or occupational therapist is required.

(iv) The amount, frequency, and duration of the services must be reasonable.

[59 FR 65496, Dec. 20, 1994]

409.45 Dependent services requirements.

(a) General. Services discussed in paragraphs (b) through (g) of this section may be covered only if the beneficiary needs skilled nursing care on an intermittent basis, as described in 409.44(b); physical therapy or speech-language pathology services as described in 409.44(c); or has a continuing need for occupational therapy services as described in 409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period; and otherwise meets the qualifying criteria (confined to the home, under the care of a physician, in need of skilled services, and under a plan of care) specified in 409.42. Home health coverage is not available for services furnished to a beneficiary who is no longer in need of one of the qualifying skilled services specified in this paragraph. Therefore, dependent services furnished after the final qualifying skilled service are not covered, except when the dependent service was not followed by a qualifying skilled service as a result of the unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event.

(b) Home health aide services. To be covered, home health aide services must meet each of the following requirements:

(1) The reason for the visits by the home health aide must be to provide hands-on personal care to the beneficiary or services that are needed to maintain the beneficiary's health or to facilitate treatment of the beneficiary's illness or injury. The physician's order must indicate the frequency of the home health aide services required by the beneficiary. These services may include but are not limited to:

(i) Personal care services such as bathing, dressing, grooming, caring for hair, nail and oral hygiene that are needed to facilitate treatment or to prevent deterioration of the beneficiary's health, changing the bed linens of an incontinent beneficiary, shaving, deodorant application, skin care with lotions and/or powder, foot care, ear care, feeding, assistance with elimination (including enemas unless the skills of a licensed nurse are required due to the beneficiary's condition, routine catheter care, and routine colostomy care), assistance with ambulation, changing position in bed, and assistance with transfers.

(ii) Simple dressing changes that do not require the skills of a licensed nurse.

(iii) Assistance with medications that are ordinarily self-administered and that do not require the skills of a licensed nurse to be provided safely and effectively.

(iv) Assistance with activities that are directly supportive of skilled therapy services but do not require the skills of a therapist to be safely and effectively performed, such as routine maintenance exercises and repetitive practice of functional communication skills to support speech-language pathology services.

(v) Routine care of prosthetic and orthotic devices.

(2) The services to be provided by the home health aide must be—

(i) Ordered by a physician in the plan of care; and

(ii) Provided by the home health aide on a part-time or intermittent basis.

(3) The services provided by the home health aide must be reasonable and necessary. To be considered reasonable and necessary, the services must—

(i) Meet the requirement for home health aide services in paragraph (b)(1) of this section;

(ii) Be of a type the beneficiary cannot perform for himself or herself; and

(iii) Be of a type that there is no able or willing caregiver to provide, or, if there is a potential caregiver, the beneficiary

is unwilling to use the services of that individual.

(4) The home health aide also may perform services incidental to a visit that was for the provision of care as described in paragraphs (b)(3)(i) through (iii) of this section. For example, these incidental services may include changing bed linens, personal laundry, or preparing a light meal.

(c) Medical social services. Medical social services may be covered if the following requirements are met:

(1) The services are ordered by a physician and included in the plan of care.

(2) (i) The services are necessary to resolve social or emotional problems that are expected to be an impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(ii) If these services are furnished to a beneficiary's family member or caregiver, they are furnished on a short-term basis and it can be demonstrated that the service is necessary to resolve a clear and direct impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(3) The frequency and nature of the medical social services are reasonable and necessary to the treatment of the beneficiary's condition.

(4) The medical social services are furnished by a qualified social worker or qualified social work assistant under the supervision of a social worker as defined in 484.4 of this chapter.

(5) The services needed to resolve the problems that are impeding the beneficiary's recovery require the skills of a social worker or a social work assistant under the supervision of a social worker to be performed safely and effectively.

(d) Occupational therapy. Occupational therapy services that are not qualifying services under 409.44(c) are nevertheless covered as dependent services if the requirements of 409.44(c)(2)(i) through (iv), as to reasonableness and necessity, are met.

(e) Durable medical equipment. Durable medical equipment in accordance with 410.38 of this chapter, which describes the scope and conditions of payment for durable medical equipment under Part B, may be covered under the home health benefit as either a Part A or Part B service. Durable medical equipment furnished by an HHA as a home health service is always covered by Part A if the beneficiary is entitled to Part A.

(f) Medical supplies. Medical supplies (including catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care but excluding drugs and biologicals) may be covered as a home health benefit. For medical supplies to be covered as a Medicare home health benefit, the medical supplies must be needed to treat the beneficiary's illness or injury that occasioned the home health care.

(g) Intern and resident services. The medical services of interns and residents in training under an approved hospital teaching program are covered if the services are ordered by the physician who is responsible for the plan of care and the HHA is affiliated with or under the common control of the hospital furnishing the medical services.

Approved means—

(1) Approved by the Accreditation Council for Graduate Medical Education;

(2) In the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association;

(3) In the case of an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association; or

(4) In the case of an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association.

[59 FR 65495, Dec. 20, 1994; 60 FR 39122, 39123, Aug. 1, 1995]

409.46 Allowable administrative costs.

Services that are allowable as administrative costs but are not separately billable include, but are not limited to, the following:

(a) Registered nurse initial evaluation visits. Initial evaluation visits by a registered nurse for the purpose

of assessing a beneficiary's health needs, determining if the agency can meet those health needs, and formulating a plan of care for the beneficiary are allowable administrative costs. If a physician specifically orders that a particular skilled service be furnished during the evaluation in which the agency accepts the beneficiary for treatment and all other coverage criteria are met, the visit is billable as a skilled nursing visit. Otherwise it is considered to be an administrative cost.

(b) Visits by registered nurses or qualified professionals for the supervision of home health aides. Visits by registered nurses or qualified professionals for the purpose of supervising home health aides as required at 484.36(d) of this chapter are allowable administrative costs. Only if the registered nurse or qualified professional visits the beneficiary for the purpose of furnishing care that meets the coverage criteria at 409.44, and the supervisory visit occurs simultaneously with the provision of covered care, is the visit billable as a skilled nursing or therapist's visit.

(c) Respiratory care services. If a respiratory therapist is used to furnish overall training or consultative advice to an HHA's staff and incidentally provides respiratory therapy services to beneficiaries in their homes, the costs of the respiratory therapist's services are allowable as administrative costs. Visits by a respiratory therapist to a beneficiary's home are not separately billable. However, respiratory therapy services that are furnished as part of a plan of care by a skilled nurse or physical therapist and that constitute skilled care may be separately billed as skilled visits.

(d) Dietary and nutrition personnel. If dieticians or nutritionists are used to provide overall training or consultative advice to HHA staff and incidentally provide dietetic or nutritional services to beneficiaries in their homes, the costs of these professional services are allowable as administrative costs. Visits by a dietician or nutritionist to a beneficiary's home are not separately billable.

[59 FR 65496, Dec. 20, 1994]

409.47 Place of service requirements.

To be covered, home health services must be furnished in either the beneficiary's home or an outpatient setting as defined in this section.

(a) Beneficiary's home. A beneficiary's home is any place in which a beneficiary resides that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1), of 1919(a)(1) of the Act, respectively.

(b) Outpatient setting. For purposes of coverage of home health services, an outpatient setting may include a hospital, SNF or a rehabilitation center with which the HHA has an arrangement in accordance with the requirements of 484.14(h) of this chapter and that is used by the HHA to provide services that either—

(1) Require equipment that cannot be made available at the beneficiary's home; or

(2) Are furnished while the beneficiary is at the facility to receive services requiring equipment described in paragraph (b)(1) of this section.

[59 FR 65496, Dec. 20, 1994]

409.48 Visits.

(a) Number of allowable visits under Part A. To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part A for an unlimited number of covered home health visits. All Medicare home health services are covered under hospital insurance unless there is no Part A entitlement.

(b) Number of visits under Part B. To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part B for an unlimited number of covered home health visits. Medicare home health services are covered under Part B only when the beneficiary is not entitled to coverage under Part A.

(c) Definition of visit. A visit is an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA, for the purpose of providing a covered service.

(1) Generally, one visit may be covered each time an HHA employee or someone providing home health services under arrangements enters the beneficiary's home and provides a covered service to a beneficiary who meets the criteria of 409.42 (confined to the home, under the care of a physician, in need of skilled services, and under a plan of care).

(2) If the HHA furnishes services in an outpatient facility under arrangements with the facility, one visit may be covered for each type of service provided.

(3) If two individuals are needed to provide a service, two visits may be covered. If two individuals are present, but only one is needed to provide the care, only one visit may be covered.

(4) A visit is initiated with the delivery of covered home health services and ends at the conclusion of delivery of covered home health services. In those circumstances in which all reasonable and necessary home health services cannot be provided in the course of a single visit, HHA staff or others providing services under arrangements with the HHA may remain at the beneficiary's residence between visits (for example, to provide non-covered services). However, if all covered services could be provided in the course of one visit, only one visit may be covered.

[59 FR 65497, Dec. 20, 1994]

409.49 Excluded services.

(a) Drugs and biologicals. Drugs and biologicals are excluded from payment under the Medicare home health benefit.

(1) A drug is any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other condition or for the relief of pain or suffering or to control or improve any physiological pathologic condition.

(2) A biological is any medicinal preparation made from living organisms and their products including, but not limited to, serums, vaccines, antigens, and antitoxins.

(b) Transportation. The transportation of beneficiaries, whether to receive covered care or for other purposes, is excluded from home health coverage. Costs of transportation of equipment, materials, supplies, or staff may be allowable as administrative costs, but no separate payment is made for them.

(c) Services that would not be covered as inpatient services. Services that would not be covered if furnished as inpatient hospital services are excluded from home health coverage.

(d) Housekeeping services. Services whose sole purpose is to enable the beneficiary to continue residing in his or her home (for example, cooking, shopping, Meals on Wheels, cleaning, laundry) are excluded from home health coverage.

(e) Services covered under the End Stage Renal Disease (ESRD) program. Services that are covered under the ESRD program and are contained in the composite rate reimbursement methodology, including any service furnished to a Medicare ESRD beneficiary that is directly related to that individual's dialysis, are excluded from coverage under the Medicare home health benefit.

(f) Prosthetic devices. Items that meet the requirements of 410.36(a)(2) of this chapter for prosthetic devices covered under Part B are excluded from home health coverage. Catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care are not considered prosthetic devices if furnished under a home health plan of care and are not subject to this exclusion from coverage.

(g) Medical social services provided to family members. Except as provided in 409.45(c)(2), medical social services provided solely to members of the beneficiary's family and that are not incidental to covered medical social services being provided to the beneficiary are not covered.

[59 FR 65497, Dec. 20, 1994; 60 FR 39123, Aug. 1, 1995]

409.50 Coinsurance for durable medical equipment (DME) furnished as a home health service.

The coinsurance liability of the beneficiary or other person for DME furnished as a home health service is 20 percent of the customary (insofar as reasonable) charge for the services.

[51 FR 41339, Nov. 14, 1986. Redesignated at 59 FR 65496, Dec. 20, 1994]

CFR Part 413—Principles of Reasonable Cost Reimbursement

42 CFR Part 413—Subpart B—Accounting Records and Reports

413.1 [Amended] Introduction.
[Amended by: 62 FR 26 - 01/02/97 - MEDICARE PROGRAM; ELECTRONIC COST REPORTING FOR SKILLED NURSING FACILITIES AND HOME HEALTH AGENCIES]

(a) Basis, scope, and applicability.
(1) Statutory basis.
(i) Basic provisions.
(A) Section 1815 of the Act requires that the Secretary make interim payments to providers and periodically determine the amount that should be paid under Part A of Medicare to each provider for the services it furnishes.
(B) Section 1814(b) of the Act (for Part A) and section 1833(a) (for Part B) provide for payment on the basis of the lesser of a provider's reasonable costs or customary charges.
(C) Section 1861(v) of the Act defines "reasonable cost."
(ii) Additional provisions.
(A) Section 1138(b) of the Act specifies the conditions for Medicare payment for organ procurement costs.
(B) Section 1814(j) of the Act provides for exceptions to the "lower of costs or charges" provisions.
(C) Section 1833(a)(4) and (i)(3) of the Act provide for payment of a blended amount for certain surgical services furnished in a hospital's outpatient department.
(D) Section 1833(n) of the Act provides for payment of a blended amount for outpatient hospital diagnostic procedures such as radiology.
(E) Section 1834(c)(1)(C) of the Act establishes the method for determining Medicare payment for screening mammograms performed by hospitals.
(F) Section 1834(g) of the Act provides for payment for rural primary care hospital (RPCH) outpatient services on the basis of prospectively determined amounts.
(G) Section 1881 of the Act authorizes payment for services furnished to ESRD patients.
(H) Section 1883 of the Act provides for payment for post-hospital SNF care furnished by a rural hospital that has swing-bed approval.
(I) Sections 1886(a) and (b) of the Act impose a ceiling on the rate of increase in hospital inpatient costs.
(J) Section 1886(h) of the Act provides for payment to a hospital for the services of interns and residents in approved teaching programs on the basis of a "per resident" amount.
(2) Scope. This part sets forth regulations governing Medicare payment for services furnished to beneficiaries by—
(i) Hospitals and rural primary care hospitals (RPCHs);
(ii) Skilled nursing facilities (SNFs);
(iii) Home health agencies (HHAs);
(iv) Comprehensive outpatient rehabilitation facilities (CORFs);
(v) End-stage renal disease (ESRD) facilities;
(vi) Providers of outpatient physical therapy and speech pathology services (OPTs); and
(vii) Organ procurement agencies (OPAs) and histocompatibility laboratories.
(viii) Community mental health centers (CMHCs) but only for purposes of furnishing partial hospitalization services.
(3) Applicability. The payment principles and related policies set forth in this part are binding on HCFA and its fiscal intermediaries, on the Provider Reimbursement Review Board,

and on the entities listed in paragraph (a)(2) of this section.

(b) Reasonable cost reimbursement. Except as provided under paragraphs (c) through (f) of this section, Medicare is generally required, under section 1814(b) of the Act (for services covered under Part A) and under section 1833(a)(2) of the Act (for services covered under Part B) to pay for services furnished by providers on the basis of reasonable costs as defined in section 1861(v) of the Act, or the provider's customary charges for those services, if lower. Regulations implementing section 1861(v) are found generally in this part beginning at 413.5.

(c) Outpatient maintenance dialysis and related services. Section 1881 of the Act authorizes special rules for the coverage of and payment for services furnished to ESRD patients. Sections 413.170 and 413.174 implement various provisions of section 1881. In particular, 413.170 establishes a prospective payment method for outpatient maintenance dialysis services that applies both to hospital-based and independent ESRD facilities, and under which Medicare pays for both home and infacility dialysis services furnished on or after August 1, 1983.

(d) Payment for inpatient hospital services.

(1) For cost reporting periods beginning before October 1, 1983, the amount paid for inpatient hospital services is determined on a reasonable cost basis.

(2) Payment to short-term general hospitals located in the 50 States and the District of Columbia for the operating costs of hospital inpatient services for cost reporting periods beginning on or after October 1, 1983, and for the capital-related costs of inpatient services for cost reporting periods beginning on or after October 1, 1991, are determined prospectively on a per discharge basis under part 412 of this chapter except as follows:

(i) Payment for capital-related costs for cost reporting periods beginning before October 1, 1991, medical education costs, kidney acquisition costs, and the costs of certain anesthesia services, is described in 412.113 of this chapter.

(ii) Payment to children's, psychiatric, rehabilitation and long-term hospitals (as well as separate psychiatric and rehabilitation units (distinct parts) of short-term general hospitals), which are excluded from the prospective payment system under subpart B of part 412 of this chapter, and to hospitals outside the 50 States and the District of Columbia is on a reasonable cost basis, subject to the provisions of 413.40.

(iii) Payment to hospitals subject to a State reimbursement control system is described in paragraph (e) of this section.

(e) State reimbursement control systems. Beginning October 1, 1983, Medicare reimbursement for inpatient hospital services may be made in accordance with a State reimbursement control system rather than under the Medicare reimbursement principles set forth in this part, if the State system is approved by HCFA. Regulations implementing this alternative reimbursement authority are set forth in subpart C of part 403 of this chapter.

(f) Services of qualified nonphysician anesthetists. For cost reporting periods, or any part of a cost reporting period, beginning on or after January 1, 1989, costs incurred for the services of qualified nonphysician anesthetists are not paid on a reasonable cost basis unless the provisions of 412.113(c)(2) of this chapter apply. These services are paid under the special rules set forth in 405.553 of this chapter.

(g) Prospectively determined payment rates for low Medicare volume SNFs. Rules governing requests by SNFs for prospectively determined payment rates under section 1888(d) of the Act are set forth in subpart I of this part.

[51 FR 34793, Sept. 30, 1986, as amended at 57 FR 33898, July 31, 1992; 57 FR 39829, Sept. 1, 1992; 58 FR 30670, May 26, 1993; 59 FR 6578, Feb. 11, 1994; 60 FR 33136, June 27, 1995; 60 FR 37594, July 21, 1995; 60 FR 50441, Sept. 29, 1995]

413.5 [Amended] [Revised] Cost reimbursement: General.

[Amended by: 60 FR 63123 - 12/08/95 - MEDICARE PROGRAM; PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 1996; PAYMENT POLICIES AND

RELATIVE VALUE UNIT ADJUSTMENTS; FINAL RULE AND NOTICE]

[Revised by: 61 FR 63740 - 12/02/96 - MEDICARE PROGRAM; CHANGES CONCERNING SUSPENSION OF MEDICARE PAYMENTS, AND DETERMINATIONS OF ALLOWABLE INTEREST EXPENSES]

(a) In formulating methods for making fair and equitable reimbursement for services rendered beneficiaries of the program, payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period or a fixed negotiated rate. All necessary and proper expenses of an institution in the production of services, including normal standby costs, are recognized. Furthermore, the share of the total institutional cost that is borne by the program is related to the care furnished beneficiaries so that no part of their cost would need to be borne by other patients. Conversely, costs attributable to other patients of the institution are not to be borne by the program. Thus, the application of this approach, with appropriate accounting support, will result in meeting actual costs of services to beneficiaries as such costs vary from institution to institution. However, payments to providers of services for services furnished Medicare beneficiaries are subject to the provisions of 413.13 and 413.30.

(b) Putting these several points together, certain tests have been evolved for the principles of reimbursement and certain goals have been established that they should be designed to accomplish. In general terms, these are the tests or objectives:

(1) That the methods of reimbursement should result in current payment so that institutions will not be disadvantaged, as they sometimes are under other arrangements, by having to put up money for the purchase of goods and services well before they receive reimbursement.

(2) That, in addition to current payment, there should be retroactive adjustment so that increases in costs are taken fully into account as they actually occurred, not just prospectively.

(3) That there be a division of the allowable costs between the beneficiaries of this program and the other patients of the provider that takes account of the actual use of services by the beneficiaries of this program and that is fair to each provider individually.

(4) That there be sufficient flexibility in the methods of reimbursement to be used, particularly at the beginning of the program, to take account of the great differences in the present state of development of recordkeeping.

(5) That the principles should result in the equitable treatment of both nonprofit organizations and profit-making organizations.

(6) That there should be a recognition of the need of hospitals and other providers to keep pace with growing needs and to make improvements.

(c) As formulated herein, the principles given recognition to such factors as depreciation, interest, bad debts, educational costs, compensation of owners, and an allowance for a reasonable return on equity capital (in the case of certain proprietary providers). With respect to allowable costs some items of inclusion and exclusion are:

(1) An appropriate part of the net cost of approved educational activities will be included.

(2) Costs incurred for research purposes, over and above usual patient care, will not be included.

(3) Grants, gifts, and income from endowments will not be deducted from operating costs unless they are designated by the donor for the payment of specific operating costs.

(4) The value of services provided by nonpaid workers, as members of an organization (including services of members of religious orders) having an agreement with the provider to furnish such services, is includable in the amount that would be paid others for similar work.

(5) Discounts and allowances received on the purchase of goods or services are reductions of the cost to which they relate.

(6) Bad debts growing out of the failure of a beneficiary to pay the deductible, or the coinsurance, will be reimbursed (after bona fide efforts at collection).

(7) Charity and courtesy allowances are not includable, although "fringe benefit" allowances for employees under a formal plan will be includable as part of their compensation.

(8) A reasonable allowance of compensation for the services of owners in profitmaking organizations will be allowed providing their services are actually performed in a necessary function.

(9) Reasonable cost of physicians' direct medical and surgical services (including supervision of interns and residents in the care of individual patients) furnished in a teaching hospital may be reimbursed as a provider cost (as described in 405.465 of this chapter) where elected as provided for in 405.521 of this chapter.

(d) In developing these principles of reimbursement for the Medicare program, all of the considerations inherent in allowances for depreciation were studied. The principles, as presented, provide options to meet varied situations. Depreciation will essentially be on an historical cost basis but since many institutions do not have adequate records of old assets, the principles provide an optional allowance in lieu of such depreciation for assets acquired before 1966. For assets acquired after 1965, the historical cost basis must be used. All assets actually in use for production of services for Medicare beneficiaries will be recognized even though they may have been fully or partially depreciated for other purposes. Assets financed with public funds may be depreciated. Although funding of depreciation is not required, there is an incentive for it since income from funded depreciation is not considered as an offset which must be taken to reduce the interest expense that is allowable as a program cost.

(e) A return on the equity capital of proprietary facilities, as described in 413.157, is an allowance in addition to the reasonable cost of covered services furnished to beneficiaries.

(f) Renal dialysis items and services furnished under the ESRD provision are reimbursed and reported under 413.170 and 413.174 respectively. For special rules concerning health maintenance organizations (HMOs), and providers of services and other health care facilities that are owned or operated by an HMO, or related to an HMO by common ownership or control, see 417.242(b)(14) and 417.250(c) of this chapter.

[51 FR 34793, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 57 FR 39829, Sept. 1, 1992]

413.9 Cost related to patient care.

Principle. All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries. Reasonable cost includes all necessary and proper costs incurred in furnishing the services, subject to principles relating to specific items of revenue and cost. However, for cost reporting periods beginning after December 31, 1973, payments to providers of services are based on the lesser of the reasonable cost of services covered under Medicare and furnished to program beneficiaries or the customary charges to the general public for such services, as provided for in 413.13.

Definitions—(1) Reasonable cost. Reasonable cost of any services must be determined in accordance with regulations establishing the method or methods to be used, and the items to be included. The regulations in this part take into account both direct and indirect costs of providers of services. The objective is that under the methods of determining costs, the costs with respect to individuals covered by the program will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by the program. These regulations also provide for the making of suitable retroactive adjustments after the provider has submitted fiscal and statistical reports. The retroactive adjustment will represent the difference between the amount received by the provider during the year for covered services from both Medicare and the beneficiaries and the amount determined in accordance with an accepted method of cost apportionment to be the actual cost of services furnished to beneficiaries during the year. Necessary and proper costs. Necessary and proper costs are costs that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. They are usually costs that are common and accepted occurrences in the field of the provider's activity.

(c) Application.

(1) It is the intent of Medicare that payments to providers of services should be fair to the providers, to the contributors to the Medicare trust funds, and to other patients.

(2) The costs of providers' services vary from one provider to another and the variations

generally reflect differences in scope of services and intensity of care. The provision in Medicare for payment of reasonable cost of services is intended to meet the actual costs, however widely they may vary from one institution to another. This is subject to a limitation if a particular institution's costs are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(3) The determination of reasonable cost of services must be based on cost related to the care of Medicare beneficiaries. Reasonable cost includes all necessary and proper expenses incurred in furnishing services, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. However, if the provider's operating costs include amounts not related to patient care, specifically not reimbursable under the program, or flowing from the provision of luxury items or services (that is, those items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services), such amounts will not be allowable. The reasonable cost basis of reimbursement contemplates that the providers of services would be reimbursed the actual costs of providing quality care however widely the actual costs may vary from provider to provider and from time to time for the same provider.

[51 FR 34795, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986]

413.13 [Amended] Amount of payment if customary charges for services furnished are less than reasonable costs.

[Amended by: 60 FR 63123 - 12/08/95 - MEDICARE PROGRAM; PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 1996; PAYMENT POLICIES AND RELATIVE VALUE UNIT ADJUSTMENTS; FINAL RULE AND NOTICE]

(a) Definitions. As used in this section—Fair compensation means, for the purpose of providers that meet the nominal charge provisions in paragraph (f) of this section, the reasonable cost of covered services furnished to beneficiaries. New provider means a provider that has operated as the type of facility for which it has been approved for participation in the Medicare program (for example, as a SNF or an HHA) under present and previous ownership for less than three full years. Provider with a significant portion of low-income patients means a nonpublic provider whose charges are 60 percent or less of the reasonable cost represented by the charges, and that demonstrates, as required under paragraph (c)(1)(iii) of this section, that its charges are less than costs because its customary practice is to charge patients based on their ability to pay. Public provider means a provider operated by a Federal, State, county, city, or other local government agency or instrumentality.

(b) Application of the principle of lesser of costs or charges.

(1) General rule. Except as provided in paragraph (c) of this section, effective with cost reporting periods beginning on or after January 1, 1974, hospitals, SNFs, HHAs, OPTs, and CMHCs but only for purposes of providing partial hospitalization services, are paid the lesser of the reasonable cost (as described in paragaraph (d) of this section) of covered services furnished to beneficiaries or the customary charges (as defined in paragraph (e) of this section) made by the provider for the same services. The carryover of unreimbursed reasonable costs from previous cost reporting periods is recognized, in accordance with the provisions of paragraph (h) of this section.

(2) Example. A provider's reasonable cost for covered services furnished to Medicare beneficiaries during a cost reporting period is $125,000. The customary charges to those beneficiaries for these services is $110,000. The provider is to be reimbursed $110,000 less deductible and coinsurance amounts that the beneficiaries are charged.

(c) Providers and services not subject to the principle.

(1) Providers.

(i) CORFs. Payment to CORFs is based on the reasonable cost of the services.

(ii) Public providers. Public providers furnishing services free of charge or at a

nominal charge (as specified in paragraph (f) of this section) are paid fair compensation for services furnished to beneficiaries.

(iii) Providers furnishing services to a significant portion of low-income patients. Effective with cost reporting periods beginning on or after October 1, 1984, a provider furnishing services at a nominal charge (as specified in paragraph (f) of this section) is paid fair compensation, upon request, for services furnished to beneficiaries if the provider can demonstrate to its intermediary that a significant portion of its patients are low income and that its charges are less than costs because its customary practice is to charge patients based on their ability to pay.

(2) Services—

(i) Part A inpatient hospital services. The lesser of costs or charges principle does not apply to Part A inpatient hospital services subject to—

(A) The rate-of-increase limits under 413.40, effective with cost reporting periods beginning on or after October 1, 1982; or

(B) The prospective payment system under Part 412 of this chapter, effective with cost reporting periods beginning on or after October 1, 1983.

(ii) Special rule for facility services related to ambulatory surgical procedures performed in outpatient hospital departments. Effective for hospitals with cost reporting periods beginning on or after October 1, 1987, reasonable costs and customary charges for those services relating to ambulatory surgical procedures that are subject to the payment methodology described in 413.118 are aggregated and treated separately from all other hospital costs and charges incurred during the cost reporting period.

(iii) Durable medical equipment furnished by HHAs—

(A) General. Except as provided in paragraph (c)(2)(iii)(B) of this section, for durable medical equipment furnished by an HHA as a home health service on or after July 18, 1984, the HHA is paid the lesser of the reasonable cost of the equipment or the customary charges (less a 20 percent coinsurance as provided in section 1866(a)(2)(A)(ii) of the Act), not to exceed 80 percent of the reasonable cost of the equipment. The lesser of cost or charges determination for durable medical equipment is made separately from all other items or services furnished in an HHA regardless of whether the equipment is furnished under Part A or Part B.

(B) HHAs meeting the nominal charge provisions. A public HHA, or an HHA that demonstrates that a significant portion of its patients are low-income patients under the nominal charge provisions, as provided in paragraph (f)(2) of this section, are paid 80 percent of fair compensation for durable medical equipment furnished as a home health service on or after July 18, 1984.

(iv) Rural Primary Care Hospital (RPCH) services. The lesser of costs or charges principle does not apply in determining payment for inpatient services furnished by a RPCH under 413.70(a) or outpatient RPCH services that are paid under the all-inclusive rate method described in 413.70(b)(3).

(3) Hospital outpatient radiology services. The reasonable costs and customary charges for hospital outpatient radiology services furnished on or after October 1, 1988, that are subject to the payment method described in 413.122, are aggregated and treated separately from all other hospital costs and charges incurred during the cost reporting period.

(4) Other diagnostic procedures performed by a hospital on an outpatient basis. The reasonable costs and customary charges for other diagnostic procedures identified by HCFA, that are performed on an outpatient basis by

a hospital on or after October 1, 1989, and that are subject to the payment method described in 413.122, are aggregated and treated separately from all other hospital costs or charges incurred during the cost reporting period.

(d) Exclusions from reasonable cost. For purposes of comparison with customary charges under this section, reasonable cost does not include—

(1) Payments made to a provider as reimbursement for bad debts arising from noncollection of Medicare deductible and coinsurance amounts (413.80);

(2) Amounts that represent the recovery of excess depreciation resulting from termination in the Medicare program or a decrease in Medicare utilization (413.134(d)(3)) applicable to prior cost reporting periods;

(3) Amounts that result from a disposition of depreciable assets (413.134(f)), applicable to prior cost reporting periods;

(4) Payments to funds for the donated services of teaching physicians (413.85); and

(5) Graduate medical education costs for cost reporting periods beginning on or after July 1, 1985.

(e) Customary charges:

(1) General. As used in this paragraph (e), customary charges means the charges for services, as defined in 413.53(b), furnished to beneficiaries. These charges must be recorded on all bills submitted for program reimbursement.

(2) Special situations in which customary charges are reduced. Customary charges are reduced in proportion to the ratio of the aggregate amount actually collected from chargepaying non-Medicare patients to the amount that would have been realized had customary charges been paid and the provider—

(i) Did not actually impose charges in the case of most patients liable for payment for its services on a charge basis; or

(ii) Failed to make a reasonable effort to collect those charges.

(f) Nominal charges:

(1) Cost reporting periods beginning before October 1, 1984. Except for durable medical equipment furnished by HHAs as provided in paragraph (c)(2)(iii) of this section, if a public provider's total charges, for cost reporting periods beginning before October 1, 1984, are less than onehalf of the reasonable cost of services or items represented by these charges, then the provider is reimbursed fair compensation.

(2) Cost reporting periods beginning on or after October 1, 1984. For cost reporting periods beginning on or after October 1, 1984, the following provisions apply in determining nominal charges:

(i) Reimbursement of fair compensation. Except for the limitations on reimbursement for durable medical equipment furnished by HHAs as provided in paragraph (c)(2)(iii) of this section, public providers, and providers with a significant portion of low-income patients that request payment under this paragraph are reimbursed fair compensation if total charges are 60 percent or less of the reasonable cost of services or items represented by these charges.

(ii) Separate determination of nominal charges. Except as provided in paragraph (f)(2)(iii) of this section, the determination of nominal charges, which is based on charges actually billed to charge-paying, non-Medicare patients, is made separately with respect to inpatient and outpatient services (other than clinical diagnostic laboratory tests that are paid under section 1833(h) of the Act).

(iii) Determination of nominal charges in special situations.

(A) For providers that have a sliding scale or discounted schedule of charges based on patients' ability to pay, the determination of nominal charges is based on charges billed to all charge-paying patients. This determination is made using the ratio of sliding scale or discounted charges to the provider's full customary charges. For determining nominal charges, the ratio is applied

to the provider's Medicare charges to equate those charges to customary charges.

(B) For HHAs, the determination of nominal charges for all items and services other than durable medical equipment is made on an aggregate basis. The nominal charge determination for durable medical equipment is made separately from other items or services furnished by HHAs.

(C) For cost reporting periods beginning on or after July 1, 1985, graduate medical education payments (or a provider's graduate medical education reasonable costs if supported by appropriate data) are included in reasonable costs when making the nominal charge determination.

(g) The aggregation method:

(1) Cost reporting periods beginning before October 1, 1984 - Application. In comparing costs and charges under the lesser of costs or charges principle for cost reporting periods beginning before October 1, 1984, the reasonable cost for items and services and the customary charges for those same items and services are to be aggregated (that is, totalled and compared) without regard to whether the services are reimbursable under Part A or Part B of Medicare. This aggregation method is to be applied after the provider's charges and costs have been adjusted to exclude the amounts described in paragraph (d) of this section and to exclude—

(i) Any amounts attributable to physician services not reimbursable to the provider on a reasonable cost basis as described in 405.480 through 405.482 of this chapter; and

(ii) All costs and charges for noncovered provider services.

(2) Cost reporting periods beginning on or after October 1, 1984. Effective with cost reporting periods beginning on or after October 1, 1984, the aggregation method used for computing the lesser of costs or charges, as set forth in paragraph (g)(1) of this section, may not be used. For covered items and services furnished during these periods, total reasonable cost of covered items and services is compared with total customary charges for those items and services, separately for Part A and for Part B.

(h) Accumulation of unreimbursed costs and carryover to subsequent periods:

(1) General rule. A provider whose charges are lower than its reasonable cost for those services in any cost reporting period beginning on or after January 1, 1974 but before April 28, 1988, may carry forward costs that are unreimbursed under paragraph (b) of this section for the two succeeding cost reporting periods. However, no recovery may be made in any period in which costs are unreimbursed because a provider's costs exceed the limitations on reimbursable costs (413.30) or the ceiling on the rate of hospital cost increases (413.40).

(2) Reimbursement as a result of carryover. The provider is reimbursed for the costs that are carried forward to a succeeding cost reporting period—

(i) If total charges for services provided in that subsequent period exceed the total reasonable cost of the services; and

(ii) To the extent that accumulation of the costs being carried forward and the costs for the services provided in that subsequent period do not exceed the customary charges for those services.

(3) Two succeeding periods less than 24 months. If the two succeeding cost reporting periods are less than 24 full calendar months, the provider may carry forward the unreimbursed costs for one additional cost reporting period.

(4) Example. In the cost reporting period ending September 30, 1982, a provider's reasonable costs were $100,000. The provider's customary charges for those services were $90,000. The provider is reimbursed $90,000 less any deductible and coinsurance amounts but is permitted to carry forward the unreimbursed reasonable costs of $10,000 for the next two succeeding cost reporting periods. If, in the cost reporting

period ending September 30, 1983, customary charges to beneficiaries exceeded the reasonable costs for those services by $10,000 or more, and the provider had no costs unreimbursed under 413.30 or 413.40, the provider would recover the entire $10,000 previously not reimbursed. If, however, beneficiary charges for that cost reporting period exceeded costs by only $8,000, this amount ($8,000) would be added to the provider's reimbursable costs for this period. The balance of the unreimbursed amount ($2,000) would be carried forward to the next cost reporting period.

(5) New providers.

(i) General rule. A new provider whose cost reporting period begins before April 28, 1988, may carry forward costs that are unreimbursed from previous periods, as described in paragraph (b) of this section, during a provider's base period. The base period includes any cost reporting period beginning on or after January 1, 1974, and ending on or before the last day of its third year of operation. The unreimbursed costs may be carried forward for the five succeeding cost reporting periods. However, no recovery may be made in any period in which costs are unreimbursed because a provider's costs exceed the limitations on reimbursable costs (413.30) or the ceiling on the rate of hospital cost increases (413.40).

(ii) Reimbursement as a result of carryover. The new provider is reimbursed for the costs that are carried forward to a succeeding cost reporting period—

(A) If total charges for the services provided in that subsequent period exceed the total reasonable cost of the services; and

(B) To the extent that accumulation of the costs being carried forward and the costs for the services provided in that subsequent period do not exceed the customary charges for those services.

(iii) Five succeeding periods less than 60 months. If the five succeeding cost reporting periods are less than 60 full calendar months, the provider may carry forward the unreimbursed costs for one additional cost reporting period.

(iv) Example. A provider begins its operations on March 5, 1972. However, it begins to participate in the Medicare program as of January 1, 1973, and reports on a calendar year basis. Because the provider would be subject to the lesser of cost or charges principle for its cost reporting period beginning with January 1, 1974, it would be permitted to accumulate any unreimbursed costs (excess of costs over its charges) incurred during this reporting period. Therefore, because this cost reporting period ends before the end of the third year of operation, its carryover period would be the succeeding five cost reporting periods ending with December 31, 1979. If this provider had begun its operation on July 1, 1973, and become a participating provider as of the same date (with a fiscal year ending June 30), it would have been able to accumulate any unreimbursed costs for the two cost reporting periods ending June 30, 1975, and June 30, 1976. Its carryover period would then be the five cost reporting periods ending no later than June 30, 1981, in the case of costs unreimbursed in either of the reporting periods ending June 30, 1975, or June 30, 1976.

[53 FR 10085, Mar. 29, 1988; 53 FR 12641, Apr. 15, 1988; 54 FR 40315, Sept. 29, 1989; 56 FR 8842, Mar. 1, 1991; 58 FR 30670, May 26, 1993; 59 FR 6578, Feb. 11, 1994]

413.17 Cost to related organizations.

(a) Principle. Except as provided in paragraph (d) of this section, costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includable in the allowable cost of the provider at the cost to the related organization. However, such cost

must not exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere.

(b) Definitions.

(1) Related to the provider. Related to the provider means that the provider to a significant extent is associated or affiliated with or has control of or is controlled by the organization furnishing the services, facilities, or supplies.

(2) Common ownership. Common ownership exists if an individual or individuals possess significant ownership or equity in the provider and the institution or organization serving the provider.

(3) Control. Control exists if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

(c) Application.

(1) Individuals and organizations associate with others for various reasons and by various means. Some deem it appropriate to do so to assure a steady flow of supplies or services, to reduce competition, to gain a tax advantage, to extend influence, and for other reasons. These goals may be accomplished by means of ownership or control, by financial assistance, by management assistance, and other ways.

(2) If the provider obtains items of services, facilities, or supplies from an organization, even though it is a separate legal entity, and the organization is owned or controlled by the owner(s) of the provider, in effect the items are obtained from itself. An example would be a corporation building a hospital or a nursing home and then leasing it to another corporation controlled by the owner. Therefore, reimbursable cost should include the costs for these items at the cost to the supplying organization. However, if the price in the open market for comparable services, facilities, or supplies is lower than the cost to the supplier, the allowable cost to the provider may not exceed the market price.

(d) Exception.

(1) An exception is provided to this general principle if the provider demonstrates by convincing evidence to the satisfaction of the fiscal intermediary (or, if the provider has not nominated a fiscal intermediary, HCFA) that—

(i) The supplying organization is a bona fide separate organization;

(ii) A substantial part of its business activity of the type carried on with the provider is transacted with others than the provider and organizations related to the supplier by common ownership or control and there is an open, competitive market for the type of services, facilities, or supplies furnished by the organization;

(iii) The services, facilities, or supplies are those that commonly are obtained by institutions such as the provider from other organizations and are not a basic element of patient care ordinarily furnished directly to patients by such institutions; and

(iv) The charge to the provider is in line with the charge for such services, facilities, or supplies in the open market and no more than the charge made under comparable circumstances to others by the organization for such services, facilities, or supplies.

(2) In such cases, the charge by the supplier to the provider for such services, facilities, or supplies is allowable as cost.

42 CFR Part 413—Subpart D—Apportionment

413.20 [Amended] Financial data and reports. [Amended by: 61 FR 63740 - 12/02/96 - MEDICARE PROGRAM; CHANGES CONCERNING SUSPENSION OF MEDICARE PAYMENTS, AND DETERMINATIONS OF ALLOWABLE INTEREST EXPENSES]

(a) General. The principles of cost reimbursement require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the program. Standardized definitions, accounting, statistics, and reporting practices that are widely accepted in the hospital and related fields are followed. Changes in these practices and systems will not be required in order to determine costs payable under the principles of reimbursement. Essentially the methods of determining costs payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services to beneficiaries.

(b) Frequency of cost reports. Cost reports are required from providers on an annual basis with reporting periods based on the provider's accounting year. In the interpretation and application of the principles of reimbursement, the fiscal intermediaries will be an important source of consultative assistance to providers and will be available to deal with questions and problems on a day-to-day basis.

(c) Recordkeeping requirements for new providers. A newly participating provider of services (as defined in 400.202 of this chapter) must make available to its selected intermediary for examination its fiscal and other records for the purpose of determining such provider's ongoing recordkeeping capability and inform the intermediary of the date its initial Medicare cost reporting period ends. This examination is intended to assure that—

(1) The provider has an adequate ongoing system for furnishing the records needed to provide accurate cost data and other information capable of verification by qualified auditors and adequate for cost reporting purposes under section 1815 of the Act; and

(2) No financial arrangements exist that will thwart the commitment of the Medicare program to reimburse providers the reasonable cost of services furnished beneficiaries. The data and information to be examined include cost, revenue, statistical, and other information pertinent to reimbursement including, but not limited to, that described in paragraph (d) of this section and in 413.24.

(d) Continuing provider recordkeeping requirements.

(1) The provider must furnish such information to the intermediary as may be necessary to—

(i) Assure proper payment by the program, including the extent to which there is any common ownership or control (as described in 413.17(b)(2) and (3)) between providers or other organizations, and as may be needed to identify the parties responsible for submitting program cost reports;

(ii) Receive program payments; and

(iii) Satisfy program overpayment determinations.

(2) The provider must permit the intermediary to examine such records and documents as are necessary to ascertain information pertinent to the determination of the proper amount of program payments due. These records include, but are not limited to, matters pertaining to—

(i) Provider ownership, organization, and operation;

(ii) Fiscal, medical, and other recordkeeping systems;

(iii) Federal income tax status;

(iv) Asset acquisition, lease, sale, or other action;

(v) Franchise or management arrangements;

(vi) Patient service charge schedules;

(vii) Costs of operation;

(viii) Amounts of income received by source and purpose; and

(ix) Flow of funds and working capital.

(3) The provider, upon request, must furnish the intermediary copies of patient service charge schedules and changes thereto as they are put into effect. The intermediary will evaluate such charge schedules to determine the extent to which they may be used for determining program payment.

(e) Suspension of program payments to a provider. If an intermediary determines that a provider does not maintain or no longer maintains adequate records for the determination of reasonable cost under the Medicare program, payments to such provider will be suspended until the intermediary is assured that adequate records are maintained. Before suspending payments to a provider, the intermediary will, in accordance with the provisions in 405.371(a) of this chapter, send written notice to such provider of its intent to suspend payments. The notice will explain the basis for the intermediary's determination with respect to the provider's records and will identify the provider's recordkeeping deficiencies. The provider must be given the opportunity, in accordance with 405.371(a) of this chapter, to submit a statement (including any pertinent evidence) as to why the suspension must not be put into effect.

413.24 [Amended] Adequate cost data and cost finding.

[Amended by: 62 FR 26 - 01/02/97 - MEDICARE PROGRAM; ELECTRONIC COST REPORTING FOR SKILLED NURSING FACILITIES AND HOME HEALTH AGENCIES]

(a) Principle. Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting. However, if governmental institutions operate on a cash basis of accounting, cost data based on such basis of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

(b) Definitions.

(1) Cost finding. Cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished. It is the determination of these costs by the allocation of direct costs and proration of indirect costs.

(2) Accrual basis of accounting. As used in this part, the term accrual basis of accounting means that revenue is reported in the period in which it is earned, regardless of when it is collected; and an expense is reported in the period in which it is incurred, regardless of when it is paid. (See 413.100 regarding limitations on allowable accrued costs in situations in which the related liabilities are not liquidated timely.)

(c) Adequacy of cost information. Adequate cost information must be obtained from the provider's records to support payments made for services furnished to beneficiaries. The requirement of adequacy of data implies that the data be accurate and in sufficient detail to accomplish the purposes for which it is intended. Adequate data capable of being audited is consistent with good business concepts and effective and efficient management of any organization, whether it is operated for profit or on a nonprofit basis. It is a reasonable expectation on the part of any agency paying for services on a costreimbursement basis. In order to provide the required cost data and not impair comparability, financial and statistical records should be maintained in a manner consistent from one period to another. However, a proper regard for consistency need not preclude a desirable change in accounting procedures if there is reason to effect such change.

(d) Cost finding methods. After the close of the accounting period, providers must use one of the following methods of cost finding to determine the actual costs of services furnished during that period. (These provisions do not apply to SNFs that elect and qualify for prospectively determined payment rates under subpart I of this part for cost reporting periods beginning on or after October 1, 1986. For the special rules that are applicable to those SNFs, see 413.321.) For cost reporting periods beginning after December 31, 1971, providers using the departmental method of cost apportionment must use the step-down method described in paragraph (d)(1) of this section or an "other method" described in paragraph (d)(2) of

this section. For cost reporting periods beginning after December 31, 1971, providers using the combination method of cost apportionment must use the modified cost finding method described in paragraph (d)(3) of this section. Effective for cost reporting periods beginning on or after October 1, 1980, HHAs not based in hospitals or SNFs must use the step-down method described in paragraph (d)(1) of this section. (HHAs based in hospitals or SNFs must use the method applicable to the parent institution.) However, an HHA not based in a hospital or SNF that received less than $35,000 in Medicare payment for the immediately preceding cost reporting period, and for whom this payment represented less than 50 percent of the total operating cost of the agency, may use a simplified version of the step-down method, as specified in instructions for the cost report issued by HCFA.

(1) Step-down Method. This method recognizes that services furnished by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers as well as by the revenue-producing centers All costs of nonrevenue-producing centers are allocated to all centers that they serve, regardless of whether or not these centers produce revenue. The cost of the nonrevenueproducing center serving the greatest number of other centers, while receiving benefits from the least number of centers, is apportioned first. Following the apportionment of the cost of the nonrevenue-producing center, that center will be considered "closed" and no further costs are apportioned to that center. This applies even though it may have received some service from a center whose cost is apportioned later. Generally, if two centers furnish services to an equal number of centers while receiving benefits from an equal number, that center which has the greatest amount of expense should be allocated first.

(2) Other methods.

(i) The double-apportionment method. The double-apportionment method may be used by a provider upon approval of the intermediary. This method also recognizes that the nonrevenue-producing departments or centers furnish services to other nonrevenue-producing centers as well as to revenue-producing centers. A preliminary allocation of the costs of non-revenue-producing centers is made. These centers or departments are not "closed" after this preliminary allocation. Instead, they remain "open," accumulating a portion of the costs of all other centers from which services are received. Thus, after the first or preliminary allocation, some costs will remain in each center representing services received from other centers. The first or preliminary allocation is followed by a second or final apportionment of expenses involving the allocation of all costs remaining in the nonrevenue-producing functions directly to revenue-producing centers.

(ii) More sophisticated methods. A more sophisticated method designed to allocate costs more accurately may be used by the provider upon approval of the intermediary. However, having elected to use the double-apportionment method, the provider may not thereafter use the step-down method without approval of the intermediary. Written request for the approval must be made on a prospective basis and must be submitted before the end of the fourth month of the prospective reporting period. Likewise, once having elected to use a more sophisticated method, the provider may not thereafter use either the double-apportionment or step-down methods without similar request and approval.

(3) Modified cost finding for providers using the Combination Method for reporting periods beginning after December 31, 1971. This method differs from the step-down method in that services furnished by nonrevenue-producing departments or centers are allocated directly to revenueproducing departments or centers even though these services may be utilized by other nonrevenue-producing departments or centers. In

the application of this method the cost of nonrevenue-producing centers having a common basis of allocation are combined and the total distributed to revenue-producing centers. All nonrevenue-producing centers having significant percentages of cost in relation to total costs will be allocated this way. The combined total costs of remaining nonrevenue-producing costs centers will be allocated to revenue-producing cost centers in the proportion that each bears to total costs, direct and indirect, already allocated. The bases which are to be used and the centers which are to be combined for allocation are not optional but are identified and incorporated in the cost report forms developed for this method. Providers using this method must use the program cost report forms devised for it. Alternative forms may not be used without prior approval by HCFA based upon a written request by the provider submitted through the intermediary.

(4) Temporary method for initial period. If the provider is unable to use either cost-finding method when it first participates in the program, it may apply to the intermediary for permission to use some other acceptable method that would accurately identify costs by department or center, and appropriately segregate inpatient and outpatient costs. Such other method may be used for cost reports covering periods ending before January 1, 1968.

(5) Simplified optional reimbursement method for small, rural hospitals with distinct parts for cost reporting periods beginning on or after July 20, 1982.

(i) A rural hospital with a Medicare-certified distinct part SNF may elect to be reimbursed for services furnished in its hospital general routine service area and distinct part SNF using the reimbursement method specified in 413.53 for swing-bed hospitals, if it meets the following conditions:

(A) The institution is located in a rural area as defined in 482.66 of this chapter.

(B) On the first day of the cost reporting period, the hospital and distinct part SNF have fewer than 50 beds in total (with the exception of beds for newborns and beds in intensive care type inpatient units).

(ii) In applying the optional reimbursement method, only those beds located in the hospital general routine service area and in the distinct part SNF certified by Medicare are combined into a single cost center for purposes of cost finding.

(iii) The reasonable cost of the routine extended care services is determined in accordance with 413.114(c). The reasonable cost of the hospital general routine services is determined in accordance with 413.53(a)(2).

(iv) The hospital must make its election to use the optional swing-bed reimbursement method in writing to the intermediary before the beginning of the hospital's cost reporting year. The hospital must make any request to revoke the election in writing before the beginning of the affected cost reporting period.

(v) The intermediary must approve requests to terminate use of the optional swing-bed reimbursement method. If a hospital terminates use of this optional method, no further elections may be made by the facility to use the optional method.

(e) Accounting basis. The cost data submitted must be based on the accrual basis of accounting which is recognized as the most accurate basis for determining costs. However, governmental institutions that operate on a cash basis of accounting may submit cost data on the cash basis subject to appropriate treatment of capital expenditures.

(f) Cost reports. For cost reporting purposes, the Medicare program requires each provider of services to submit periodic reports of its operations that generally cover a consecutive 12-month period of the provider's operations. Amended cost reports to revise cost report information that has been previously submitted by a provider may be permitted or required as determined by HCFA.

(1) Cost reports. Terminated providers and changes of ownership. A provider that voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change of ownership must file a cost report for that period under the program beginning with the first day not included in a previous cost reporting period and ending with the effective date of termination of its provider agreement or change of ownership.

(2) Due dates for cost reports.

(i) Cost reports are due on or before the last day of the fifth month following the close of the period covered by the report. For cost reports ending on a day other than the last day of the month, cost reports are due 150 days after the last day of the cost reporting period.

(ii) Extensions of the due date for filing a cost report may be granted by the intermediary only when a provider's operations are significantly adversely affected due to extraordinary circumstances over which the provider has no control, such as flood or fire.

(3) Changes in cost reporting periods. A provider may change its cost reporting period if a change in ownership is experienced or if the—

(i) Provider requests the change in writing from its intermediary;

(ii) Intermediary receives the request at least 120 days before the close of the new reporting period requested by the provider; and

(iii) Intermediary determines that good cause for the change exists. Good cause would not be found to exist if the effect is to change the initial date that a hospital would be affected by the rate of increase ceiling (see 413.40), or be paid under the prospective payment systems (see part 412 of this chapter).

(4) Electronic submission of cost reports.

(i) Effective for cost reporting periods beginning on or after October 1, 1989, a hospital is required to submit its cost reports in a standardized electronic format. The hospital's electronic program must be capable of producing the HCFA standardized output file in a form that can be read by intermediary's automated system. This electronic file, which must contain the input data required to complete the cost report and the data required to pass specified edits, is forwarded to the fiscal intermediary for processing through its system.

(ii) The fiscal intermediary stores the hospital's as-filed electronic cost report and may not alter that file for any reason. The fiscal intermediary makes a "working copy" of the as-filed electronic cost report to be used, as necessary, throughout the settlement process (that is, desk review, processing audit adjustments, final settlement, etc). The hospital's electronic program must be able to disclose if any changes have been made to the as-filed electronic cost report after acceptance by the intermediary. If the as-filed electronic cost report does not pass all specified edits, the fiscal intermediary rejects the cost report and returns it to the hospital for correction. For purposes of the requirements in paragraph (f)(2) of this section concerning due dates, an electronic cost report is not considered to be filed until it is accepted by the intermediary.

(iii) Effective for cost reporting periods ending on or after September 30, 1994, a hospital must submit a hard copy of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a statement signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. The following statement must immediately precede the dated signature of the hospital's administrator or chief financial officer:

I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet Statement of Revenue and Expenses prepared by

XXXX (Provider Name(s) and Number(s)) for the cost reporting period beginning XXXX and ending XXXX and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

(iv) A hospital may request a delay or waiver of the electronic submission requirement in paragraph (f)(4)(i) of this section if this requirement would cause a financial hardship. The hospital must submit a written request for delay or waiver with necessary supporting documentation to its intermediary at least 120 days prior to the end of its cost reporting period. The intermediary reviews the request and forwards it with a recommendation for approval or denial, to HCFA central office within 30 days of receipt of the request. HCFA central office either approves or denies the request and notifies the intermediary within 60 days of receipt of the request.

(5) An acceptable cost report submission is defined as follows:

(i) All providers. The provider, must complete and submit the required cost reporting forms, including all necessary signatures. A cost report is rejected for lack of supporting documentation only if it does not include the Provider Cost Reimbursement Questionnaire. Additionally, a cost report for a teaching hospital is rejected for lack of supporting documentation if the cost report does not include a copy of the Intern and Resident Information System diskette.

(ii) For providers that are required to file electronic cost reports. In addition to the requirements of paragraphs (f)(4) and (f)(5)(i) of this section, the provider must submit its cost reports in an electronic cost report format in conformance with the requirements contained in the Electronic Cost Report (ECR) Specifications Manual (unless the provider has received an exemption from HCFA).

(iii) The intermediary makes a determination of acceptability within 30 days of receipt of the provider's cost report. If the cost report is considered unacceptable, the intermediary returns the cost report with a letter explaining the reasons for the rejection. When the cost report is rejected, it is deemed an unacceptable submission and treated as if a report had never been filed.

(g) Exception from full cost reporting for lack of program utilization. If a provider does not furnish any covered services to Medicare beneficiaries during a cost reporting period, it is not required to submit a full cost report. It must, however, submit an abbreviated cost report, as prescribed by HCFA.

(h) Waiver of full or simplified cost reporting for low program utilization.

(1) If the provider has had low utilization of covered services by Medicare beneficiaries (as determined by the intermediary) and has received correspondingly low interim payments for the cost reporting period, the intermediary may waive a full cost report or the simplified cost report described in 413.321 if it decides that it can determine, without a full or simplified report, the reasonable cost of covered services provided during that period.

(2) If a full or simplified cost report is waived, the provider must submit within the same time period required for full or simplified cost reports:

(i) The cost reporting forms prescribed by HCFA for this situation; and

(ii) Any other financial and statistical data the intermediary requires.

[51 FR 34793, Sept. 30, 1986, as amended at 57 FR 39829, Sept. 1, 1992; 59 FR 26964, May 25, 1994; 60 FR 33125, 33136, 33143, June 27, 1995; 60 FR 37594, July 21, 1995]

42 CFR Part 413—Subpart C—Limits on Cost Reimbursement

413.30 Limitations on reimbursable costs.

(a) Introduction.

(1) Scope. This section implements section 1861(v)(1)(A) of the Act, by setting forth the general rules under which HCFA may establish limits on provider costs recognized as reasonable in determining Medicare program payments, and sections 1861(v)(7)(B) and 1886(a) of the Act, by setting forth the general rules under which HCFA may establish limits on the operating costs of inpatient hospital services that are recognized as reasonable in determining Medicare program payments. (For cost reporting periods beginning on or after October 1, 1983, the operating costs incurred in furnishing inpatient hospital services are not subject to the provisions of this section.) This section also sets forth rules governing exemptions, exceptions, and adjustments to limits established under this section that HCFA may make as appropriate in consideration of special needs or situations of particular providers.

(2) General principle. Reimbursable provider costs may not exceed the costs estimated by HCFA to be necessary for the efficient delivery of needed health services. HCFA may establish estimated cost limits for direct or indirect overall costs or for costs of specific items or services or groups of items or services. These limits will be imposed prospectively and may be calculated on a per admission, per discharge, per diem, per visit, or other basis.

(b) Procedure for establishing limits.

(1) In establishing limits under this section, HCFA may classify providers by type of provider (for example, hospitals, SNFs, and HHAs) and by other factors HCFA finds appropriate and practical, including—

(i) Type of services furnished;

(ii) Geographical area where services are furnished, allowing for grouping of noncontiguous areas having similar demographic and economic characteristics;

(iii) Size of institution;

(iv) Nature and mix of services furnished; or

(v) Type and mix of patients treated.

(2) Estimates of the costs necessary for efficient delivery of health services may be based on cost reports or other data providing indicators of current costs. Current and past period data will be adjusted to arrive at estimated costs for the prospective periods to which limits are being applied.

(3) Prior to the beginning of a cost period to which revised limits will be applied, HCFA will publish a notice in the FEDERAL REGISTER, establishing cost limits and explaining the basis on which they were calculated.

(4) In establishing limits under paragraph (b)(1) of this section, HCFA may find it inappropriate to apply particular limits to a class of providers due to the characteristics of the provider class, the data on which those limits are based, or the method by which the limits are determined. In such cases, HCFA may exclude that class of providers from the limits, explaining the basis of the exclusion in the notice setting forth the limits for the appropriate cost reporting periods.

(c) Provider requests regarding applicability of cost limits. A provider may request a reclassification, exception, or exemption from the cost limits imposed under this section. In addition, a hospital may request an adjustment to the cost limits imposed under this section. The provider's request must be made to its fiscal intermediary within 180 days of the date on the intermediary's notice of program reimbursement. The intermediary makes a recommendation on the provider's request to HCFA, which makes the decision. HCFA responds to the request within 180 days from the date HCFA receives the request from the intermediary. The intermediary notifies the provider of HCFA's decision. The time required for HCFA to review the request is considered good cause for the granting of an extension of the time limit to apply for a Board review, as specified in 405.1841 of this

chapter. HCFA's decision is subject to review under subpart R of part 405 of this chapter.

(d) Reclassification. A provider may obtain a reclassification if it can show that its classification is at variance with the criteria specified in promulgating the limits.

(e) Exemptions. Exemptions from the limits imposed under this section may be granted to a new provider. A new provider is a provider of inpatient services that has operated as the type of provider (or the equivalent) for which it is certified for Medicare, under present and previous ownership, for less than three full years. An exemption granted under this paragraph expires at the end of the provider's first cost reporting period beginning at least two years after the provider accepts its first patient.

(f) Exceptions. Limits established under this section may be adjusted upward for a provider under the circumstances specified in paragraphs (f)(1) through (f)(5) of this section. An adjustment is made only to the extent the costs are reasonable, attributable to the circumstances specified, separately identified by the provider, and verified by the intermediary.

(1) Atypical services. The provider can show that the—

(i) Actual cost of items or services furnished by a provider exceeds the applicable limit because such items or services are atypical in nature and scope, compared to the items or services generally furnished by providers similarly classified; and

(ii) Atypical items or services are furnished because of the special needs of the patients treated and are necessary in the efficient delivery of needed health care.

(2) Extraordinary circumstances. The provider can show that it incurred higher costs due to extraordinary circumstances beyond its control. These circumstances include, but are not limited to, strikes, fire, earthquake, flood, or similar unusual occurrences with substantial cost effects.

(3) Providers in areas with fluctuating populations.

(i) The provider is located in an area (for example, a resort area) that has a population that varies significantly during the year;

(ii) The appropriate health planning agency has determined that the area does not have a surplus of beds and similar services and has certified that the beds and services made available by the provider are necessary; and

(iii) The provider meets occupancy standards established by the Secretary.

(4) Medical and paramedical education. The provider can demonstrate that, if compared to other providers in its group, it incurs increased costs for items or services covered by limits under this section because of its operation of an approved education program specified in 413.85.

(5) Unusual labor costs. The provider has a percentage of labor costs that varies more than 10 percent from that included in the promulgation of the limits.

(g) Operational review of providers receiving an exception. Any provider that applies for an exception to the limits established under paragraph (f) of this section must agree to an operational review at the discretion of HCFA. The findings from any such review may be the basis for recommendations for improvements in the efficiency and economy of the provider's operations. If such recommendations are made, any future exceptions shall be contingent on the provider's implementation of these recommendations.

(h) Adjustments. For cost reporting periods beginning on or after October 1, 1982 and before October 1, 1983, HCFA may adjust the amount of a hospital's inpatient operating costs to take into account factors that could result in a significant distortion in the operating costs of inpatient hospital services. Such factors could include a decrease in the inpatient services that a hospital provides that are customarily provided directly by similar hospitals, or the manipulation of discharges to increase reimbursement. A decrease in inpatient services could result from changes that include, but are not limited to, such actions as closing a special care unit or changing the arrangements under which such services may be furnished, such as leasing a department.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 53 FR 38533, Sept. 30, 1988; 60 FR 45849, Sept. 1, 1995]

413.35 Limitations on coverage of costs: Charges to beneficiaries if cost limits are applied to services.

Principle. A provider of services that customarily furnishes an individual items or services that are more expensive than the items or services determined to be necessary in the efficient delivery of needed health services described in 413.30, may charge an individual entitled to benefits under Medicare for such more expensive items or services even though not requested by the individual. The charge, however, may not exceed the amount by which the cost of (or, if less, the customary charges for) such more expensive items or services furnished by such provider in the second cost reporting period immediately preceding the cost reporting period in which such charges are imposed exceeds the applicable limit imposed under the provisions of 413.30. This charge may be made only if—

(1) The intermediary determines that the charges have been calculated properly in accordance with the provisions of this section;

(2) The services are not emergency services as defined in paragraph (d) of this section;

(3) The admitting physician has no direct or indirect financial interest in such provider;

(4) HCFA has provided notice to the public through notice in a newspaper of general circulation servicing the provider's locality and such other notice as the Secretary may require, of any charges the provider is authorized to impose on individuals entitled to benefits under Medicare on account of costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare; and

(5) The provider has, in the manner described in paragraph (e) of this section, identified such charges to such individual or person acting on his behalf as charges to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare.

(b) Provider request to charge beneficiaries for costs in excess of limits.

(1) If a provider's actual costs (or, if less, the customary charges) in the second preceding cost period exceed the prospective limits established for such costs, the intermediary will, at the provider's request, validate in advance the charges that may be made to the beneficiaries for the excess.

(2) If a provider does not have a second preceding cost period and is a new provider as defined in 413.30(e), the provider, subject to validation by the intermediary, will estimate the current cost of the service to which a limit is being applied. Such amount will be adjusted to an amount equivalent to costs in the second preceding year by use of a factor to be developed based on estimates of cost increases during the preceding two years and published by SSA or HCFA. The amount thus derived will be used in lieu of the second preceding cost period amount in determining the charge to the beneficiary.

(3) To obtain consideration of such a request, the provider must submit to the intermediary a statement indicating the chagre for which it is seeking validation and providing the data and method used to determine the amount. Such statement should include the—

(i) Provider's name and number;

(ii) Identity of class and prospective cost limit for the class in which the provider has been included;

(iii) Amount of charge and cost period in which the charge is to be imposed;

(iv) Cost and customary charge for items and services furnished to beneficiaries; and

(v) Cost period ending date of the second reporting period immediately preceding the cost period in which the charge is to be imposed. The intermediary may request such additional information as it finds necessary with respect to the request.

(c) Provider charges.

(1) Establishing the charges. If the actual cost incurred (or, if less, the customary charges) in the prior period determined under paragraph (a) of this section exceeds the limits applicable to the pertinent period, the provider may charge the beneficiary to the extent costs in the second preceding cost reporting period (or the equivalent when

there is no second preceding period) exceed the current cost limits. (Data from the most recently submitted appropriate cost report will be used in determining the actual cost.) For example, if a limit of $58 per day is applied to the cost of general routine services for the provider's cost reporting period starting in calendar year 1975 and if the provider's actual general routine cost in the second preceding reporting period, that is, the reporting period starting in calendar year 1973, was $60 per day, the provider (after first having obtained intermediary validation and subject to the considerations and requirements specified in paragraph (a) of this section) may charge Medicare Part A beneficiaries up to $2 per day for general routine services.

(2) Adjusting cost. Program reimbursement for the costs to which limits imposed under 413.30 are applied in any cost reporting period will not exceed the lesser of the provider's actual cost or the limits imposed under 413.30. If program reimbursement for items or services to which such limits are applied plus the charges to beneficiaries for such items or services imposed under this section exceed the provider's actual cost for such items or services, program payment to the provider will be reduced to the extent program payment plus charges to the beneficiaries exceed actual cost. If the provider's actual cost for general routine services in 1975 was $57,000, the cost limit was $58,000, and billed charges to Medicare Part A beneficiaries were $2,000, the provider would receive $55,000 from the program ($57,000 actual cost minus the $2,000 in charges to the beneficiaries).

(d) Definition of emergency services. For purposes of paragraph (a)(2) of this section, emergency services are those hospital services that are necessary to prevent the death or serious impairment of the health of the individual, and which, because of the threat to the life or health of the individual, necessitate the use of the most accessible hospital (as determined under 424.106 of this chapter) available and equipped to furnish such services. If an individual has been admitted to such hospital as an inpatient because of an emergency, the emergency will be deemed to continue until it is safe from a medical standpoint to move the individual to another hospital or other institution or to discharge him.

(e) Identification of charges to individual. For purposes of paragraph (a)(5) of this section, a provider must give or send to the individual or his representative, a schedule of all items and services that the individual might need and for which the provider imposes charges under this section, and the charge for each. Such schedule must specify that the charges are necessary to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare and include such other information as HCFA considers necessary to protect the individual's rights under this section. The provider, in arranging for the individual's admission, first service, or start of care, must give or send this schedule to the individual or his representative when arrangements are being made for such services or if this is not feasible, as soon thereafter as is practicable but no later than at the initiation of services.

[51 FR 34793, Sept. 30, 1986, as amended at 53 FR 6648, Mar. 20, 1988; 60 FR 45849, Sept. 1, 1995]

42 CFR Part 413—Subpart D—Apportionment

413.50 Apportionment of allowable costs.

(a) Consistent with prevailing practice in which third-party organizations pay for health care on a cost basis, reimbursement under the Medicare program involves a determination of—

(1) Each provider's allowable costs for producing services; and

(2) The share of these costs which is to be borne by Medicare. The provider's costs are to be determined in accordance with the principles reviewed in the preceding discussion relating to allowable costs. The share to be borne by Medicare is to be determined in accordance with principles relating to apportionment of cost.

(b) In the study and consideration devoted to the method of apportioning costs, the objective has been to adopt methods for use under Medicare that would, to the extent reasonably possible, result in the program's share of a provider's total allowable costs being the same as the program's share of the provider's total services. This result is essential for carrying out the statutory directive that the program's payments to providers should be such that the costs of covered services for beneficiaries would not be passed on to nonbeneficiaries, nor would the cost of services for nonbeneficiaries be borne by the program.

(c) A basic factor bearing upon apportionment of costs is that Medicare beneficiaries are not a cross section of the total population. Nor will they constitute a cross section of all patients receiving services from most of the providers that participate in the program. Available evidence shows that the use of services by persons age 65 and over differs significantly from other groups. Consequently, the objective sought in the determination of the Medicare share of a provider's total costs means that the methods used for apportionment must take into account the differences in the amount of services received by patients who are beneficiaries and other patients serviced by the provider.

(d) The method of cost reimbursement most widely used at the present time by third-party purchasers of inpatient hospital care apportions a provider's total costs among groups served on the basis of the relative number of days of care used. This method, commonly referred to as average-per-diem cost, does not take into account, variations in the amount of service which a day of care may represent and thereby assumes that the patients for whom payment is made on this basis are average in their use of service.

(e) In considering the average-per-diem method of apportioning cost for use under the program, the difficulty encountered is that the preponderance of presently available evidence strongly indicates that the over-age 65 patient is not typical from the standpoint of average-per-diem cost. On the average this patient stays in the hospital twice as long and therefore the ancillary services that he uses are averaged over the longer period of time, resulting in an average-per-diem cost for the aged alone, significantly below the average-per-diem for all patients.

(f) Moreover, the relative use of services by aged patients as compared to other patients differs significantly among institutions. Consequently, considerations of equity among institutions are involved as well as that of effectiveness of the apportionment method under the program in accomplishing the objective of paying each provider fully, but only for services to beneficiaries.

(g) A further consideration of long-range importance is that the relative use of services by aged and other patients can be expected to change, possibly to a significant extent in future years. The ability of apportionment methods used under the program to reflect such change is an element of flexibility which has been regarded as important in the formulation of the cost reimbursement principles.

(h) An alternative to the relative number of days of care as a basis for apportioning costs is the relative amount of charges billed by the provider

for services to patients. The amount of charges is the basis upon which the cost of hospital care is distributed among patients who pay directly for the services they receive. Payment for services on the basis of charges applies generally under insurance programs in which individuals are indemnified for incurred expenses, a form of health insurance widely held throughout the United States. Also, charges to patients are commonly a factor in determining the amount of payment to hospitals under insurance programs providing service benefits, many of which pay "costs or charges, whichever is less" and some of which pay exclusively on the basis of charges. In all of these instances, the provider's own charge structure and method of itemizing services for the purpose of assessing charges is utilized as a measure of the amount of services received and as the basis for allocating responsibility for payment among those receiving the provider's services.

(i) An increasing number of third-party purchasers who pay for services on the basis of cost are developing methods that utilize charges to measure the amount of services for which they have responsibility for payment. In this approach, the amount of charges for such services as a proportion of the provider's total charges to all patients is used to determine the proportion of the provider's total costs for which the third-party purchaser assumes responsibility. The approach is subject to numerous variations. It can be applied to the total of charges for all services combined or it can be applied to components of the provider's activities for which the amount of costs and charges are ascertained through a breakdown of data from the provider's accounting records.

(j) For the application of the approach to components, which represent types of services, the breakdown of total costs is accomplished by "cost-finding" techniques under which indirect costs and nonrevenue activities are allocated to revenue producing components for which charges are made as services are furnished.

413.53 [Amended] Determination of cost of services to beneficiaries.

[Amended by: 61 FR 51611 - 10/03/96 - MEDICARE AND MEDICAID PROGRAMS; NEW PAYMENT METHODOLOGY FOR ROUTINE EXTENDED CARE SERVICES PROVIDED IN A SWING-BED HOSPITAL]

Principle. Total allowable costs of a provider will be apportioned between program beneficiaries and other patients so that the share borne by the program is based upon actual services received by program beneficiaries. The methods of apportionment are defined as follows:

(1) Departmental method.

(i) Methodology. Except as provided in paragraph (a)(1)(ii) of this section with respect to the treatment of the private room cost differential for cost reporting periods starting on or after October 1, 1982, the ratio of beneficiary charges to total patient charges for the services of each ancillary department is applied to the cost of the department; to this is added the cost of routine services for program beneficiaries, determined on the basis of a separate average cost per diem for general routine patient care areas as defined in paragraph (b) of this section, taking into account, in hospitals, a separate average cost per diem for each intensive care unit, coronary care unit, and other intensive care type inpatient hospital units.

(ii) Exception: Indirect cost of private rooms. For cost reporting periods starting on or after October 1, 1982, except with respect to a hospital receiving payment under part 412 of this chapter, the additional cost of furnishing services in private room accommodations is apportioned to Medicare only if these accommodations are furnished to program beneficiaries, and are medically necessary. To determine routine service cost applicable to beneficiaries—

(A) Multiply the average cost per diem (as defined in paragraph (b) of this section) by the total number of Medicare patient days (including private room days whether or not medically necessary);

(B) Add the product of the average per diem private room cost differential

(as defined in paragraph (b) of this section) and the number of medically necessary private room days used by beneficiaries; and

(C) Do not include private rooms furnished for SNF-type and ICF-type services under the swingbed provision in the number of days in paragraphs (a)(1)(ii)(A) and (B) of this section.

(2) Carve out method.

(i) The carve out method is used to allocate hospital inpatient general routine service costs in a participating swing-bed hospital, as defined in 413.114(b). Under this method, the total costs attributable to the SNF-type and ICF-type services furnished to all classes of patients are subtracted from total general routine inpatient service costs before computing the average cost per diem for general routine hospital care.

(ii) The cost per diem attributable to the routine SNF-type services furnished by a swing-bed hospital is based on the reasonable cost per diem for services determined in accordance with 413.114.

(iii) The cost per diem attributable to the routine ICF services furnished by the swing-bed hospital is determined as follows:

(A) If the hospital is located in a State that provides for ICF services under Medicaid, the cost per diem for ICF services furnished by a swing-bed hospital in that State is based on the Statewide average rate paid for routine services in ICFs (other than ICFs for the mentally retarded) during the preceding calendar year under the State Medicaid plan. The Statewide average rate will be computed either by the State and furnished to HCFA, or by HCFA directly based on the best available data.

(B) If the hospital is located in a State that does not provide for ICF services under Medicaid or that does not have a Medicaid program, the cost per diem for ICF services will be based on the average ratio of the ICF rate to the SNF rate in those States that provide for both SNF and ICF services under Medicaid. The ratio will be applied to the SNF cost per diem determined under paragraph (a)(2)(ii) of this section.

(iv) The sum of total SNF-type days furnished to all classes of patients multiplied by the SNF cost per diem, and total ICF-type days furnished to all classes of patients multiplied by the appropriate ICF cost per diem, will be subtracted from inpatient general routine service costs. The cost per diem for inpatient general routine hospital care will be based on the remaining general routine service costs.

(v) Costs other than general inpatient routine service costs will be determined in the same manner as specified in the Departmental Method in paragraph (a)(1) of this section.

(3) Cost per visit by type-of-service method—HHAs. For cost reporting periods beginning on or after October 1, 1980, all HHAs must use the cost per visit by type-of-service method of apportioning costs between Medicare and non-Medicare beneficiaries. Under this method, the total allowable cost of all visits for each type of service is divided by the total number of visits for that type of service. Next, for each type of service, the number of Medicare covered visits is multiplied by the average cost per visit just computed. This represents the cost Medicare will recognize as the cost for that service, subject to cost limits published by HCFA (see 413.30).

Definitions. As used in this section—

Ancillary services means the services for which charges are customarily made in addition to routine services.

Apportionment means an allocation or distribution of allowable cost between the beneficiaries of the Medicare program and other patients.

Average cost per diem for general routine services means the following:

(1) For cost reporting periods beginning on or after October 1, 1982, subject to the provisions on swing-bed hospitals, the average cost of general routine services net of the private room cost differential. The average cost per diem is computed by the following methodology:

(i) Determine the total private room cost differential by multiplying the average per diem private room cost differential determined in paragraph (c) of this section by the total number of private room patient days.

(ii) Determine the total inpatient general routine service costs net of the total private room cost differential by subtracting the total private room cost differential from total inpatient general routine service costs.

(iii) Determine the average cost per diem by dividing the total inpatient general routine service cost net of private room cost differential by all inpatient general routine days, including total private room days.

(2) For swing-bed hospitals, the amount computed by—

(i) Subtracting the costs attributable to SNF-type and ICF-type services from the total allowable inpatient cost for routine services (excluding the cost of services provided in intensive care units, coronary care units, and other intensive care type inpatient hospital units, and nursery costs); and

(ii) Dividing the remainder (excluding the total private room cost differential) by the total number of inpatient hospital days of care (excluding SNFtype and ICF-type days of care, days of care in intensive care units, coronary care units, and other intensive care type inpatient hospital units, and newborn days and including total private room days).

Average cost per diem for hospital intensive care type units means the amount computed by dividing the total allowable costs for routine services in each of these units by the total number of inpatient days of care furnished in each of these units.

Average per diem private room cost differential means the difference in the average per diem cost of furnishing routine services in a private room and in a semi-private room. (This differential is not applicable to hospital intensive care type units.) (The method for computing this differential is described in paragraph (c) of this section.)

Charges means the regular rates for various services that are charged to both beneficiaries and other paying patients who receive the services. Implicit in the use of charges as the basis for apportionment is the objective that charges for services be related to the cost of the services.

ICF-type services means routine services furnished by a swing-bed hospital that would constitute intermediate care facility (ICF) services, as defined in 440.150 of this chapter, if furnished by an ICF. ICF-type services are not covered under the Medicare program.

Intensive care type inpatient hospital unit means a hospital unit that furnishes services to critically ill inpatients. Examples of intensive care type units include, but are not limited to, intensive care units, trauma units, coronary care units, pulmonary care units, and burn units. Excluded as intensive care type units are postoperative recovery rooms, postanesthesia recovery rooms, maternity labor rooms, and subintensive or intermediate care units. (The unit must also meet the criteria of paragraph (d) of this section.)

SNF-type services means routine services furnished by a swing-bed hospital that would constitute extended care services if furnished by an SNF. SNFtype services include routine services furnished in the distinct part SNF of a hospital complex that is combined with the hospital general routine service area cost center under 413.24(d)(5).

Ratio of beneficiary charges to total charges on a departmental basis means

Hospital Y

Department	Charges to Program Beneficiaries	Total Charges	Ratio of Beneficiary Charges to Total Charges	Total Cost	Cost of Beneficiary Services
			Percent		
Operating rooms	$20,000	$70,000	28 4/7	$77,000	$22,000
Delivery rooms	0	12,000	0	30,000	0
Pharmacy	20,000	60,000	33 1/3	45,000	15,000
X-ray	24,000	100,000	24	75,000	18,000
Laboratory	40,000	140,000	28 4/7	98,000	28,000
Others	6,000	30,000	20	25,000	5,000
Total	110,000	412,000		350,000	88,000

	Total Inpatient beneficiaries	Total Cost	Average Cost per Diem	Program in Patient Days	Cost of Beneficiary Services
General routine	30,000	$630,000	$21	8,000	$168,000
Coronary care unit	500	20,000	40	200	8,000
Intensive care unit	3,000	108,000	36	1,000	36,000
	33,500	758,000		9,200	212,000
Total					300,000

the ratio of charges to beneficiaries of the Medicare program for services of a revenue-producing department or center to the charges to all patients for that center during an accounting period. After each revenue-producing center's ratio is determined, the cost of services furnished to beneficiaries of the Medicare program is computed by applying the individual ratio for the center to the cost of the related center for the period.

Routine services means the regular room, dietary, and nursing services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made.

(c) Method for computing the average per diem private room cost differential. Compute the average per diem private room cost differential as follows:

(1) Determine the average per diem private room charge differential by subtracting the average per diem charge for all semi-private room accommodations from the average per diem charge for all private room accommodations. The average per diem charge for private room accommodations is determined by dividing the total charges for

private room accommodations by the total number of days of care furnished in private room accommodations. The average per diem charge for semi-private accommodations is determined by dividing the total charges for semi-private room accommodations by the total number of days of care furnished in semi-private accommodations.

(2) Determine the inpatient general routine cost to charge ratio by dividing total inpatient general routine service cost by the total inpatient general routine service charges.

(3) Determine the average per diem private room cost differential by multiplying the average per diem private room charge differential determined in paragraph (c)(1) of this section by the ratio determined in paragraph (c)(2) of this section.

(d) Criteria for identifying intensive care type units. For purposes of determining costs under this section, a unit will be identified as an intensive care type inpatient hospital unit only if the unit—

(1) Is in a hospital;

(2) Is physically and identifiably separate from general routine patient care areas, including subintensive or intermediate care units, and ancillary service areas. There cannot be a concurrent sharing of nursing staff between an intensive care type unit and units or areas furnishing different levels or types of care. However, two or more intensive care type units that concurrently share nursing staff can be reimbursed as one combined intensive care type unit if all other criteria are met. Float nurses (nurses who work in different units on an as-needed basis) can be utilized in the intensive care type unit. If a float nurse works in two different units during the same eight hour shift, then the costs must be allocated to the appropriate units depending upon the time spent in those units. The hospital must maintain adequate records to support the allocation. If such records are not available, then the costs must be allocated to the general routine services cost areas;

(3) Has specific written policies that include criteria for admission to, and discharge from, the unit;

(4) Has registered nursing care available on a continuous 24-hour basis with at least one registered nurse present in the unit at all times;

(5) Maintains a minimum nurse-patient ratio of one nurse to two patients per patient day. Included in the calculation of this nurse-patient ratio are registered nurses, licensed vocational nurses, licensed practical nurses, and nursing assistants who provide patient care. Not included are general support personnel such as ward clerks, custodians, and housekeeping personnel; and

(6) Is equipped, or has available for immediate use, lifesaving equipment necessary to treat the critically ill patients for which it is designed. This equipment may include, but is not limited to, respiratory and cardiac monitoring equipment, respirators, cardiac defibrillators, and wall or canister oxygen and compressed air.

(e) Application -

(1) Departmental method. Cost reporting periods beginning on or after October 1, 1982.

(i) The following example illustrates how costs would be determined, using only inpatient data, for cost reporting periods beginning on or after October 1, 1982, based on apportionment of—

(A) The average cost per diem for general routine services (subject to the private room differential provisions of paragraph (a)(1)(iii) of this section);

(B) The average cost per diem for each intensive care type unit;

(C) The ratio of beneficiary charges to total charges applied to cost by department.

(ii) The following illustrates how apportionment based on an average cost per diem for general routine services is determined.

Hospital E

Facts	Private Accomodations	Semi-Private Accomodations	Total
Total charges	$20,000	$175,000	$195,000
Total days	100	1,000	1,100
Program days	70	400	470
Medically necessary for program beneficiaries	20		20
Total general routine service costs			165,000
Average private room per diem charge ($20,000 private room charges 100 days)			1 $200
Average semi-private room per diem charge ($175,000 semi-private charge 1,000 days)			1 $175
1 per diem			

Average per diem private room cost differential.

1. Average per diem private room charge differential ($200 private room per diem—$175, semi-private room per diem), $25.
2. Inpatient general routine cost/charge ratio ($165,000 total costs + $195,000 total charges), 0.8461538.
3. Average per diem private room cost differential ($25 charge differential x .8461538 cost/charge ratio), $21.15. Average cost per diem for inpatient general routine services.
4. Total private room cost differential ($21.15 average per diem cost differential x 100 private room days), $2,115.
5. Total inpatient general routine service costs net of private room cost differential ($165,000 total routine cost -$2,115 private room cost differential), $162,885.
6. Average cost per diem for inpatient general routine services ($162,885 routine cost net of private room cost differential 1,100 patient days), $148.08. Medicare general routine service cost.
7. Total routine per diem cost applicable to Medicare ($148.08 average cost per diem x 470 Medicare private and semi-private patient days), $69,598.
8. Total private room cost differential applicable to Medicare ($21.15 average per diem private room cost differential x 20 medically necessary private room days), $423.
9. Medicare inpatient general routine service cost ($423 Medicare private room cost differential + $69,598 Medicare cost of general routine inpatient services), $70,021.

(2) Carve out method. The following illustrates how apportionment is determined in a hospital reimbursed under the carve out method (subject to the private room differential provisions of paragraph (a)(1)(ii) of this section):

[51 FR 34793, Sept. 30, 1986, as amended at 59 FR 45401, Sept. 1, 1994]

Facts	DAYS OF CARE General Routine Hospital	SNF-Type	ICF-Type
	2,000	400	100
Total days of care	600	300	
Medicare days of care	n/a	$35	$20
Average Medicaid rate			

Total inpatient general routine service costs: $250,000

Calculation of cost of routine SNF-type services applicable to Medicare:

$35 x 300 = $10,500

Calculation of cost of general routine hospital services

Cost of SNF-type services: $35 x 400 ..... $14,000

Cost of ICF-type services: $35 x 400 2,000

Total $16,000

Average cost per diem of general routine hospital services:

$250,000 -- $16,000 2,000 days = $117

Medicare general routine hospital cost:

$117 x 600 = $70,200

Total Medicare reasonable cost for general routine inpatient days:

$10,500 + $70,200 = $80,700

42 CFR Part 413—Subpart E—Payments to Providers

413.60 Payments to providers: General.

(a) The fiscal intermediaries will establish a basis for interim payments to each provider. This may be done by one of several methods. If an intermediary is already paying the provider on a cost basis, the intermediary may adjust its rate of payment to an estimate of the result under the Medicare principles of reimbursement. If no organization is paying the provider on a cost basis, the intermediary may obtain the previous year's financial statement from the provider and, by applying the principles of reimbursement, compute or approximate an appropriate rate of payment. The interim payment may be related to the last year's average per diem, or to charges, or to any other ready basis of approximating costs.

(b) At the end of the period, the actual apportionment, based on the cost finding and apportionment methods selected by the provider, determines the Medicare reimbursement for the actual services provided to beneficiaries during the period.

(c) Basically, therefore, interim payments to providers will be made for services throughout the year, with final settlement on a retroactive basis at the end of the accounting period. Interim payments will be made as often as possible and in no event less frequently than once a month. The retroactive payments will take fully into account the costs that were actually incurred and settle on an actual, rather than on an estimated basis.

413.64 Payments to providers: Specific rules.

(a) Reimbursement on a reasonable cost basis. Providers of services paid on the basis of the reasonable cost of services furnished to beneficiaries will receive interim payments approximating the actual costs of the provider. These payments will be made on the most expeditious schedule administratively feasible but not less often than monthly. A retroactive adjustment based on actual costs will be made at the end of a reporting period.

(b) Amount and frequency of payment. Medicare states that providers of services will be paid the reasonable cost of services furnished to beneficiaries. Since actual costs of services cannot be determined until the end of the accounting period, the providers must be paid on an estimated cost basis during the year. While Medicare provides that interim payments will be made no less often than monthly, intermediaries are expected to make payments on the most expeditious basis administratively feasible. Whatever estimated cost basis is used for determining interim payments during the year, the intent is that the interim payments shall approximate actual costs as nearly as is practicable so that the retroactive adjustment based on actual costs will be as small as possible.

(c) Interim payments during initial reporting period. At the beginning of the program or when a provider first participates in the program, it will be necessary to establish interim rates of payment to providers of services. Once a provider has filed a cost report under the Medicare program, the cost report may be used as a basis for determining the interim rate of reimbursement for the following period. However, since initially there is no previous history of cost under the program, the interim rate of payment must be determined by other methods, including the following:

(1) If the intermediary is already paying the provider on a cost or cost-related basis, the intermediary will adjust its rate of payment to the program's principles of reimbursement. This rate may be either an amount per inpatient day, or a percent of the provider's charges for services furnished to the program's beneficiaries.

(2) If an organization other than the intermediary is paying the provider for services on a cost or cost-related basis, the intermediary may obtain from that organization or from the provider itself the rate of payment being used and other cost information as may be needed to adjust that rate of payment to give recognition to the program's principles of reimbursement.

(3) It no organization is paying the provider on a cost or cost-related basis, the intermediary

will obtain the previous year's financial statement from the provider. By analysis of such statement in light of the principles of reimbursement, the intermediary will compute an appropriate rate of payment.

(4) After the initial interim rate has been set, the provider may at any time request, and be allowed, an appropriate increase in the computed rate, upon presentation of satisfactory evidence to the intermediary that costs have increased. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(d) Interim payments for new providers.

(1) Newly established providers will not have cost experience on which to base a determination of an interim rate of payment. In such cases, the intermediary will use the following methods to determine an appropriate rate:

(i) If there is a provider or providers comparable in substantially all relevant factors to the provider for which the rate is needed, the intermediary will base an interim rate of payment on the costs of the comparable provider.

(ii) If there are no substantially comparable providers from whom data are available, the intermediary will determine an interim rate of payment based on the budgeted or projected costs of the provider.

(2) Under either method, the intermediary will review the provider's cost experience after a period of three months. If need for an adjustment is indicated, the interim rate of payment will be adjusted in line with the provider's cost experience.

(e) Interim payments after initial reporting period. Interim rates of payment for services provided after the initial reporting period will be established on the basis of the cost report filed for the previous year covering Medicare services. The current rate will be determined - whether on a per diem or percentage of charges basis - using the previous year's costs of covered services and making any appropriate adjustments required to bring, as closely as possible, the current year's rate of interim payment into agreement with current year's costs. This interim rate of payment may be adjusted by the intermediary during an accounting period if the provider submits appropriate evidence that its actual costs are or will be significantly higher than the computed rate. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(f) Retroactive adjustment.

(1) Medicare provides that providers of services will be paid amounts determined to be due, but not less often than monthly, with necessary adjustments due to previously made overpayments or underpayments. Interim payments are made on the basis of estimated costs. Actual costs reimbursable to a provider cannot be determined until the cost reports are filed and costs are verified. Therefore, a retroactive adjustment will be made at the end of the reporting period to bring the interim payments made to the provider during the period into agreement with the reimbursable amount payable to the provider for the services furnished to program beneficiaries during that period.

(2) In order to reimburse the provider as quickly as possible, an initial retroactive adjustment will be made as soon as the cost report is received. For this purpose, the costs will be accepted as reported, unless there are obvious errors or inconsistencies, subject to later audit. When an audit is made and the final liability of the program is determined, a final adjustment will be made.

(3) To determine the retroactive adjustment, the amount of the provider's total allowable cost apportioned to the program for the reporting year is computed. This is the total amount of reimbursement the provider is due to receive from the program and the beneficiaries for covered services furnished during the reporting period. The total of the interim payments made by the program in the reporting year and the deductibles and coinsurance amounts receivable from beneficiaries is computed. The difference between the reimbursement due and the payments made is the amount of the retroactive adjustment.

(g) Accelerated payments to providers. Upon request, an accelerated payment may be made to a provider of services that is not receiving periodic interim payments under paragraph (h) of this section if the provider has experienced financial difficulties due to a delay by the intermediary in making payments or in exceptional situations, in which the provider has experienced a temporary delay in preparing and submitting bills to the intermediary beyond its normal billing cycle. Any such payment must be approved first by the intermediary and then by HCFA. The amount of the payment is computed as a percentage of the net reimbursement for unbilled or unpaid covered services. Recovery of the accelerated payment may be made by recoupment as provider bills are processed or by direct payment.

(h) Periodic interim payment method of reimbursement—

(1) Covered services furnished before July 1, 1987. In addition to the regular methods of interim payment on individual provider billings for covered services, the periodic interim payment (PIP) method is available for Part A hospital and SNF inpatient services and for both Part A and Part B HHA services.

(2) Covered services furnished on or after July 1, 1987. Effective with claims received on or after July 1, 1987, the periodic interim payment (PIP) method is available for the following:

(i) Part A inpatient hospital services furnished in hospitals that are excluded from the prospective payment systems under subpart B of part 412 of this chapter.

(ii) Part A services furnished in hospitals receiving payment in accordance with a demonstration project authorized under section 402(a) of Public Law 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Public Law 92-603 (42 U.S.C. 1395b-1 (note)), or a State reimbursement control system approved under section 1886(c) of the Act and subpart C of part 403 of this chapter, if that type of payment is specifically approved by HCFA as an integral part of the demonstration or control system. If that type of payment is not an integral part of the demonstration or control system, PIP is available for the hospital under paragraph (h)(1)(i) of this section for hospitals excluded from the prospective payment systems or under 412.116(b) of this chapter for prospective payment hospitals.

(iii) Part A SNF services.

(iv) Part A and Part B HHA services.

(v) Part A services furnished in hospitals paid under the prospective payment system, including distinct part psychiatric or rehabilitation units, as described in 412.116(b) of this chapter.

(vi) Services furnished in a hospice as specified in part 418 of this chapter. Payment on a PIP basis is described in 418.307 of this chapter.

(3) Any participating provider furnishing the services described in paragraph (h)(1) of this section that establishes to the satisfaction of the intermediary that it meets the following requirements may elect to be reimbursed under the PIP method, beginning with the first month after its request that the intermediary finds administratively feasible:

(i) The provider's estimated total Medicare reimbursement for inpatient services is at least $25,000 a year computed under the PIP formula or, in the case of an HHA, either its estimated—

(A) Total Medicare reimbursement for Part A and Part B services is at least $25,000 a year computed under the PIP formula; or

(B) Medicare reimbursement computed under the PIP formula is at least 50 percent of estimated total allowable cost.

(ii) The provider has filed at least one completed Medicare cost report accepted by the intermediary as providing an accurate basis for computation of program payment (except in the case of a provider requesting reimbursement under the PIP method upon first entering the Medicare program).

(iii) The provider has the continuing capability of maintaining in its records the

cost, charge, and statistical data needed to accurately complete a Medicare cost report on a timely basis.

(iv) The provider has repaid or agrees to repay any outstanding current financing payment in full, such payment to be made before the effective date of its requested conversion from a regular interim payment method to the PIP method.

(4) No conversion to the PIP method may be made with respect to any provider until after that provider has repaid in full its outstanding current financing payment.

(5) The intermediary's approval of a provider's request for reimbursement under the PIP method will be conditioned upon the intermediary's best judgment as to whether payment can be made to the provider under the PIP method without undue risk of its resulting in an overpayment because of greatly varying or substantially declining Medicare utilization, inadequate billing practices, or other circumstances. The intermediary may terminate PIP reimbursement to a provider at any time it determines that the provider no longer meets the qualifying requirements or that the provider's experience under the PIP method shows that proper payment cannot be made under this method.

(6) Payment will be made biweekly under the PIP method unless the provider requests a longer fixed interval (not to exceed one month) between payments. The payment amount will be computed by the intermediary to approximate, on the average, the cost of covered inpatient or home health services furnished by the provider during the period for which the payment is to be made, and each payment will be made two weeks after the end of such period of services. Upon request, the intermediary will, if feasible, compute the provider's payments to recognize significant seasonal variation in Medicare utilization of services on a quarterly basis starting with the beginning of the provider's reporting year.

(7) A provider's PIP amount may be appropriately adjusted at any time if the provider presents or the intermediary otherwise obtains evidence relating to the provider's costs or Medicare utilization that warrants such adjustment. In addition, the intermediary will recompute the payment immediately upon completion of the desk review of a provider's cost report and also at regular intervals not less often than quarterly. The intermediary may make a retroactive lump sum interim payment to a provider, based upon an increase in its PIP amount, in order to bring past interim payments for the provider's current cost reporting period into line with the adjusted payment amount. The objective of intermediary monitoring of provider costs and utilization is to assure payments approximating, as closely as possible, the reimbursement to be determined at settlement for the cost reporting period. A significant factor in evaluating the amount of the payment in terms of the realization of the projected Medicare utilization of services is the timely submittal to the intermediary of completed admission and billing forms. All providers must complete billings in detail under this method as under regular interim payment procedures.

(i) Bankruptcy or insolvency of provider. If on the basis of reliable evidence, the intermediary has a valid basis for believing that, with respect to a provider, proceedings have been or will shortly be instituted in a State or Federal court for purposes of determining whether such provider is insolvent or bankrupt under an appropriate State or Federal law, any payments to the provider will be adjusted by the intermediary, notwithstanding any other regulation or program instruction regarding the timing or manner of such adjustments, to a level necessary to insure that no overpayment to the provider is made.

(j) Interest payments resulting from judicial review—

(1) Application. If a provider of services seeks judicial review by a Federal court (see 405.1877 of this chapter) of a decision furnished by the Provider Reimbursement Review Board or subsequent reversal, affirmation, or

modification by the Secretary, the amount of any award of such Federal court will be increased by interest payable by the party against whom the judgment is made (see 413.153 for treatment of interest). The interest is payable for the period beginning on the first day of the first month following the 180-day period which began on either the date the intermediary made a final determination or the date the intermediary would have made a final determination had it been done on a timely basis (see 405.1835(b) and 405.1841(a) of this chapter).

(2) Amount due. Section 1878(f) of the Act, 42 U.S.C. 1395oo(f), authorizes a court to award interest in favor of the prevailing party on any amount due as a result of the court's decision. If the intermediary withheld any portion of the amount in controversy prior to the date the provider seeks judicial review by a Federal court, and the Medicare program is the prevailing party, interest is payable by the provider only on the amount not withheld. Similarly, if the Medicare program seeks to recover amounts previously paid to a provider, and the provider is the prevailing party, interest on the amounts previously paid to a provider is not payable by the Medicare program since that amount had been paid and is not due the provider.

(3) Rate. The amount of interest to be paid is equal to the rate of return on equity capital (see 413.157) in effect for the month in which the civil action is commenced.

Example: An intermediary made a final determinaton on the amount of Medicare program reimbursement on June 15, 1974, and the provider appealed that determination to the Provider Reimbursement Review Board. The Board heard the appeal and rendered a decision adverse to the provider. On October 28, 1974, the provider commenced civil action to have such decision reviewed. The rate of return on equity capital for the month of October 1974 was 11.625 percent. The period for which interest is computed begins on January 1, 1975, and the interest beginning January 1, 1975, would be at the rate of 11.625 percent per annum.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 42238, Nov. 24, 1986; 53 FR 1628, Jan. 21, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 36713, July 19, 1994]

413.70 Payment for services of an RPCH.

(a) Payment for inpatient services furnished by an RPCH.

(1) Initial 12-month period of operation. Payment for the first 12month cost reporting period for which the RPCH operates as an RPCH is made on a per diem basis for the reasonable costs of the RPCH for inpatient services. This payment does not include physician and other practitioner services paid on a charge or fee basis, and is subject to the principles of cost reimbursement in this part and in part 405, subpart D of this chapter; however, the principle of the lesser of costs or charges in 413.13 does not apply.

(2) Subsequent periods. Payment for a cost reporting period subsequent to the initial 12-month period for which the RPCH operates as an RPCH is made on the basis of adjusting the amount determined in paragraph (a)(1) of this section. The adjustment added to the per diem amount is the market basket percentage increase under section 1886(b)(3)(B)(i) of the Act for the subsequent cost reporting period applicable to hospitals located in rural areas.

(3) Reduction for grants. The payment amounts otherwise determined under this paragraph (a) are reduced to the extent necessary to avoid any duplication of any grant payments made under section 1820(a)(2) of the Act or under section 4005(e) of the Omnibus Budget Reconciliation Act of 1987, Grant Program for Rural Health Care Transition, to cover the provision of inpatient RPCH services.

(b) Payment for outpatient services furnished by an RPCH.

(1) General. An RPCH may elect either the method in paragraph (b)(2) of this section or the method in paragraph (b)(3) of this section for payment for outpatient services. The method of payment elected by the RPCH

must be made in writing on an annual basis prior to the beginning of the affected cost reporting period.

(2) Cost-based RPCH payment plus professional services method.

(i) RPCH services. Payment under this method for outpatient RPCH services is equal to the amounts described in section 1833(a)(2)(B) of the Act (which describes amounts paid for hospital outpatient services) and subject to the applicable principles of cost reimbursement in this part and in part 405, subpart D of this chapter, except for the principle of the lesser of costs or charges in 413.13. This payment is subject to applicable part B deductible and coinsurance amounts. This payment does not include payment for physician services or other professional services paid on a charge or other fee basis.

(ii) Professional services. Payment for professional medical services furnished in an RPCH is made on a charge or other fee basis under the provisions of this chapter that would apply to payment for the services if they had not been furnished in an RPCH. For purposes of RPCH payment, professional medical services are defined as those services provided by a physician or other professional (for example, a physician assistant, an anesthetist, and a nurse practitioner) that could be billed separately to a carrier under Medicare.

(3) All-inclusive rate method.

(i) If the RPCH elects payment under this method, a combined payment including both RPCH facility services and professional medical services is made at an all-inclusive rate per visit. This rate is subject to applicable part B deductible and coinsurance amounts, as described in 410.3(b) of this chapter. The all-inclusive rate is an average rate based on the reasonable costs of RPCH facility services and professional services, as defined in the principles of cost reimbursement, divided by the number of outpatient RPCH visits. In determining reasonable costs, the principle of the lesser of costs or charges in 413.13 does not apply.

(ii) All health professionals must have a compensation arrangement with the RPCH. The health professionals' actual time is divided among inpatient services, outpatient services, and nonallowable activities such as research; the percentage of actual time applicable to outpatient services is applied to total compensation. The resulting amount is included with the RPCH's outpatient facility costs for determination of the average cost per outpatient RPCH visit. (No breakdown is required for physician professional services versus technical services.)

(iii) A RPCH outpatient visit represents a face-to-face encounter between the patient and a health professional during which the RPCH outpatient services are furnished. Encounters with more than one health professional and multiple encounters with the same health professionals which take place on the same day constitute a single visit, except for cases in which subsequent encounters occur on the same day for an injury or illness requiring additional diagnosis or treatment different from the injury or illness associated with the initial encounter. These subsequent encounters are counted as separate visits.

(iv) Final reimbursement to the RPCH is based on a year-end cost report, as required under 413.20(b), that provides for the average per visit amount methodology.

[58 FR 30670, May 26, 1993, as amended at 60 FR 45850, Sept. 1, 1995]

413.74 Payment to a foreign hospital.

(a) Principle. Section 1814(f) of the Act provides for the payment of emergency and nonemergency inpatient hospital services furnished by foreign hospitals to Medicare beneficiaries. Subpart H of part 424 of this chapter, together with this section, specify the conditions for payment.

These conditions may result in payments only to Canadian and Mexican hospitals.

(b) Amount of payment. Effective with admissions on or after January 1, 1980, the reasonable cost for services covered under the Medicare program furnished to beneficiaries by a foreign hospital will be equal to 100 percent of the hospital's customary charges (as defined in 413.13(b)) for the services.

(c) Submittal of claims. The hospital must establish its customary charges for the services by submitting an itemized bill with each claim it files in accordance with its election under 424.104 of this chapter.

(d) Exchange rate. Payment to the hospital will be subject to the official exchange rate on the date the patient is discharged and to the applicable deductible and coinsurance amounts described in 409.80 through 409.83.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

CFR Part 418—Hospice Care

42 CFR Part 418—Subpart A—General Provisions and Definitions

418.1 Statutory basis.

This part implements section 1861(dd) of the Social Security Act. Section 1861(dd) specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program. The following sections of the Act are also pertinent:

(a) Sections 1812(a)(4) and (d) of the Act specify eligibility requirements for the individual and the benefit periods.

(b) Section 1813(a)(4) of the Act specifies coinsurance amounts.

(c) Sections 1814(a)(7) and 1814(i) of the Act contain conditions and limitations on coverage of, and payment for, hospice care.

(d) Sections 1862(a)(1), (6) and (9) of the Act establish limits on hospice coverage.

[48 FR 56026, Dec. 16, 1983, as amended at 57 FR 36017, Aug. 12, 1992]

418.2 Scope of part.

Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B specifies the eligibility requirements and the benefit periods. Subpart C specifies conditions of participation for hospices. Subpart D describes the covered services and specifies the limits on services covered as hospice care. Subpart E specifies the reimbursement methods and procedures. Subpart F specifies coinsurance amounts applicable to hospice care.

418.3 Definitions.

For purposes of this part—

Attending physician means a physician who—

(a) Is a doctor of medicine or osteopathy; and

(b) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

Bereavement counseling means counseling services provided to the individual's family after the individual's death.

Cap period means the twelve-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in 418.309.

Employee means an employee (defined by section 210(j) of the Act)of the hospice or, if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice unit. "Employee" also refers to a volunteer under the jurisdiction of the hospice.

Hospice means a public agency or private organization or subdivision of either of these that - is primarily engaged in providing care to terminally ill individuals.

Physician means physician as defined in 410.20 of this chapter.

Representative means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is mentally or physically incapacitated.

Social worker means a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education.

Terminally ill means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

[48 FR 56026, Dec. 16, 1983, as amended at 52 FR 4499, Feb. 12, 1987; 50 FR 50834, Dec. 11, 1990]

42 CFR Part 418—Subpart B—Eligibility, Election, and Duration of Benefits

418.20 Eligibility requirements.

In order to be eligible to elect hospice care under Medicare, an individual must be—

(a) Entitled to Part A of Medicare; and

(b) Certified as being terminally ill in accordance with 418.22.

418.21 Duration of hospice care coverage—Election periods.

(a) Subject to the conditions set forth in this part, an individual may elect to receive hospice care during one or more of the following election periods:

(1) An initial 90-day period.

(2) A subsequent 90-day period.

(3) A subsequent 30-day period.

(4) A subsequent extension period of unlimited duration during the individual's lifetime.

(b) The periods of care are available in the order listed and may be elected separately at different times.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992]

418.22 Certification of terminal illness.

(a) Timing of certification—

(1) General rule. The hospice must obtain written certification of terminal illness for each of the periods listed in 418.21, even if a single election continues in effect for two, three, or four periods, as provided in 418.24(c).

(2) Basic requirement. Except as provided in paragraph (a)(3)of this section, the hospice must obtain the written certification no later than two calendar days after the period begins.

(3) Exception. For the initial 90-day period, if the hospice cannot obtain the written certifications within two calendar days, it must obtain oral certifications within two calendar days, and written certifications no later than eight calendar days after the period begins.

(b) Content of certification. The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.

(c) Sources of certification.

(1) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (a)(3) of this section) from —

(i) The medical director of the hospice or the physician member of the hospice interdisciplinary group; and

(ii) The individual's attending physician if the individual has an attending physician.

(2) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (c)(1)(i) of this section.

(d) Maintenance of records. Hospice staff must -

(1) Make an appropriate entry in the patient's medical record as soon as they receive an oral certification; and

(2) File written certifications in the medical record.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992]

418.24 Election of hospice care.

(a) Filing an election statement. An individual who meets the eligibility requirement of 418.20 may file an election statement with a particular hospice. If the individual is physically or mentally incapacitated, his or her representative (as defined in 418.3) may file the election statement.

(b) Content of election statement. The election statement must include the following:

(1) Identification of the particular hospice that will provide care to the individual.

(2) The individual's or representative's acknowledgement

that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(3) Acknowledgement that certain Medicare services, as set forth in paragraph (d) of this section, are waived by the election.

(4) The effective date of the election, which may be the first day of hospice care or a later date,

but may be no earlier than the date of the election statement.

(5) The signature of the individual or representative.

(c) Duration of election. An election to receive hospice care will be considered to continue through the initial election period and through the subsequent election periods without a break in care as long as the individual—

(1) Remains in the care of a hospice; and

(2) Does not revoke the election under the provisions of 418.28.

(d) Waiver of other benefits. For the duration of an election of hospice care, an individual waives all rights to Medicare payments for the following services—

(1) Hospice care provided by a hospice other than the hospice designated by the individual (unless provided under arrangements made by the designated hospice).

(2) Any Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition or that are equivalent to hospice care except for services—

(i) Provided by the designated hospice:

(ii) Provided by another hospice under arrangements made by the designated hospice; and

(iii) Provided by the individual's attending physician if that physician is not an employee of the designated hospice or receiving compensation from the hospice for those services.

(e) Re-election of hospice benefits. If an election has been revoked in accordance with 418.28, the individual (or his or her representative if the individual is mentally or physically incapacitated) may at any time file an election, in accordance with this section, for any other election period that is still available to the individual.

[55 FR 50834, Dec. 11, 1990]

418.28 Revoking the election of hospice care.

(a) An individual or representative may revoke the individual's election of hospice care at any time during an election period.

(b) To revoke the election of hospice care, the individual or representative must file a statement with the hospice that includes the following information:

(1) A signed statement that the individual or representative revokes the individual's election for Medicare coverage of hospice care for the remainder of that election period.

(2) The date that the revocation is to be effective. (An individual or representative may not designate an effective date earlier than the date that the revocation is made).

(c) An individual, upon revocation of the election of Medicare coverage of hospice care for a particular election period—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under 418.24(e)(2); and

(3) May at any time elect to receive hospice coverage for any other hospice election periods that he or she is eligible to receive.

418.30 Change of the designated hospice.

(a) An individual or representative may change, once in each election period, the designation of the particular hospice from which hospice care will be received.

(b) The change of the designated hospice is not a revocation of the election for the period in which it is made.

(c) To change the designation of hospice programs, the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:

(1) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.

(2) The date the change is to be effective.

42 CFR Part 418—Subpart C—Conditions of Participation—General Provisions and Administration

418.50 Condition of participation—General provisions.

(a) Standard: Compliance. A hospice must maintain compliance with the conditions of this subpart and subparts D and E of this part.

(b) Standard: Required services. A hospice must be primarily engaged in providing the care and services described in 418.202, must provide bereavement counseling and must—

(1) Make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis;

(2) Make all other covered services available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions; and

(3) Provide these services in a manner consistent with accepted standards of practice.

(c) Standard: Disclosure of information. The hospice must meet the disclosure of information requirements at 420.206 of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50834, Dec. 11, 1990]

418.52 Condition of participation—Governing body.

A hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospice's total operation. The governing body must designate an individual who is responsible for the day to day management of the hospice program. The governing body must also ensure that all services provided are consistent with accepted standards of practice.

418.54 Condition of participation—Medical director.

The medical director must be a hospice employee who is a doctor of medicine or osteopathy who assumes overall responsibility for the medical component of the hospice's patient care program.

418.56 Condition of participation—Professional management.

Subject to the conditions of participation pertaining to services in 418.80 and 418.90, a hospice may arrange for another individual or entity to furnish services to the hospice's patients. If services are provided under arrangement, the hospice must meet the following standards:

(a) Standard: Continuity of care. The hospice program assures the continuity of patient/family care in home, outpatient, and inpatient settings.

(b) Standard: Written agreement. The hospice has a legally binding written agreement for the provision of arranged services. The agreement includes at least the following:

(1) Identification of the services to be provided.

(2) A stipulation that services may be provided only with the express authorization of the hospice.

(3) The manner in which the contracted services are coordinated, supervised, and evaluated by the hospice.

(4) The delineation of the role(s) of the hospice and the contractor in the admission process, patient/family assessment, and the interdisciplinary group care conferences.

(5) Requirements for documenting that services are furnished in accordance with the agreement.

(6) The qualifications of the personnel providing the services.

(c) Standard: Professional management responsibility. The hospice retains professional management responsibility for those services and ensures that they are furnished in a safe and effective manner by persons meeting the qualifications of this part, and in accordance with the patient's plan of care and the other requirements of this part.

(d) Standard: Financial responsibility. The hospice retains responsibility for payment for services.

(e) Standard: Inpatient care. The hospice ensures that inpatient care is furnished only in a facility which meets the requirements in 418.98 and its arrangement for inpatient care is described in a legally binding written agreement that meets the requirements of paragraph (b) and that also specifies, at a minimum—

(1) That the hospice furnishes to the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;
(2) That the inpatient provider has established policies consistent with those of the hospice and agrees to abide by the patient care protocols established by the hospice for its patients;
(3) That the medical record includes a record of all inpatient services and events and that a copy of the discharge summary and, if requested, a copy of the medical record are provided to the hospice;
(4) The party responsible for the implementation of the provisions of the agreement; and
(5) That the hospice retains responsibility for appropriate hospice care training of the personnel who provide the care under the agreement.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983]

418.58 Condition of participation—Plan of care.

A written plan of care must be established and maintained for each individual admitted to a hospice program, and the care provided to an individual must be in accordance with the plan.

(a) Standard: Establishment of plan. The plan must be established by the attending physician, the medical director or physician designee and interdisciplinary group prior to providing care.
(b) Standard: Review of plan. The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director or physician designee and interdisciplinary group. These reviews must be documented.
(c) Standard: Content of plan. The plan must include an assessment of the individual's needs and identification of the services including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

418.60 Condition of participation—Continuation of care.

A hospice may not discontinue or diminish care provided to a Medicare beneficiary because of the beneficiary's inability to pay for that care.

418.62 Condition of participation—Informed consent.

A hospice must demonstrate respect for an individual's rights by ensuring that an informed consent form that specifies the type of care and services that may be provided as hospice care during the course of the illness has been obtained for every individual, either from the individual or representative as defined in 418.3.

418.64 Condition of participation—Inservice training.

A hospice must provide an ongoing program for the training of its employees.

418.66 Condition of participation—Quality assurance.

A hospice must conduct an ongoing, comprehensive, integrated, selfassessment of the quality and appropriateness of care provided, including inpatient care, home care and care provided under arrangements. The findings are used by the hospice to correct identified problems and to revise hospice policies if necessary. Those responsible for the quality assurance program must—

(a) Implement and report on activities and mechanisms for monitoring the quality of patient care;
(b) Identify and resolve problems; and
(c) Make suggestions for improving patient care.

418.68 Condition of participation—Interdisciplinary group.

The hospice must designate an interdisciplinary group or groups composed of individuals who provide or supervise the care and services offered by the hospice.

(a) Standard: Composition of group. The hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice:
  (1) A doctor of medicine or osteopathy.
  (2) A registered nurse.
  (3) A social worker.
  (4) A pastoral or other counselor.
(b) Standard: Role of group. The interdisciplinary group is responsible for—
  (1) Participation in the establishment of the plan of care;
  (2) Provision or supervision of hospice care and services;

(3) Periodic review and updating of the plan of care for each individual receiving hospice care; and

(4) Establishment of policies governing the day-to-day provision of hospice care and services.

(c) If a hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.

(d) Standard: Coordinator. The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.

418.70 Condition of participation—Volunteers.

The hospice in accordance with the numerical standards, specified in paragraph (e) of this section, uses volunteers, in defined roles, under the supervision of a designated hospice employee.

(a) Standard: Training. The hospice must provide appropriate orientation and training that is consistent with acceptable standards of hospice practice.

(b) Standard: Role. Volunteers must be used in administrative or direct patient care roles.

(c) Standard: Recruiting and retaining. The hospice must document active and ongoing efforts to recruit and retain volunteers.

(d) Standard: Cost saving. The hospice must document the cost savings achieved through the use of volunteers. Documentation must include—

(1) The identification of necessary positions which are occupied by volunteers;

(2) The work time spent by volunteers occupying those positions; and

(3) Estimates of the dollar costs which the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) for the amount of time specified in paragraph (d)(2).

(e) Standard: Level of activity. A hospice must document and maintain a volunteer staff sufficient to provide administrative or direct patient care in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. The hospice must document a continuing level of volunteer activity. Expansion of care and services achieved through the use of volunteers, including the type of services and the time worked, must be recorded.

(f) Standard: Availability of clergy. The hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request such visits and must advise patients of this opportunity.

418.72 Condition of participation—Licensure.

The hospice and all hospice employees must be licensed in accordance with applicable Federal, State and local laws and regulations.

(a) Standard: Licensure of program. If State or local law provides for licensing of hospices, the hospice must be licensed.

(b) Standard: Licensure of employees. Employees who provide services must be licensed, certified or registered in accordance with applicable Federal or State laws.

418.74 Condition of participation—Central clinical records.

In accordance with accepted principles of practice, the hospice must establish and maintain a clinical record for every individual receiving care and services. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval.

(a) Standard: Content. Each clinical record is a comprehensive compilation of information. Entries are made for all services provided. Entries are made and signed by the person providing the services. The record includes all services whether furnished directly or under arrangements made by the hospice. Each individual's record contains—

(1) The initial and subsequent assessments;

(2) The plan of care;

(3) Identification data;

(4) Consent and authorization and election forms;

(5) Pertinent medical history; and

(6) Complete documentation of all services and events (including evaluations, treatments, progress notes, etc.).

(b) Standard; Protection of information. The hospice must safeguard the clinical record against loss, destruction and unauthorized use.

42 CFR Part 418—Subpart D—Conditions of Participation: Core Services

418.80 Condition of participation—Furnishing of core services.

Except as permitted in 418.83, a hospice must ensure that substantially all the core services described in this subpart are routinely provided directly by hospice employees. A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this subpart.

[52 FR 7416, Mar. 11, 1987, as amended at 55 FR 50835, Dec. 11, 1990]

418.82 Condition of participation—Nursing services.

The hospice must provide nursing care and services by or under the supervision of a registered nurse.

(a) Nursing services must be directed and staffed to assure that the nursing needs of patients are met.

(b) Patient care responsibilities of nursing personnel must be specified.

(c) Services must be provided in accordance with recognized standards of practice.

418.83 Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

(a) HCFA may approve a waiver of the requirement in 418.80 for nursing services provided by a hospice which is located in a non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence that it was operational on or before January 1, 1983, and that it made a good faith effort to hire a sufficient number of nurses to provide services directly. HCFA bases its decision as to whether to approve a waiver application on the following:

(1) The current Bureau of the Census designations for determining non-urbanized areas.

(2) Evidence that a hospice was operational on or before January 1, 1983 including:

(i) Proof that the organization was established to provide hospice services on or before January 1, 1983;

(ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983; and

(iii) Evidence that the hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.

(3) Evidence that a hospice made a good faith effort to hire nurses, including:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts;

(ii) Job descriptions for nurse employees;

(iii) Evidence that salary and benefits are competitive for the area; and

(iv) Evidence of any other recruiting activities (e.g., recruiting efforts at health fairs and contacts with nurses at other providers in the area);

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) Waivers will remain effective for one year at a time.

(d) HCFA may approve a maximum of two one-year extensions for each initial waiver. If a hospice wishes to receive a one-year extension, the hospice must submit a certification to HCFA, prior to the expiration of the waiver period, that the employment market for nurses has not changed significantly since the time the initial waiver was granted.

[52 FR 7416, Mar. 11, 1987]

418.84 Condition of participation—Medical social services.

Medical social services must be provided by a qualified social worker, under the direction of a physician.

418.86 Condition of participation—Physician services.

In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.

418.88 Condition of participation—Counseling services.

Counseling services must be available to both the individual and the family. Counseling includes bereavement counseling, provided after the patient's death as well as dietary, spiritual and any other counseling services for the individual and family provided while the individual is enrolled in the hospice.

(a) Standard: Bereavement counseling. There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery (up to one year following the death of the patient). A special coverage provision for bereavement counseling is specified 418.204(c).

(b) Standard: Dietary counseling. Dietary counseling, when required, must be provided by a qualified individual.

(c) Standard: Spiritual counseling. Spiritual counseling must include notice to patients as to the availability of clergy as provided in 418.70(f).

(d) Standard: Additional counseling. Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice.

42 CFR Part 418—Subpart E—Conditions of Participation: Other Services

418.90 Condition of participation—Furnishing of other services.

A hospice must ensure that the services described in this subpart are provided directly by hospice employees or under arrangements made by the hospice as specified in 418.56.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

418.92 Condition of participation—Physical therapy, occupational therapy, and speech-language pathology.

(a) Physical therapy services, occupational therapy services, and speech-language patholgy services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

(b) (1) If the hospice engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the hospice chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

[57 FR 7135, Feb. 28, 1992]

418.94 Condition of participation—Home health aide and homemaker services.

Home health aide and homemaker services must be available and adequate in frequency to meet the needs of the patients. A home health aide is a person who meets the training, attitude and skill requirements specified in 484.36 of this chapter.

(a) Standard: Supervision. A registered nurse must visit the home site at least every two weeks when aide services are being provided, and the visit must include an assessment of the aide services.

(b) Standard: Duties. Written instructions for patient care are prepared by a registered nurse. Duties include, but may not be limited to, the duties specified in 484.36(c) of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

418.96 Condition of participation—Medical supplies.

Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness and related conditions.

(a) Standard: Administration. All drugs and biologicals must be administered in accordance with accepted standards of practice.

(b) Standard: Controlled drugs in the patient's home. The hospice must have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.

(c) Standard: Administration of drugs and biologicals. Drugs and biologicals are administered only by the following individuals:

(1) A licensed nurse or physician.

(2) An employee who has completed a State-approved training program in medication administration.

(3) The patient if his or her attending physician has approved.

(4) Any other individual in accordance with applicable State and local laws. The persons, and each drug and biological they are authorized to administer, must be specified in the patient's plan of care.

418.98 Condition of participation—Short term inpatient care.

Inpatient care must be available for pain control, symptom management and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

(a) Standard: Inpatient care for symptom control. Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A hospice that meets the condition of participation for providing inpatient care directly as specified in 418.100.

(2) A hospital or an SNF that also meets the standards specified in 418.100 (a) and (e) regarding 24-hour nursing service and patient areas.

(b) Standard: Inpatient care for respite purposes. Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) An ICF that also meets the standards specified in 418.100 (a) and (e) regarding 24-hour nursing service and patient areas.

(c) Standard: Inpatient care limitation. The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in any 12-month period preceding a certification survey in a particular hospice may not exceed 20 percent of the total number of hospice days for this group of beneficiaries.

(d) Standard: Exemption from limitation. Until October 1, 1986, any hospice that began operation before January 1, 1975 is not subject to the limitation specified in paragraph (c).

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

418.100 Condition of participation: Hospices that provide inpatient care directly.

A hospice that provides inpatient care directly must comply with all of the following standards.

(a) Standard: Twenty-four-hour nursing services.

(1) The facility provides 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care. Each patient receives treatments, medications, and diet as prescribed, and is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) Each shift must include a registered nurse who provides direct patient care.

(b) Standard: Disaster preparedness. The hospice has an acceptable written plan, periodically rehearsed with staff, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.

(c) Standard: Health and safety laws. The hospice must meet all Federal, State, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating

(1) Construction, maintenance, and equipment for the hospice;

(2) Sanitation;

(3) Communicable and reportable diseases; and

(4) Post mortem procedures.

(d) Standard: Fire protection.

(1) Except as provided in paragraphs (d) (2) and (3) of this section, the hospice must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference) [1] that are applicable to hospices.

(2) In consideration of a recommendation by the State survey agency, HCFA may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of the patients.

(3) Any hospice that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, as long as the hospice continues to remain in compliance with that edition of the Life Safety Code.

(4) Any facility of two or more stories that is not of fire resistive construction and is participating on the basis of a waiver of construction type or height, may not house blind, nonambulatory, or physically handicapped patients above the street-level floor unless the facility—

(i) Is one of the following construction types (as defined in the Life Safety Code):

(A) Type II (1, 1, 1)—protected noncombustible.

(B) Fully sprinklered Type II (0, 0, 0)—non-combustible.

(C) Fully sprinklered Type III (2, 1, 1)—protected ordinary.

[1] *See footnote to 405.1134(a) of this chapter.*

(D) Fully sprinklered Type V (1, 1, 1)-protected wood frame; or

(ii) Achieves a passing score on the Fire Safety Evaluation System (FSES).

(e) Standard: Patient areas. (1) The hospice must design and equip areas for the comfort and privacy of each patient and family members.

(2) The hospice must have—

(i) Physical space for private patient/family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night;

(iii) Accommodations for family privacy after a patient's death; and

(iv) Decor which is homelike in design and function.

(3) Patients must be permitted to receive visitors at any hour, including small children.

(f) Standard: Patient rooms and toilet facilities. Patient rooms are designed and equipped for adequate nursing care and the comfort and privacy of patients.

(1) Each patient's room must—

(i) Be equipped with or conveniently located near toilet and bathing facilities;

(ii) Be at or above grade level;

(iii) Contain a suitable bed for each patient and other appropriate furniture;

(iv) Have closet space that provides security and privacy for clothing and personal belongings;

(v) Contain no more than four beds;

(vi) Measure at least 100 square feet for a single patient room or 80 square feet for each patient for a multipatient room; and

(vii) Be equipped with a device for calling the staff member on duty.

(2) For an existing building, HCFA may waive the space and occupancy requirements of paragraphs (f)(1) (v) and (vi) of this section for as long as it is considered appropriate if it finds that—

(i) The requirements would result in unreasonable hardship on the hospice if strictly enforced; and

(ii) The waiver serves the particular needs of the patients and does not adversely affect their health and safety.

(g) Standard: Bathroom facilities. The hospice must—

(1) Provide an adequate supply of hot water at all times for patient use; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(h) Standard: Linen. The hospice has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(i) Standard: Isolation areas. The hospice must make provision for isolating patients with infectious diseases.

(j) Standard: Meal service, menu planning, and supervision. The hospice must—

(1) Serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast;

(2) Procure, store, prepare, distribute, and serve all food under sanitary conditions;

(3) Have a staff member trained or experienced in food management or nutrition who is responsible for—

(i) Planning menus that meet the nutritional needs of each patient, following the orders of the patient's physician and, to the extent medically possible, the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances (9th ed., 1981) is available from the Printing and Publications Office, National Academy of Sciences, Washington, DC 20418); and

(ii) Supervising the meal preparation and service to ensure that the menu plan is followed; and

(4) If the hospice has patients who require medically prescribed special diets, have the menus for those patients planned by a professionally qualified dietitian and supervise the preparation and serving of meals to ensure that the patient accepts the special diet.

(k) Standard: Pharmaceutical services. The hospice provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the facility, the facility is responsible for drugs and biologicals for its patients, insofar as they are covered under the program and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate Federal, State, and local laws. (See 405.1124(g), (h), and (i) of this chapter.)

(1) Licensed pharmacist. The hospice must—

(i) Employ a licensed pharmacist; or

(ii) Have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

(2) Orders for medications.

(i) A physician must order all medications for the patient.

(ii) If the medication order is verbal—

(A) The physician must give it only to a licensed nurse, pharmacist, or another physician; and

(B) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.

(3) Administering medications. Medications are administered only by one of the following individuals:

(i) A licensed nurse or physician.

(ii) An employee who has completed a State-approved training program in medication administration.

(iii) The patient if his or her attending physician has approved.

(4) Control and accountability. The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility. Drugs are dispensed in compliance with Federal and State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

(5) Labeling of drugs and biologicals. The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.

(6) Storage. In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit is kept readily available.

(7) Drug disposal. Controlled drugs no longer needed by the patient are disposed of in compliance with State requirements. In the absence of State requirements, the pharmacist and a registered nurse dispose of the drugs and prepare a record of the disposal.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983; 49 FR 23010, June 1, 1984, as amended at 53 FR 11509, Apr. 7, 1988; 55 FR 50835, Dec. 11, 1990]=

42 CFR Part 418—Subpart F—Covered Services

418.200 Requirements for coverage.

To be covered, hospice services must meet the following requirements.

They must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions. The individual must elect hospice care in accordance with 418.24 and a plan of care must be established as set forth in 418.58 before services are provided. The services must be consistent with the plan of care. A certification that the individual is terminally ill must be completed as set forth in 418.22.

418.202 Covered services.

All services must be performed by appropriately qualified personnel, but it is the nature of the service, rather than the qualification of the person who provides it, that determines the coverage category of the service. The following services are covered hospice services:

(a) Nursing care provided by or under the supervision of a registered nurse.

(b) Medical social services provided by a social worker under the direction of a physician.

(c) Physicians' services performed by a physician as defined in 410.20 of this chapter except that the services of the hospice medical director or the physician member of the interdisciplinary group must be performed by a doctor of medicine or osteopathy.

(d) Counseling services provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other caregiver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death.

(e) Short-term inpatient care provided in a participating hospice inpatient unit, or a participating hospital or SNF, that additionally meets the standards in 418.202 (a) and (e) regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management.

Inpatient care may also be furnished as a means of providing respite for the individual's family or other persons caring for the individual at home. Respite care must be furnished as specified in 418.98(b). Payment for inpatient care will be made at the rate appropriate to the level of care as specified in 418.302.

(f) Medical appliances and supplies, including drugs and biologicals. Only drugs as defined in section 1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment as described in 410.38 of this chapter as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness. Equipment is provided by the hospice for use in the patient's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care.

(g) Home health aide services furnished by qualified aides as designated in 418.94 and homemaker services. Home health aides may provide personal care services as defined in 409.45(b) of this chapter. Aides may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing bed linens or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.

(h) Physical therapy, occupational therapy and speech-language pathology services in addition to the services described in 409.33 (b) and (c) of this chapter provided for purposes of symptom control or to enable the patient to maintain activities of daily living and basic functional skills.

[48 FR 56026, Dec. 16, 1983, as amended at 51 FR 41351, Nov. 14, 1986; 55 FR 50835, Dec. 11, 1990; 59 FR 65498, Dec. 20, 1994]

418.204 Special coverage requirements.

(a) Periods of crisis. Nursing care may be covered on a continuous basis for as much as 24 hours a day during periods of crisis as necessary to maintain an individual at home. Either homemaker or home health aide services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which the individual requires continuous care to achieve palliation or management of acute medical symptoms.

(b) Respite care.

(1) Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual.

(2) Respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time.

(c) Bereavement counseling. Bereavement counseling is a required hospice service but it is not reimbursable.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

42 CFR Part 424—Subpart G—Payment for Hospice Care

418.301 Basic rules.

(a) Medicare payment for covered hospice care is made in accordance with the method set forth in 418.302.

(b) Medicare reimbursement to a hospice in a cap period is limited to a cap amount specified in 418.309.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991]

418.302 Payment procedures for hospice care.

(a) HCFA establishes payment amounts for specific categories of covered hospice care.

(b) Payment amounts are determined within each of the following categories:

(1) Routine home care day. A routine home care day is a day on which an individual who has elected to receive hospice care is at home and is not receiving continuous care as defined in paragraph (b)(2) of this section.

(2) Continuous home care day. A continuous home care day is a day on which an individual who has elected to receive hospice care is not in an inpatient facility and receives hospice care consisting predominantly of nursing care on a continuous basis at home. Home health aide or homemaker services or both may also be provided on a continuous basis. Continuous home care is only furnished during brief periods of crisis as described in 418.204(a) and only as necessary to maintain the terminally ill patient at home.

(3) Inpatient respite care day. An inpatient respite care day is a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.

(4) General inpatient care day. A general inpatient care day is a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.

(c) The payment amounts for the categories of hospice care are fixed payment rates that are established by HCFA in accordance with the procedures described in 418.306. Payment rates are determined for the following categories:

(1) Routine home care.

(2) Continuous home care.

(3) Inpatient respite care.

(4) General inpatient care.

(d) The intermediary reimburses the hospice at the appropriate payment amount for each day for which an eligible Medicare beneficiary is under the hospice's care.

(e) The intermediary makes payment according to the following procedures:

(1) Payment is made to the hospice for each day during which the beneficiary is eligible and under the care of the hospice, regardless of the amount of services furnished on any given day.

(2) Payment is made for only one of the categories of hospice care described in 418.302(b) for any particular day.

(3) On any day on which the beneficiary is not an inpatient, the hospice is paid the routine home care rate, unless the patient receives continuous care as defined in paragraph (b)(2) of this section for a period of at least 8 hours. In that case, a portion of the continuous care day rate is paid in accordance with paragraph (e)(4) of this section.

(4) The hospice payment on a continuous care day varies depending on the number of hours of continuous services provided. The continuous home care rate is divided by 24 to yield an hourly rate. The number of hours of continuous care provided during a continuous home care day is then multiplied by the hourly rate to yield the continuous home care payment for that day. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care rate.

(5) Subject to the limitations described in paragraph (f) of this section, on any day on which

the beneficiary is an inpatient in an approved facility for inpatient care, the appropriate inpatient rate (general or respite) is paid depending on the category of care furnished. The inpatient rate (general or respite) is paid for the date of admission and all subsequent inpatient days, except the day on which the patient is discharged. For the day of discharge, the appropriate home care rate is paid unless the patient dies as an inpatient. In the case where the beneficiary is discharged deceased, the inpatient rate (general or respite) is paid for the discharge day. Payment for inpatient respite care is subject to the requirement that it may not be provided consecutively for more than 5 days at a time. Payment for the sixth and any subsequent day of respite care is made at the routine home care rate.

(f) Payment for inpatient care is limited as follows:

(1) The total payment to the hospice for inpatient care (general or respite) is subject to a limitation that total inpatient care days for Medicare patients not exceed 20 percent of the total days for which these patients had elected hospice care.

(2) At the end of a cap period, the intermediary calculates a limitation on payment for inpatient care to ensure that Medicare payment is not made for days of inpatient care in excess of 20 percent of the total number of days of hospice care furnished to Medicare patients.

(3) If the number of days of inpatient care furnished to Medicare patients is equal to or less than 20 percent of the total days of hospice care to Medicare patients, no adjustment is necessary. Overall payments to a hospice are subject to the cap amount specified in 418.309.

(4) If the number of days of inpatient care furnished to Medicare patients exceeds 20 percent of the total days of hospice care to Medicare patients, the total payment for inpatient care is determined in accordance with the procedures specified in paragraph (f)(5) of this section. That amount is compared to actual payments for inpatient care, and any excess reimbursement must be refunded by the hospice. Overall payments to the hospice are subject to the cap amount specified in 418.309.

(5) If a hospice exceeds the number of inpatient care days described in paragraph (f)(4), the total payment for inpatient care is determined as follows:

(i) Calculate the ratio of the maximum number of allowable inpatient days to the actual number of inpatient care days furnished by the hospice to Medicare patients.

(ii) Multiply this ratio by the total reimbursement for inpatient care made by the intermediary.

(iii) Multiply the number of actual inpatient days in excess of the limitation by the routine home care rate.

(iv) Add the amounts calculated in paragraphs (f)(5)(ii) and (iii) of this section.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991]

418.304 Payment for physician services.

(a) The following services performed by hospice physicians are included in the rates described in 418.302:

(1) General supervisory services of the medical director.

(2) Participation in the establishment of plans of care, supervision of care and services, periodic review and updating of plans of care, and establishment of governing policies by the physician member of the interdisciplinary group.

(b) For services not described in paragraph (a) of this section, a specified Medicare contractor pays the hospice an amount equivalent to 100 percent of the physician's reasonable charge for those physician services furnished by hospice employees or under arrangements with the hospice. Reimbursement for these physician services is included in the amount subject to the hospice payment limit described in 418.309. Services furnished voluntarily by physicians are not reimbursable.

(c) Services of the patient's attending physician, if he or she is not an employee of the hospice or providing services under arrangements with the hospice, are not considered hospice services and are not included in the amount subject to the hospice payment limit described in 418.309.

These services are paid by the carrier under the procedures in subparts D or E, part 405 of this chapter.

418.306 Determination of payment rates.

(a) Applicability. HCFA establishes payment rates for each of the categories of hospice care described in 418.302(b). The rates are established using the methodology described in section 1814(i)(1)(C) of the Act.

(b) Payment rates. The payment rates for routine home care and other services included in hospice care are as follows:

(1) The following rates, which are 120 percent of the rates in effect on September 30, 1989, are effective January 1, 1990 through September 30, 1990 and October 21, 1990 through December 31, 1990:

Routine home care	$75.80
Continuous home care:	
Full rate for 24 hours	442.40
Hourly rate	18.43
Inpatient respite care	78.40
General inpatient care	37.20

(2) Except for the period beginning October 21, 1990, through December 31, 1990, the payment rates for routine home care and other services included in hospice care for Federal fiscal years 1991, 1992, and 1993 and those that begin on or after October 1, 1997, are the payment rates in effect under this paragraph during the previous fiscal year increased by the market basket percentage increase as defined in section 1886(b)(3)(B)(iii) of the Act, otherwise applicable to discharges occurring in the fiscal year. The payment rates for the period beginning October 21, 1990, through December 31, 1990, are the same as those shown in paragraph (b)(1) of this section.

(3) For Federal fiscal years 1994 through 1997, the payment rate is the payment rate in effect during the previous fiscal year increased by a factor equal to the market basket percentage increase minus—

(i) 2 percentage points in FY 1994;

(ii) 1.5 percentage points in FYs 1995 and 1996; and

(iii) 0.5 percentage points in FY 1997.

(c) Adjustment by intermediary. The payment rates established by HCFA are adjusted by the intermediary to reflect local differences in wages.

(d) Federal Register notices. HCFA publishes as a notice in the FEDERAL REGISTER any proposal to change the methodology for determining the payment rates.

[56 FR 26919, June 12, 1991, as amended at 59 FR 26960, May 25, 1994]

418.307 Periodic interim payments.

Subject to the provisions of 413.64(h) of this chapter, a hospice may elect to receive periodic interim payments (PIP) effective with claims received on or after July 1, 1987. Payment is made biweekly under the PIP method unless the hospice requests a longer fixed interval (not to exceed one month) between payments. The biweekly interim payment amount is based on the total estimated Medicare payments for the reporting period (as described in 418.302-418.306). Each payment is made 2 weeks after the end of a biweekly period of service as described in 413.64(h)(5) of this chapter. Under certain circumstances that are described in 413.64(g) of this chapter, a hospice that is not receiving PIP may request an accelerated payment.

[59 FR 36713, July 19, 1994]

418.308 Limitation on the amount of hospice payments.

(a) Except as specified in paragraph (b) of this section, the total Medicare payment to a hospice for care furnished during a cap period is limited by the hospice cap amount specified in 418.309.

(b) Until October 1, 1986, payment to a hospice that began operation before January 1, 1975 is not limited by the amount of the hospice cap specified in 418.309.

(c) The intermediary notifies the hospice of the determination of program reimbursement at the end of the cap year in accordance with procedures similar to those described in 405.1803 of this chapter.

(d) Payments made to a hospice during a cap period that exceed the cap amount are overpayments and must be refunded.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983]

418.309 Hospice cap amount.

The hospice cap amount is calculated using the following procedures:

(a) The cap amount is $6,500 per year and is adjusted for inflation or deflation for cap years that end after October 1, 1984, by using the percentage

change in the medical care expenditure category of the Consumer Price Index (CPI) for urban consumers that is published by the Bureau of Labor Statistics. This adjustment is made using the change in the CPI from March 1984 to the fifth month of the cap year. The cap year runs from November 1 of each year until October 31 of the following year.

(b) Each hospice's cap amount is calculated by the intermediary by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries who elected to receive hospice care from that hospice during the cap period. For purposes of this calculation, the number of Medicare beneficiaries includes—

(1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care, in accordance with 418.24, from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).

(2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total stay in all hospices that was spent in that hospice. (The hospice can obtain this information by contacting the intermediary.)

418.310 Reporting and recordkeeping requirements.
Hospices must provide reports and keep records as the Secretary determines necessary to administer the program.

418.311 Administrative appeals.
A hospice that believes its payments have not been properly determined in accordance with these regulations may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB) if the amount in controversy is at least $1,000 or $10,000, respectively. In such a case, the procedure in 42 CFR part 405, subpart R, will be followed to the extent that it is applicable. The PRRB, subject to review by the Secretary under 405.1874 of this chapter, shall have the authority to determine the issues raised. The methods and standards for the calculation of the payment rates by HCFA are not subject to appeal.

42 CFR Part 418—Subpart H—Coinsurance

418.400 Individual liability for coinsurance for hospice care.

An individual who has filed an election for hospice care in accordance with 418.24 is liable for the following coinsurance payments.

Hospices may charge individuals the applicable coinsurance amounts.

(a) Drugs and biologicals. An individual is liable for a coinsurance payment for each palliative drug and biological prescription furnished by the hospice while the individual is not an inpatient. The amount of coinsurance for each prescription approximates 5 percent of the cost of the drug or biological to the hospice determined in accordance with the drug copayment schedule established by the hospice, except that the amount of coinsurance for each prescription may not exceed $5. The cost of the drug or biological may not exceed what a prudent buyer would pay in similar circumstances. The drug copayment schedule must be reviewed for reasonableness and approved by the intermediary before it is used.

(b) Respite care.

(1) The amount of coinsurance for each respite care day is equal to 5 percent of the payment made by HCFA for a respite care day.

(2) The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began.

(3) The individual hospice coinsurance period—

(i) Begins on the first day an election filed in accordance with 418.24 is in effect for the beneficiary; and

(ii) Ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

418.402 Individual liability for services that are not considered hospice care.

Medicare payment to the hospice discharges an individual's liability for payment for all services, other than the hospice coinsurance amounts described in 418.400, that are considered covered hospice care (as described in 418.202). The individual is liable for the Medicare deductibles and coinsurance payments and for the difference between the reasonable and actual charge on unassigned claims on other covered services that are not considered hospice care. Examples of services not considered hospice care include: Services furnished before or after a hospice election period; services of the individual's attending physician, if the attending physician is not an employee of or working under an arrangement with the hospice; or Medicare services received for the treatment of an illness or injury not related to the individual's terminal condition.

418.405 Effect of coinsurance liability on Medicare payment.

The Medicare payment rates established by HCFA in accordance with 418.306 are not reduced when the individual is liable for coinsurance payments. Instead, when establishing the payment rates, HCFA offsets the estimated cost of services by an estimate of average coinsurance amounts hospices collect.

[56 FR 26919, June 12, 1991]

CFR Part 420—Program Integrity: Medicare

42 CFR Part 420—Subpart C—Disclosure of Ownership and Control Information

420.200 Purpose.

This subpart implements sections 1124, 1124A, 1126, and 1861(v)(1)(i) of the Social Security Act. It sets forth requirements for providers, Part B suppliers, intermediaries, and carriers to disclose ownership and control information and the identities of managing employees. It also sets forth requirements for disclosure of information about a provider's or Part B supplier's owners, those with a controlling interest, or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs.

[57 FR 27306, June 18, 1992, as amended at 60 FR 50442, Sept. 29, 1995]

420.201 Definitions.

As used in this subpart unless the context indicates otherwise:

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means:

(1) A provider of services, an independent clinical laboratory, a renal disease facility, a rural health clinic, a Federally qualified health center, or a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act);

(2) A carrier or other agency or organization that is acting for one or more providers of services for purposes of part A and part B of Medicare; and

(3) A part B supplier, as defined in 400.202 of this chapter.

Other disclosing entity means any other Medicare disclosing entity and any entity that does not participate in Medicare, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XIX, or XX of the Act. This includes:

(1) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services for which payment may be claimed by the entity under any plan or program established under title V of the Social Security Act or under an approved State Medicaid plan;

(2) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which payment may be claimed by the entity under an approved State plan and services program under title XX of the Act; or

(3) A Medicaid fiscal agent.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managing employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the institution, organization, or agency.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

(1) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(2) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(4) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(5) Is an officer or director of a disclosing entity that is organized as a corporation; or

(6) Is a partner in a disclosing entity that is organized as a partnership.

Significant business transaction means any business transaction or series of transactions during any one fiscal year, the total of which exceeds the lesser of $25,000 and 5 percent of the total operating expenses of the provider.

Subcontractor means—

(1) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(2) An individual, agency, or organization with which an intermediary or carrier has entered into a contract, agreement, purchase order or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicare agreement.

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41642, July 17, 1979, as amended at 57 FR 24982, June 12, 1992; 57 FR 27306, June 18, 1992; 57 FR 35760, Aug. 11, 1992]

420.202 Determination of ownership or control percentages.

(a) Indirect ownership interest. The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) Person with an ownership or control interest. In order to determine the percentage of ownership interest in any mortgage, deed of trust, note, or other obligation, the percentage of interest owned in obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

420.203 Disclosure of hiring of intermediary's former employees.

A provider must notify the Secretary promptly if it, or its home office (in the case of a chain organization), employs or obtains the services of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity by an agency or organization which currently serves, or at any time during the preceding year, served as a Medicare fiscal intermediary or carrier for the provider. Similar capacity means the performance of essentially the same work functions as those of a manager, accountant, or auditor even though the individual is not so designated by title.

420.204 Principals convicted of a program-related crime.

(a) Information required. Prior to HCFA's acceptance of a provider agreement or issuance or reissuance of a supplier billing number, or at any time upon written request by HCFA, the provider or part B supplier must furnish HCFA with the identity of any person who:

(1) Has an ownership or control interest in the provider or part B supplier;

(2) Is an agent or managing employee of the provider or part B supplier; or

(3) Is a person identified in paragraph (a)(1) or (a)(2) of this section and has been convicted of, or was an owner of, had a controlling

interest in, or was a managing employee of a corporation that has been convicted of a criminal offense, subjected to any civil monetary penalty, or excluded from the programs for any activities related to involvement in the Medicare, Medicaid, title V or title XX social services program, since the inception of those programs.

(b) Refusal to enter into or renew agreement or to issue or reissue billing numbers. HCFA may refuse to enter into or renew an agreement with a provider of services, or to issue or reissue a billing number to a part B supplier, if any person who has an ownership or control interest in the provider or supplier, or who is an agent or managing employee, has been convicted of a criminal offense or subjected to any civil penalty or sanction related to the involvement of that person in Medicare, Medicaid, title V or title XX social services programs. In making this decision, HCFA considers the facts and circumstances of the specific case, including the nature and severity of the crime, penalty or sanction and the extent to which it adversely affected beneficiaries and the programs involved. HCFA also considers whether it has been given reasonable assurance that the person will not commit any further criminal or civil offense against the programs.

(c) Notification of Inspector General. HCFA promptly notifies the Inspector General of the Department of the receipt of any application or request for participation, certification, recertification, or for a billing number that identifies any person described in paragraph (a)(3) of this section and the action taken on that application or request.

[57 FR 27306, June 18, 1992]

420.205 Disclosure by providers and part B suppliers of business transaction information.

A provider or part B supplier must submit to HCFA, within 35 days after the date of a written request, full and complete information on—

(a) The ownership of a subcontractor with which the provider or part B supplier has had, during the previous 12 months, business transactions in an aggregate amount in excess of $25,000;

(b) Any significant business transactions between the provider or part B supplier and any wholly owned supplier or between the provider or part B supplier and any subcontractor, during the 5 year period ending on the date of the request;

(c) The names of managing employees of the subcontractors;

(d) The identity of any other entities to which payment may be made by Medicare, which a person with an ownership or control interest or a managing employee in the subcontractor has or has had an ownership or control interest in the 3-year period preceding disclosure; and

(e) Any penalties, assessments, or exclusions under sections 1128, 1128A and 1128B of the Act incurred by the subcontractor, its owners, managing employees or those with a controlling interest in the subcontract.

[57 FR 27306, June 18, 1992]

420.206 Disclosure of persons having ownership, financial, or control interest.

(a) Information that must be disclosed. A disclosing entity must submit the following information in the manner specified in paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the entity or in any subcontractor in which the entity has direct or indirect ownership interest totaling 5 percent or more. In the case of a part B supplier that is a joint venture, ownership of 5 percent or more of any company participating in the joint venture should be reported. Any physician who has been issued a Unique Physician Identification Number by the Medicare program must provide this number.

(2) Whether any of the persons named, in compliance with paragraph (a)(1) of this section, is related to another as spouse, parent, child, or sibling.

(3) The name of any other disclosing entity in which any person with an ownership or control interest, or who is a managing employee in the reporting disclosing entity, has, or has had in the previous three-year period, an ownership or control interest or position as managing employee, and the nature of

the relationship with the other disclosing entity. If any of these other disclosing entities has been convicted of a criminal offense or received a civil monetary or other administrative sanction related to participation in Medicare, Medicaid, title V (Maternal and Child Health) or title XX (Social Services) programs, such as penalties assessments and exclusions under sections 1128, 1128A or 1128B of the Act, the disclosing entity must also provide that information.

(b) Time and manner of disclosure.

(1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicare standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency will promptly furnish the information to the Secretary.

(2) Any disclosing entity that is not subject to periodic survey and certification must supply the information specified in paragraph (a) of this section to HCFA before entering into a contract or agreement with Medicare or before being issued or reissued a billing number as a part B supplier.

(3) A disclosing entity must furnish updated information to HCFA at intervals between recertification, or re-enrollment, or contract renewals, within 35 days of a written request. In the case of a part B supplier, the supplier must report also within 35 days, on its own initiative, any changes in the information it previously supplied.

(c) Consequences of failure to disclose.

(1) HCFA does not approve an agreement or contract with, or make a determination of eligibility for, or (in the case of a part B supplier) issue or reissue a billing number to, any disclosing entity that fails to comply with paragraph (b) of this section.

(2) HCFA terminates any existing agreement or contract with, or withdraws a determination of eligibility for or (in the case of a part B supplier) revokes the billing number of, any disclosing entity that fails to comply with paragraph (b) of this section.

(d) Public disclosure. Information furnished to the Secretary under the provisions of this section shall be subject to public disclosure as specified in 20 CFR part 422.

[44 FR 41642, July 17, 1979, as amended at 57 FR 27306, June 18, 1992]

CFR Part 424—Conditions for Medicare Payment

42 CFR Part 424—Subpart A—General Provisions

424.1 Basis and scope.

(a) Statutory basis.

(1) This part is based on the indicated provisions of the following sections of the Act:

1814—Basic conditions for, and limitations on, Medicare payments for Part A services.

1815—Payment to providers for Part A services.

1835—Procedures for payment to providers for Part B services. 1842(b)(3)(B)(ii)—Assignment of Part B Medicare claims.

1842(b)(6)—Payment to entities other than the supplier.

1848—Payment for physician services.

1870(e) and (f)—Settlement of claims after death of the beneficiary.

(2) Section 424.444(c) is also based on section 216(j) of the Act.

(b) Scope. This part sets forth certain specific conditions and limitations applicable to Medicare payments and cites other conditions and limitations set forth elsewhere in this chapter. This subpart A provides a general overview. Other subparts deal specifically with—

(1) The requirement that the need for services be certified and that a physician establish a plan of treatment (subpart B);

(2) The procedures and time limits for filing claims (subpart C);

(3) The individuals or entities to whom payment may be made (subparts D and E);

(4) The limitations on assignment and reassignment of claims (subpart F);

(5) Special requirements that apply to services furnished by nonparticipating U.S. hospitals and foreign hospitals (subparts G and H); and

(6) The replacement and reclamation of Medicare payment checks (subpart M).

(c) Other applicable rules. Except for 424.40(c)(3), this part does not deal with the conditions for payment of rural health clinic (RHC) services, Federally qualified health center (FQHC) services, or ambulatory surgical center (ASC) services. Those conditions are set forth in part 405, subpart X, and part 481 subpart A of this chapter for RHC and FQHC services; and in part 416 of this chapter, for ASC services. The rules for physician certification of terminal illness, required in connection with hospice care, are set forth in 418.22 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 60 FR 38271, July 26, 1995; 60 FR 50442, Sept. 29, 1995]

424.3 Definitions.

As used in this part, unless the context indicates otherwise—*ICD-9-CM* means International Classification of Diseases, Ninth Revision, Clinical Modification.

Nonparticipating hospital means a hospital that does not have in effect a provider agreement to participate in Medicare.

Participating hospital means a hospital that has in effect a provider agreement to participate in Medicare.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994]

424.5 Basic conditions.

(a) As a basis for Medicare payment, the following conditions must be met:

(1) Types of services. The services must be—

(i) Covered services, as specified in part 409 or part 410 of this chapter; or

(ii) Services excluded from coverage as custodial care or services not reasonable and necessary, but reimbursable in accordance with 405.332 through 405.334 of this chapter, pertaining to limitation of liability.

(2) Sources of services. The services must have been furnished by a provider, nonparticipating hospital, or supplier that was, at the time it furnished the services, qualified to have payment made for them.

(3) Recipient of services. Except as provided in

409.68 of this chapter, the services must have been furnished while the individual was eligible to have payment made for them. (Section 409.68 provides for payment of inpatient hospital services furnished before the hospital is notified that the beneficiary has exhausted the Medicare benefits available for the current benefit period.)

(4) Certification of need for services. When required, the provider must obtain certification and recertification of the need for the services in accordance with subpart B of this part.

(5) Claim for payment. The provider, supplier, or beneficiary, as appropriate, must file a claim that includes or makes reference to a request for payment, in accordance with subpart C of this part.

(6) Sufficient information. The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment.

(b) Additional conditions applicable in certain circumstances or to certain services are set forth in other sections of this part.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 60 FR 38271, July 26, 1995]

424.7 General limitations.

(a) Utilization review finding on medical necessity. When a PRO or a UR committee notifies a hospital or SNF of its finding that further services are not medically necessary, the following rules apply:

(1) Hospitals subject to PPS. Payment may not be made for inpatient hospital services furnished by a PPS hospital after the second day after the day on which the hospital received the notice.

(2) Hospitals not subject to PPS and SNFs—

(i) Basic rule. Except as provided in paragraph (a)(2)(ii) of this section, payment may not be made for inpatient hospital services or posthospital SNF care furnished after the day on which the hospital or SNF received the notice.

(ii) Exception. Payment may be made for 1 or 2 additional days if the PRO or UR committee approves them as necessary for planning for post-discharge care.

(b) Failure to make timely utilization review. Payment may not be made for inpatient hospital services or posthospital SNF care furnished, after the 20th consecutive day of a stay, to an individual who is admitted to the hospital or SNF after HCFA has determined that the hospital or SNF has failed to make timely utilization review in long stay cases. (This provision does not apply to a hospital or SNF for which a PRO has assumed binding review.)

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

42 CFR Part 424—Subpart B—Certification and Plan of Treatment Requirements

424.10 Purpose and scope.

(a) Purpose. The physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of stay. Accordingly, sections 1814(a)(2) and 1835(a)(2) of the Act establish as a condition for Medicare payment that a physician certify the necessity of the services and, in some instances, recertify the continued need for those services. Section 1814(a)(2) of the Act also permits nurse practitioners or clinical nurse specialists to certify and recertify the need for post-hospital extended care services.

(b) Scope. This subpart sets forth the timing, content, and signature requirements for certification and recertification with respect to certain Medicare services furnished by providers.

[60 FR 38271, July 26, 1995]

424.11 General procedures.

(a) Responsibility of the provider. The provider must—

(1) Obtain the required certification and recertification statements;

(2) Keep them on file for verification by the intermediary, if necessary; and

(3) Certify, on the appropriate billing form, that the statements have been obtained and are on file.

(b) Obtaining the certification and recertification statements. No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except as provided in paragraph (d) of this section for delayed certifications, there must be a separate signed statement for each certification or recertification.

(c) Required information. The succeeding sections of this subpart set forth specific information required for different types of services. If that information is contained in other provider records, such as physicians' progress notes, it need not be repeated. It will suffice for the statement to indicate where the information is to be found.

(d) Timeliness.

(1) The succeeding sections of this subpart also specify the time frames for certifications and for initial and subsequent recertifications.

(2) A hospital or SNF may provide for obtaining a certification or recertification earlier than required by these regulations, or vary the time frame (within the prescribed outer limits) for different diagnostic or clinical categories.

(3) Delayed certification and recertification statements are acceptable when there is a legitimate reason for delay. (For instance, the patient was unaware of his or her entitlement when he or she was treated.) Delayed certification and recertification statements must include an explanation of the reason for the delay.

(4) A delayed certification may be included with one or more recertifications on a single signed statement.

(e) Limitation on authorization to sign statements. A certification or recertification statement may be signed only by one of the following:

(1) A physician who is a doctor of medicine or osteopathy.

(2) A dentist in the circumstances specified in 424.13(c).

(3) A doctor of podiatric medicine if his or her certification is consistent with the functions he or she is authorized to perform under State law.

(4) A nurse practitioner or clinical nurse specialist, as defined in paragraph (e)(5) or (e)(6) of this section, in the circumstances specified in 424.20(e).

(5) For purposes of this section, to qualify as a nurse practitioner, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices;

be authorized to perform the services of a nurse practitioner in accordance with State law; and have a master's degree in nursing;

(ii) Be certified as a nurse practitioner by a professional association recognized by HCFA that has, at a minimum, eligibility requirements that meet the standards in paragraph (e)(5)(i) of this section; or

(iii) Meet the requirements for a nurse practitioner set forth in paragraph (e)(5)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

(6) For purposes of this section, to qualify as a clinical nurse specialist, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a clinical nurse specialist in accordance with State law; and have a master's degree in a defined clinical area of nursing;

(ii) Be certified as a clinical nurse specialist by a professional association recognized by HCFA that has at a minimum, eligibility requirements that meet the standards in paragraph (e)(6)(i) of this section; or

(iii) Meet the requirements for a clinical nurse specialist set forth in paragraph (e)(6)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

[53 FR 6634, Mar. 2, 1988, as amended at 56 FR 8845, Mar. 1, 1991; 60 FR 38272, July 26, 1995]

424.13 Requirements for inpatient services of hospitals other than psychiatric hospitals.

(a) Content of certification and recertification. Medicare Part A pays for inpatient hospital services of hospitals other than psychiatric hospitals only if a physician certifies and recertifies the following:

(1) The reasons for either—

(i) Continued hospitalization of the patient for medical treatment or medically required inpatient diagnostic study; or

(ii) Special or unusual services for cost outlier cases (under the prospective payment system set forth in subpart F of part 412 of this chapter).

(2) The estimated time the patient will need to remain in the hospital.

(3) The plans for posthospital care, if appropriate.

(b) Certification of need for hospitalization when a SNF bed is not available.

(1) A physician may certify or recertify need for continued hospitalization if the physician finds that the patient could receive proper treatment in a SNF but no bed is available in a participating SNF.

(2) If this is the basis for the physician's certification or recertification, the required statement must so indicate; and the physician is expected to continue efforts to place the patient in a participating SNF as soon as a bed becomes available.

(c) Signatures.

(1) Basic rule. Except as specified in paragraph (c)(2) of this section, certifications and recertifications must be signed by the physician responsible for the case, or by another physician who has knowledge of the case and who is authorized to do so by the responsible physician or by the hospital's medical staff.

(2) Exception. If the intermediary requests certification of the need to admit a patient in connection with dental procedures, because his or her underlying medical condition and clinical status or the severity of the dental procedures require hospitalization, that certification may be signed by the dentist caring for the patient.

(d) Timing of certifications and recertifications: Cases not subject to the prospective payment system (PPS).

(1) For cases that are not subject to PPS, certification is required no later than as of the 12th

day of hospitalization. A hospital may, at its option, provide for the certification to be made earlier, or it may vary the timing of the certification within the 12-day period by diagnostic or clinical categories.

(2) The first recertification is required no later than as of the 18th day of hospitalization.

(3) Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) Timing of certification and recertification: Cases subject to PPS. For cases subject to PPS, certification is required as follows:

(1) For day-outlier cases, certification is required no later than one day after the hospital reasonably assumes that the case meets the outlier criteria, established in accordance with 412.80(a)(1)(i) of this chapter, or no later than 20 days into the hospital stay, whichever is earlier. The first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses) but not less frequently than every 30 days.

(2) For cost-outlier cases, certification is required no later than the date on which the hospital requests cost outlier payment or 20 days into the hospital stay, whichever is earlier. If possible, certification must be made before the hospital incurs costs for which it will seek cost outlier payment. In cost outlier cases, the first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses).

(f) Recertification requirement fulfilled by utilization review.

(1) At the hospital's option, extended stay review by its UR committee may take the place of the second and subsequent physician recertifications required for cases not subject to PPS and for PPS day-outlier cases.

(2) A utilization review that is used to fulfill the recertification requirement is considered timely if performed no later than the seventh day after the day the physician recertification would have been required. The next physician recertification would need to be made no later than the 30th day following such review; if review by the UR committee took the place of this physician recertification, the review could be performed as late as the seventh day following the 30th day.

(g) Description of procedures. The hospital must have available on file a written description that specifies the time schedule for certifications and recertifications, and indicates whether utilization review of long-stay cases fulfills the requirement for second and subsequent recertifications of all cases not subject to PPS and of PPS day outlier cases.

424.16 Timing of certification for individual admitted to a hospital before entitlement to Medicare benefits.

Basic rule. If an indivdual is admitted to a hospital before becoming entitled to Medicare benefits (for instance, before attaining age 65), the day of entitlement (instead of the day of admission) is the starting point for the time limits specified in 424.13(e) for certification and recertification.

Example. (Hospital that is not a psychiatric hospital and is not subject to PPS). For a patient who is admitted on August 15 and becomes entitled on September 1—

(1) The certification is required no later than September 12;

(2) The first recertification is required no later than September 18; and

(3) Subsequent recertifications are required at least every 30 days after September 18.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

424.20 Requirements for posthospital SNF care.

Medicare Part A pays for posthospital SNF care furnished by a SNF, or a hospital or RPCH with a swing-bed approval, only if the certification and recertification for services are consistent with the content of paragraph (a) or (c) of this section, as appropriate.

(a) Content of certification.

(1) General requirements.

(i) Posthospital SNF care is or was required because the individual needs or needed on a daily basis skilled nursing care (furnished directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only

be provided in a SNF or a swing-bed hospital on an inpatient basis; and

(ii) The SNF care is or was needed for a condition for which the individual received inpatient care in a participating hospital or a qualified hospital, as defined in 409.3 of this chapter.

(2) Special requirement: A swing-bed hospital with more than 49 beds (but fewer than 100) that does not transfer a swingbed patient to a SNF within 5 days of the availability date. Transfer of the extended care patient to the SNF is not medically appropriate.

(b) Timing of certification.

(1) General rule. The certification must be obtained at the time of admission or as soon thereafter as is reasonable and practicable.

(2) Special rules for certain swing-bed hospitals. For swingbed hospitals with more than 49 beds that are approved after March 31, 1988, the extended care patient's physician has 5 days (excluding weekends and holidays) beginning on the availability date as defined in 413.114(b), to certify that the transfer of the extended care patient is not medically appropriate.

(c) Content of recertifications.

(1) The reasons for the continued need for posthopsital SNF care:

(2) The estimated time the individual will need to remain in the SNF;

(3) Plans for home care, if any; and

(4) If appropriate, the fact that continued services are needed for a condition that arose after admission to the SNF and while the individual was still under treatment for the condition for which he or she had received inpatient hospital services.

(d) Timing of recertifications.

(1) The first recertification is required no later than the 14th day of posthospital SNF care.

(2) Subsequent recertifications are required at least every 30 days after the first recertification.

(e) Signature. Certification and recertification statements may be signed by—

(1) The physician responsible for the case or, with his or her authorization, by a physician on the SNF staff or a physician who is available in case of an emergency and has knowledge of the case; or

(2) A nurse practitioner or clinical nurse specialist, neither of whom has a direct or indirect employment relationship with the facility but who is working in collaboration with a physician. For purposes of this section, collaboration means a process whereby a nurse practitioner or clinical nurse specialist works with a doctor of medicine or osteopathy to deliver health care services. The services are delivered within the scope of the nurse's professional expertise, with medical direction and appropriate supervision as provided for in guidelines jointly developed by the nurse and the physician or other mechanisms defined by Federal regulations and the law of the State in which the services are performed.

(f) Recertification requirement fulfilled by utilization review. A SNF may substitute utilization review of extended stay cases for the second and subsequent recertifications, if it includes this procedure in its utilization review plan.

(g) Description of procedures. The SNF must have available on file a written description that specifies the certification and recertification time schedule and indicates whether utilization review is used as an alternative to the second and subsequent recertifications.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 37275, Sept. 7, 1989; 58 FR 30671, May 26, 1993; 60 FR 38272, July 26, 1995]

424.22 Requirements for home health services.

Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) Certification—

(1) Content of certification. As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify as follows:

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy.

(ii) Home health services were required because the individual was confined to the home except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and is periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

(iv) The services were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.[1]

(2) Timing and signature. The certification of need for home health services must be obtained at the time the plan of treatment is established or as soon thereafter as possible and must be signed by the physician who establishes the plan.

(b) Recertification.

(1) Timing and signature of recertification. Recertification is required at least every 2 months, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the plan.

(2) Content and basis of recertification. The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical or speech therapy.

(d) Limitations on the performance of certification and plan of treatment functions.

(1) Basic rule. Beginning November 26, 1982, and except as provided in paragraph (e) of this section, need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a significant ownership interest in, or a significant financial or contractual relationship with, that HHA.

(2) Significant ownership interest. A physician is considered to have a significant ownership interest in an HHA if he or she—

(i) Has a direct or indirect ownership interest of 5 percent or more in the capital, the stock, or the profits of the home health agency; or

(ii) Has an ownership interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation that is secured by the agency, if that interest equals 5 percent or more of the agency's assets.

(3) Significant financial or contractual relationship. Beginning November 26, 1982, a physician is considered to have a significant financial or contractual relationship with an HHA if he or she—

(i) Receives any compensation as an officer or director of the HHA; or

(ii) Has direct or indirect business transactions with the HHA that, in any fiscal year, amount to more than $25,000 or 5 percent of the agency's total operating expenses, whichever is less. Business transactions means contracts, agreements, purchase orders, or leases to obtain services, supplies, equipment, and space and, after August 29, 1986, salaried employment.

(4) Exemption of uncompensated officer or director. A physician who serves as an uncompensated officer or director of an HHA is not precluded from performing physician certification and plan of treatment functions for that HHA.

(e) Exceptions to limitations.

(1) Exceptions for governmental entities. The limitations of paragraph (d) of this section do not apply to an HHA that is operated by a Federal, State, or local governmental authority.

(2) Exception for sole community HHAs. The limitations of paragraph (d) of this section

[1] *As a condition of Medicare Part A payment for home health services furnished before July 1981, the physician was also required to certify that the services were needed for a condition for which the individual had received inpatient hospital or SNF services.*

do not apply on or after the date on which the HHA is classified as a sole community HHA in accordance with paragraphs (f) and (g) of this section.

(f) Procedures for classification as a sole community HHA.

(1) The HHA must submit to its intermediary a request for classification, showing that it meets the conditions of paragraph (g) of this section.

(2) The intermediary reviews the request and sends the request, with its recommendations, to HCFA.

(3) HCFA reviews the request and the intermediary's recommendation and forwards its approval or disapproval to the intermediary

(4) An approved classification as sole community HHA remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved.

(g) Basis for classification as a sole community HHA. HCFA approves a classification as a sole community HHA only if the HHA designates a particular area and shows that no other HHA provides services within that area.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, Mar. 1, 1991]

42 CFR Part 424—Subpart C—Claims for Payment

424.30 Scope.

This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments. Claims must be filed in all cases except when services are furnished on a prepaid capitation basis by a health maintenance organization (HMO), a competitive medical plan (CMP), or a health care prepayment plan (HCPP). Special procedures for claiming payment after the beneficiary has died and for certain bills paid by organizations are set forth in subpart E of this part.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

424.32 Basic requirements for all claims.

(a) A claim must meet the following requirements:

(1) A claim must be filed with the appropriate intermediary or carrier on a form prescribed by HCFA in accordance with HCFA instructions.

(2) A claim for physician services must include appropriate diagnostic coding using ICD-9-CM.

(3) A claim must be signed by the beneficiary or the beneficiary's representative (in accordance with 424.36(b)).

(4) A claim must be filed within the time limits specified in 424.44.

(b) The prescribed forms for claims are the following: HCFA-1450—Uniform Institutional Provider Bill. (This form is for institutional provider billing for Medicare inpatient, outpatient and home health services.)

HCFA-1490S—Request for Medicare payment. (For use by a patient to request payment for medical expenses.)

HCFA-1490U—Request for Medicare Payment by Organization. (For use by an organization requesting payment for medical services.)

HCFA-1491—Request for Medicare Payment-Ambulance. (For use by an organization requesting payment for ambulance services.)

HCFA-1500—Health Insurance Claim Form. (For use by physicians and other suppliers to request payment for medical services.) HCFA-1660—Request for Information-Medicare Payment for Services to a Patient now Deceased. (For use in requesting amounts payable under title XVIII to a deceased beneficiary.)

(c) Where claims forms are available. Excluding forms HCFA-1450 and HCFA-1500, all claims forms prescribed for use in the Medicare program are distributed free-of-charge to the public, institutions, or organizations. The HCFA-1450 and HCFA-1500 may be obtained only by commercial purchase. All other claims forms can be obtained upon request from HCFA or any Social Security branch or district office, or from Medicare intermediaries or carriers. The HCFA-1490S is also available at local Social Security Offices.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 59 FR 10299, Mar. 4, 1994]

424.33 Additional requirements: Claims for services of providers and claims by suppliers and nonparticipating hospitals.

All claims for services of providers and all claims by suppliers and nonparticipating hospitals must be—

(a) Filed by the provider, supplier, or hospital; and

(b) Signed by the provider, supplier, or hospital unless HCFA instructions waive this requirement.

424.34 Additional requirements: Beneficiary's claim for direct payment.

(a) Basic rule. A beneficiary's claim for direct payment for services furnished by a supplier, or by a nonparticipating hospital that has not elected to claim payment for emergency services, must include an itemized bill or a "report of services", as specified in paragraphs (b) and (c) of this section.

(b) Itemized bill from the hospital or supplier. The itemized bill for the services, which may be receipted or unpaid, must include all of the following information:

(1) The name and address of—

(i) The beneficiary;

(ii) The supplier or nonparticipating hospital that furnished the services; and

(iii) The physician who prescribed the services if they were furnished by a supplier other than the physician.

(2) The place where each service was furnished, e.g., home, office, independent laboratory, hospital.
(3) The date each service was furnished.
(4) A listing of the services in sufficient detail to permit determination of payment under the fee schedule for physicians' services; for itemized bills from physicians, appropriate diagnostic coding using ICD-9-CM must be used.
(5) The charges for each service.

(c) Report of services furnished by a supplier. For Medicare Part B services furnished by a supplier, the beneficiary claims may include the "Report of Services" portion of the appropriate claims form, completed by the supplier in accordance with HCFA instructions, in lieu of an itemized bill.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 59 FR 26740, May 24, 1994]

424.36 Signature requirements.

(a) General rule. The beneficiary's own signature is required on the claim unless the beneficiary has died or the provisions of paragraph (b), (c), or (d) of this section apply.

(b) Who may sign when the beneficiary is incapable. If the beneficiary is physically or mentally incapable of signing the claim, the claim may be signed on his or her behalf by one of the following:
(1) The beneficiary's legal guardian.
(2) A relative or other person who receives social security or other governmental benefits on the beneficiary's behalf.
(3) A relative or other person who arranges for the beneficiary's treatment or exercises other responsibility for his or her affairs.
(4) A representative of an agency or institution that did not furnish the services for which payment is claimed but furnished other care, services, or assistance to the beneficiary.
(5) A representative of the provider or of the nonparticipating hospital claiming payment for services it has furnished if the provider or nonparticipating hospital is unable to have the claim signed in accordance with paragraph (b) (1), (2), (3), or (4) of this section.

(c) Who may sign if the beneficiary was not present for the service. If a provider, nonparticipating hospital, or supplier files a claim for services that involved no personal contact between the provider, hospital, or supplier and the beneficiary (for example, a physician sent a blood sample to the provider for diagnostic tests), a representative of the provider, hospital, or supplier may sign the claim on the beneficiary's behalf.

(d) Claims by entities that provide coverage complementary to Medicare. A claim by an entity that provides coverage complementary to Medicare Part B may be signed by the entity on the beneficiary's behalf.

(e) Acceptance of other signatures for good cause. If good cause is shown, HCFA may honor a claim signed by a party other than those specified in paragraphs (a) through (c) of this section.

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 53 FR 28388, July 28, 1988]

424.37 Evidence of authority to sign on behalf of the beneficiary.

(a) Beneficiary incapable. When a party specified in 424.36(b) signs a claim or request for payment statement, he or she must also submit a brief statement that—
(1) Describes his or her relationship to the beneficiary; and
(2) Explains the circumstances that make it impractical for the beneficiary to sign the claim or statement.

(b) Beneficiary not present for services. When a representative of the provider, nonparticipating hospital, or supplier signs a claim or request for payment statement under 424.36(c), he or she must explain why it was not possible to obtain the beneficiary's signature. (For example: "Patient not physically present for test.")

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

424.40 Request for payment effective for more than one claim.

(a) Basic procedure. A separate request for payment statement prescribed by HCFA and signed by the beneficiary (or by his or her representative) may be included in claims by reference, in the circumstances specified in paragraphs (b) through (d) of this section.

(b) Claims filed by a provider or nonparticipating hospital—

(1) Inpatient services. A signed request for payment statement, included in the first claim for Part A services furnished by a facility (a participating hospital or SNF, or a nonparticipating hospital that has elected to claim payment) during a beneficiary's period of confinement, may be effective for all claims for Part A services the facility furnishes that beneficiary during that confinement.

(2) Home health services and outpatient physical therapy or speech pathology services. A signed request for payment statement, included in the first claim for home health services or outpatient physical therapy or speech pathology services furnished by a provider under a plan of treatment, may be effective for all claims for home health services or outpatient physical therapy or speech pathology services furnished by the provider under that plan of treatment.

(c) Signed statement in the provider record—

(1) Services to inpatients. A signed request for payment statement in the files of a participating hospital or SNF may be effective for all claims for services furnished to the beneficiary during a single inpatient stay in that facility—

(i) By the hospital or SNF;

(ii) By physicians, if their services are billed by the hospital or SNF in its name; or

(iii) By physicians who bill separately, if the services were furnished in the hospital or SNF.

(2) Services to outpatients: Providers and renal dialysis facilities. A signed request for payment statement retained in the provider's or facility's files may be effective indefinitely, for all claims for services furnished to that beneficiary on an outpatient basis—

(i) By the provider or facility;

(ii) By physicians whose services are billed by the provider or facility in its name; or

(iii) By physicians who bill separately, if the services were furnished in the provider or facility.

(3) Services to outpatients: Independent rural health clinics and Federally qualified health centers. A signed request for payment statement retained in the clinic's or center's files may be effective indefinitely for all claims for services furnished to that beneficiary by the clinic.

(d) Signed statement in the supplier's record. A signed request for payment statement retained in the supplier's file may be effective indefinitely subject to the following restrictions:

(1) This policy does not apply to unassigned claims for rental of durable medical equipment (DME).

(2) With respect to assigned claims for rental or purchase of DME, a new statement is required if another item of equipment is rented or purchased.

[53 FR 6634, Mar. 2, 1988, as amended at 57 FR 24982, June 12, 1992]

424.44 Time limits for filing claims.

(a) Basic limits. Except as provided in paragraph (b) of this section, the claim must be mailed or delivered to the intermediary or carrier, as appropriate—

(1) On or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year; and

(2) On or before December 31 of the second following year for services that were furnished during the last 3 months of the calendar year.

(b) Extension of filing time because of error or misrepresentation.

(1) The time for filing a claim will be extended if failure to meet the deadline in paragraph (a) of this section was caused by error or misrepresentation of an employee, intermediary, carrier, or agent of the Department that was performing Medicare functions and acting within the scope of its authority.

(2) The time will be extended through the last day of the 6th calendar month following the month in which the error or misrepresentation is corrected.

(c) Extension of period ending on a nonworkday. If the last day of the period allowed under

paragraph (a) or (b) of this section falls on a Federal nonworkday (a Saturday, Sunday, legal holiday, or a day which by statute or Executive Order is declared to be a nonworkday for Federal employees), the time is extended to the next succeeding workday.

424.45 What constitutes a claim for purposes of meeting the time limits.

A written statement of intent to claim Medicare benefits constitutes a claim if—

(a) The statement is filed with HCFA or any carrier or intermediary within the time limits specified in 424.44;

(b) The statement indicates the intent to claim Medicare payment for specified services furnished to an identified beneficiary; and

(c) A claim that meets the requirements of 424.32(a) is filed within 6 months after the month in which the intermediary or carrier, as appropriate, advises the claimant to file that claim.

CFR Part 440—Services: General Provisions (Medicaid Program)

42 CFR Part 440—Subpart A—Definitions

440.1 [Amended] Basis and purpose.

[Amended by: 61 FR 38395 - MEDICAID PROGRAM; MEDICAID ELIGIBILITY QUALITY CONTROL, PROGRESSIVE REDUCTIONS IN FEDERAL FINANCIAL PARTICIPATION FOR FYS 1982-1984, PAYMENT FOR PHYSICIAN BILLING]

This subpart interprets and implements the following sections of the Act:

1902(a)(43) Laboratory services. (See also 447.10 and 447.342 for related provisions on laboratory services.)

1905(a) Services included in the term "medical assistance."

1905 (c), (d), (f) through (i), (l), and (m) Definitions of institutions and services that are included in the term "medical assistance."

1913 "Swing-bed" services. (See 447.280 and 482.66 of this chapter for related provisions on "swing-bed" services.)

1915(c) Home and community-based services listed as "medical assistance" and furnished under waivers under that section to individuals who would otherwise require the level of care furnished in a hospital, NF, or ICF/MR.

1915(d) Home and community-based services listed as "medical assistance" and furnished under waivers under that section to individuals age 65 or older who would otherwise require the level of care furnished in a NF.

[57 FR 29155, June 30, 1992]

440.2 Specific definitions; definitions of services for FFP purposes.

(a) Specific definitions.

Inpatient means a patient who has been admitted to a medical institution as an inpatient on recommendation of a physician or dentist and who—

(1) Receives room, board and professional services in the institution for a 24-hour period or longer, or

(2) Is expected by the institution to receive room, board and professional services in the institution for a 24-hour period or longer even though it later develops that the patient dies, is discharged or is transferred to another facility and does not actually stay in the institution for 24 hours.

Outpatient means a patient of an organized medical facility, or distinct part of that facility who is expected by the facility to receive and who does receive professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used, or whether or not the patient remains in the facility past midnight.

Patient means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward the maintenance, improvement, or protection of health, or lessening of illness, disability, or pain. (See also 435.1009 of this subchapter for definitions relating to institutional care.)

(b) Definitions of services for FFP purposes. Except as limited in part 441, FFP is available in expenditures under the State plan for medical or remedial care and services as defined in this subpart.

[43 FR 45224, Sept. 29, 1978, as amended at 52 FR 47934, Dec. 17, 1987]

440.20 [Revised] Outpatient hospital services and rural health clinic services.

[Revised by: 60 FR 61483 - 11/30/95 - MEDICAID PROGRAM: NURSE-MIDWIFE SERVICES]

(a) Outpatient hospital services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that -

(1) Are furnished to outpatients;

(2) Except in the case of nurse-midwife services, as specified in 440.165, are furnished by or under the direction of a physician or dentist; and

(3) Are furnished by an institution that -

(i) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and

(ii) Except in the case of medical supervision of nurse-midwife services, as

specified in 440.165, meets the requirements for participation in Medicare as a hospital; and

(4) May be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of "outpatient hospital services" those types of items and services that are not generally furnished by most hospitals in the State.

(b) Rural health clinic services. If nurse practitioners or physician assistants (as defined in 481.1 of this chapter) are not prohibited by State law from furnishing primary health care, "rural health clinic services" means the following services when furnished by a rural health clinic that has been certified in accordance with part 491 of this chapter.

(1) Services furnished by a physician within the scope of practice of his profession under State law, if the physician performs the services in the clinic or the services are furnished away from the clinic and the physician has an agreement with the clinic providing that he will be paid by it for such services.

(2) Services furnished by a physician assistant, nurse practitioner, nurse midwife or other specialized nurse practitioner (as defined in 405.2401 and 491.2 of this chapter) if the services are furnished in accordance with the requirements specified in 405.2414(a) of this chapter.

(3) Services and supplies that are furnished as an incident to professional services furnished by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner. (See 405.2413 and 405.2415 of this chapter for the criteria for determining whether services and supplies are included under this paragraph.)

(4) Part-time or intermittent visiting nurse care and related medical supplies (other than drugs and biologicals) if:

(i) The clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies (see 405.2417 of this chapter):

(ii) The services are furnished by a registered nurse or licensed practical nurse or a licensed vocational nurse employed by, or otherwise compensated for the services by, the clinic;

(iii) The services are furnished under a written plan of treatment that is established and reviewed at least every 60 days by a supervising physician of the clinic or that is established by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner and reviewed and approved at least every 60 days by a supervising physician of the clinic; and

(iv) The services are furnished to a homebound recipient. For purposes of visiting nurse care, a "homebound" recipient means one who is permanently or temporarily confined to his place of residence because of a medical or health condition. He may be considered homebound if he leaves the place of residence infrequently. For this purpose, "place of residence" does not include a hospital or a skilled nursing facility.

(c) Other ambulatory services furnished by a rural health clinic. If the State plan covers rural health clinic services, other ambulatory services means ambulatory services other than rural health clinic services, as defined in paragraph (b) of this section, that are otherwise included in the plan and meet specific State plan requirements for furnishing those services. Other ambulatory services furnishd by a rural health clinic are not subject to the physician supervision requirements specified in 491.8(b) of this chapter, unless required by State law or the State plan.

[43 FR 45224, Sept. 29, 1978, as amended at 47 FR 21050, May 17, 1982; 52 FR 47934, Dec. 17, 1987]

440.30 Other laboratory and X-ray services.

Other laboratory and X-ray services means professional and technical laboratory and radiological services—

(a) Ordered and provided by or under the direction of a physician or other licensed practioner of the healing arts within the scope of his practice as defined by State law or ordered by a physician but provided by referral laboratory;

(b) Provided in an office or similar facility other than a hospital outpatient department or clinic; and

(c) Furnished by a laboratory that meets the requirements of part 493 of this chapter.

[46 FR 42672, Aug. 24, 1981, as amended at 57 FR 7135, Feb. 28, 1992]

440.60 Medical or other remedial care provided by licensed practitioners.

(a) "Medical care or any other type remedial care provided by licensed practitioners" means any medical or remedial care or services, other than physicians' services, provided by licensed practitioners within the scope of practice as defined under State law.

(b) Chiropractors' services include only services that—

(1) Are provided by a chiropractor who is licensed by the State and meets standards issued by the Secretary under 405.232(b) of this chapter; and

(2) Consists of treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform.

440.70 Home health services.

(a) Home health services means the services in paragraph (b) of this section that are provided to a recipient—

(1) At his place of residence, as specified in paragraph (c) of this section; and

(2) On his physician's orders as part of a written plan of care that the physician reviews every 60 days.

(b) Home health services include the following services and items. Those listed in paragraphs (b) (1), (2) and (3) of this section are required services; those in paragraph (b)(4) of this section are optional.

(1) Nursing service, as defined in the State Nurse Practice Act, that is provided on a part-time or intermittent basis by a home health agency as defined in paragraph (d) of this section, or if there is no agency in the area, a registered nurse who—

(i) Is currently licensed to practice in the State;

(ii) Receives written orders from the patient's physician;

(iii) Documents the care and services provided; and

(iv) Has had orientation to acceptable clinical and administrative recordkeeping from a health department nurse.

(2) Home health aide service provided by a home health agency,

(3) Medical supplies, equipment, and appliances suitable for use in the home, and

(4) Physical therapy, occupational therapy, or speech pathology and audiology services, provided by a home health agency or by a facility licensed by the State to provide medical rehabilitation services. (See 441.15 of this subchapter.)

(c) A recipient's place of residence, for home health services, does not include a hospital, skilled nursing facility, or intermediate care facility except for home health services in an intermediate care facility that are not required to be provided by the facility under subparts F and G of part 442 of this subchapter. For example, a registered nurse may provide short-term care for a recipient in an intermediate care facility during an acute illness to avoid the recipient's transfer to a skilled nursing facility.

(d) "Home health agency" means a public or private agency or organization, or part of an agency or organization, that meets requirements for participation in Medicare.

(e) A "facility licensed by the State to provide medical rehabilitation services" means a facility that—

(1) Provides therapy services for the primary purpose of assisting in the rehabilitation of disabled individuals through an integrated program of—

(i) Medical evaluation and services; and

(ii) Psychological, social, or vocational evaluation and services; and

(2) Is operated under competent medical supervision either—

(i) In connection with a hospital; or

(ii) As a facility in which all medical and related health services are prescribed by or under the direction of individuals licensed to practice medicine or surgery in the State.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980]

440.80 Private duty nursing services.

Private duty nursing services means nursing services for recipients who require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing staff of the hospital or skilled nursing facility. These services are provided—

(a) By a registered nurse or a licensed practical nurse;

(b) Under the direction of the recipient's physician; and

(c) To a recipient in one or more of the following locations at the option of the State—

(1) His or her own home;

(2) A hospital; or

(3) A skilled nursing facility.

[52 FR 47934, Dec. 17, 1987]

440.180 Home or community-based services.

(a) Description and requirements for services. Home or community-based services means services, not otherwise furnished under the State's Medicaid plan, that are furnished under a waiver granted under the provisions of part 441, subpart G of this chapter.

(1) These services may consist of any or all of the services listed in paragraph (b) of this section, as those services are defined by the agency and approved by HCFA.

(2) The services must meet the standards specified in 441.302(a) of this chapter concerning health and welfare assurances.

(3) The services are subject to the limits on FFP described in 441.310 of this chapter.

(b) Included services. Home or community-based services may include the following services, as they are defined by the agency and approved by HCFA:

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Habilitation services.

(7) Respite care services.

(8) Day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services (whether or not furnished in a facility) for individuals with chronic mental illness, subject to the conditions specified in paragraph (d) of this section.

(9) Other services requested by the agency and approved by HCFA as cost effective and necessary to avoid institutionalization.

(c) Expanded habilitation services, effective April 7, 1986—

(1) General rule. Expanded habilitation services are those services specified in paragraph (c)(2) of this section, that are provided to recipients who have been discharged from a Medicaidcertified NF or ICF/MR, regardless of when the discharge occurred.

(2) Services included. The agency may include as expanded habilitation services the following services:

(i) Prevocational services, which means services that prepare an individual for paid or unpaid employment and that are not job-task oriented but are, instead, aimed at a generalized result. These services may include, for example, teaching an individual such concepts as compliance, attendance, task completion, problem solving and safety.

Prevocational services are distinguishable from noncovered vocational services by the following criteria:

(A) The services are provided to persons who are not expected to be able to join the general work force or participate in a transitional sheltered workshop within one year (excluding supported employment programs).

(B) If the recipients are compensated, they are compensated at less than 50 percent of the minimum wage;

(C) The services include activities which are not primarily directed at teaching specific job skills but at underlying habilitative goals (for example, attention span, motor skills); and

(D) The services are reflected in a plan of care directed to habilitative rather than explicit employment objectives.

(ii) Educational services, which means special education and related services (as defined in sections 602(16) and (17) of the Education of the Handicapped Act) (20 U.S.C. 1401 (16 and 17)) to the

extent they are not prohibited under paragraph (c)(3)(i) of this section.

(iii) Supported employment services, which facilitate paid employment, that are—

(A) Provided to persons for whom competitive employment at or above the minimum wage is unlikely and who, because of their disabilities, need intensive ongoing support to perform in a work setting;

(B) Conducted in a variety of settings, particularly worksites in which persons without disabilities are employed; and

(C) Defined as any combination of special supervisory services, training, transportation, and adaptive equipment that the State demonstrates are essential for persons to engage in paid employment and that are not normally required for nondisabled persons engaged in competitive employment.

(3) Services not included. The following services may not be included as habilitation services:

(i) Special education and related services (as defined in sections 602(16) and (17) of the Education of the Handicapped Act) (20 U.S.C. 1401 (16) and (17)) that are otherwise available to the individual through a local educational agency.

(ii) Vocational rehabilitation services that are otherwise available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

(d) Services for the chronically mentally ill.

(1) Services included. Services listed in paragraph (b)(8) of this section include those provided to individuals who have been diagnosed as being chronically mentally ill, for which the agency has requested approval as part of either a new waiver request or a renewal and which have been approved by HCFA on or after October 21, 1986.

(2) Services not included. Any home and community-based service, including those indicated in paragraph (b)(8) of this section, may not be included in home and communitybased service waivers for the following individuals:

(i) For individuals aged 22 through 64 who, absent the waiver, would be institutionalized in an institution for mental diseases (IMD); and, therefore, subject to the limitation on IMDs specified in 435.1008(a)(2) of this subchapter.

(ii) For individuals, not meeting the age requirements described in paragraph (d)(2)(i) of this section, who, absent the waiver, would be placed in an IMD in those States that have not opted to include the benefits defined in 440.140 or 440.160.

[59 FR 37716, July 25, 1994]

EFFECTIVE DATE NOTE: At 59 FR 37716, July 25, 1994, 440.180 was revised. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget. A notice will be published in the FEDERAL REGISTER once approval has been obtained.

440.181 Home and community-based services for individuals age 65 or older.

(a) Description of services. Home and community-based services for individuals age 65 or older means services, not otherwise furnished under the State's Medicaid plan, or services already furnished under the State's Medicaid plan but in expanded amount, duration, or scope, which are furnished to individuals age 65 or older under a waiver granted under the provisions of part 441, subpart H of this subchapter. Except as provided in 441.310, the services may consist of any of the services listed in paragraph (b) of this section that are requested by the State, approved by HCFA, and furnished to eligible recipients. Service definitions for each service in paragraph (b) of this section must be approved by HCFA.

(b) Included services.

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Respite care services.

CFR Part 484—Conditions of Participation: Home Health Agencies

42 CFR Part 484—Subpart A—General Provisions

441.10 Basis.

This subpart is based on the following sections of the Act which state requirements and limits on the services specified or provide Secretarial authority to prescribe regulations relating to services:

(a) Section 1102 for end-stage renal disease (441.40).

(b) Section 1138(b) for organ procurement organization services (441.13(c)).

(c) Sections 1902(a)(10)(A) and 1905(a)(21) for nurse practitioner services (441.22).

(d) Sections 1902(a)(10)(D) and 1905(a)(7) for home health services (441.15).

(e) Section 1903(i)(1) for organ transplant procedures (441.35).

(f) Section 1903(i)(5) for certain prescribed drugs (441.25).

(g) Section 1903(i)(6) for prohibition (except in emergency situations) of FFP in expenditures for inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner (441.12).

(h) Section 1905(a)(4)(C) for family planning (441.20).

(i) Sections 1905 (a)(12) and (e) for optometric services (441.30).

(j) Section 1905(a)(17) for nurse-midwife services (441.21).

(k) Section 1905(a) (following (a)(24)) for prohibition of FFP in expenditures for certain services (441.13).

[60 FR 19862, Apr. 21, 1995]

441.15 Home health services.

With respect to the services defined in 440.70 of this subchapter, a State plan must provide that—

(a) Home health services include, as a minimum—

(1) Nursing services;

(2) Home health aide services; and

(3) Medical supplies, equipment, and appliances.

(b) The agency provides home health services to—

(1) Categorically needy recipients age 21 or over;

(2) Categorically needy recipients under age 21, if the plan provides skilled nursing facility services for them; individuals; and

(3) Medically needy recipients to whom skilled nursing facility services are provided under the plan.

(c) The eligibility of a recipient to receive home health services does not depend on his need for or discharge from institutional care.

[43 FR 45229, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980]

(7) Other medical and social services requested by the Medicaid agency and approved by HCFA, which will contribute to the health and well-being of individuals and their ability to reside in a community-based care setting.

[57 FR 29156, June 30, 1992]

440.185 Respiratory care for ventilator-dependent individuals.

(a) "Respiratory care for ventilator-dependent individuals" means services that are not otherwise available under the State's Medicaid plan, provided on a part-time basis in the recipient's home by a respiratory therapist or other health care professional trained in respiratory therapy (as determined by the State) to an individual who—

(1) Is medically dependent on a ventilator for life support at least 6 hours per day;

(2) Has been so dependent for at least 30 consecutive days (or the maximum number of days authorized under the State plan, whichever is less) as an inpatient in one or more hospitals, NFs, or ICFs/MR;

(3) Except for the availability of respiratory care services, would require respiratory care as an inpatient in a hospital, NF, or ICF/MR and would be eligible to have payment made for inpatient care under the State plan;

(4) Has adequate social support services to be cared for at home;

(5) Wishes to be cared for at home; and

(6) Receives services under the direction of a physician who is familiar with the technical and medical components of home ventilator support, and who has medically determined that in-home care is safe and feasible for the individual.

(b) For purposes of paragraphs (a)(4) and (5) of this section, a recipient's home does not include a hospital, NF, ICF/MR or other institution as defined in 435.1009.

[59 FR 37717, July 25, 1994]

42 CFR Part 484—Subpart B—Administration

484.1 Basis and scope.

(a) Basis and scope. This part is based on the indicated provisions of the following sections of the Act:
  (1) Sections 1861(o) and 1891 establish the conditions that an HHA must meet in order to participate in Medicare.
  (2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.

(b) This part also sets forth additional requirements that are considered necessary to ensure the health and safety of patients

[60 FR 50443, Sept. 29, 1995]

484.2 Definitions.

As used in this part, unless the context indicates otherwise—Bylaws or equivalent means a set of rules adopted by an HHA for governing theagency's operation.

Branch office means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition.HHA stands for home health agency.

Nonprofit agency means an agency exempt from Federal income taxationunder section 501 of the Internal Revenue Code of 1954.

Parent home health agency means the agency that develops and maintainsadministrative controls of subunits and/or branch offices.

Primary home health agency means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

Progress note means a written notation, dated and signed by a member of the health team, that summarizes facts about care furnished and the patient's response during a given period of time.

Proprietary agency means a private profit-making agency licensed by the State.

Public agency means an agency operated by a State or local government.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has subunits or branch offices is considered a parent agency.Subunit means a semi-autonomous organization that—
  (1) Serves patients in a geographic area different from that of the parent agency; and
  (2) Must independently meet the conditions of participation for HHAs because it is too far from the parent agency to share administration, supervision, and services on a daily basis.Summary report means the compilation of the pertinent factors of a patient's clinical notes and progress notes that is submitted to the patient's physician.

Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Unless otherwise specified in this part, the supervisor must be on the premises to supervise an individual who does not meet the qualifications specified in 484.4.

484.4 Personnel qualifications.

Staff required to meet the conditions set forth in this part are staff who meet the qualifications specified in this section.

Administrator, home health agency. A person who:
(a) Is a licensed physician; or
(b) Is a registered nurse; or
(c) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

Audiologist. A person who:
(a) Meets the education and experience requirements for a Certificate of Clinical Competence in

audiology granted by the American Speech-Language-Hearing Association; or

(b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Home health aide. Effective for services furnished after August 14, 1990, a person who has successfully completed a Stateestablished or other training program that meets the requirements of 484.36(a) and a competency evaluation program or State licensure program that meets the requirements of 484.36 (b) or (e), or a competency evaluation program or State licensure program that meets the requirements of 484.36 (b) or (e). An individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in 409.40 of this chapter for compensation.

Occupational therapist. A person who:

(a) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(b) Is eligible for the National Registration Examination ofthe American Occupational Therapy Association; or

(c) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

Occupational therapy assistant. A person who:

(a) Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or

(b) Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

Physical therapist. A person who is licensed as a physical therapist by the State in which practicing, and

(a) Has graduated from a physical therapy curriculum approved by:
  (1) The American Physical Therapy Association, or
  (2) The Committee on Allied Health Education and Accreditation of the American Medical Association, or
  (3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or

(b) Prior to January 1, 1966,
  (1) Was admitted to membership by the American PhysicalTherapy Association, or
  (2) Was admitted to registration by the American Registry of Physical Therapist, or
  (3) Has graduated from a physical therapy curriculum in a 4year college or university approved by a State department of education; or

(c) Has 2 years of appropriate experience as a physical therapist, and has achieved a satifactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(d) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(e) If trained outside the United States,
  (1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.
  (2) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy,

Physical therapy assistant. A person who is licensed as a physical therapy assistant, if applicable, by the State in which practicing, and

(1) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

(2) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

Physician. A doctor of medicine, osteophathy or podiatry legally authorized to practice medicine and surgery by the State in which such function or action is performed.

Practical (vocational) nurse. A person who is licensed as a practical (vocational) nurse by the State in which practicing.

Public health nurse. A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content aproved by the National League for Nursing for public health nursing preparation.

Registered nurse (RN). A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing

Social work assistant. A person who:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

Social worker. A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

Speech-language pathologist. A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in (speech pathology or audiology) granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991]

42 CFR Part 484—Subpart B—Administration

484.10 Condition of participation: Patient rights. The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

(a) Standard: Notice of rights.

(1) The HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

(2) The HHA must maintain documentation showing that it has complied with the requirements of this section.

(b) Standard: Exercise of rights and respect for property and person.

(1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) The patient's family or guardian may exercise the patient's rights when the patient has been judged incompetent.

(3) The patient has the right to have his or her property treated with respect.

(4) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

(5) The HHA must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the HHA, and must document both the existence of the complaint and the resolution of the complaint.

(c) Standard: Right to be informed and to participate in planning care and treatment.

(1) The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.

(2) The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(ii) The HHA complies with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(d) Standard: Confidentiality of medical records. The patient has the right to confidentiality of the clinical records maintained by the HHA. The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records.

(e) Standard: Patient liability for payment.

(1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient. Before the care is initiated, the HHA must inform the patient, orally and in writing, of—

(i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA;

(ii) The charges for services that will not be covered by Medicare; and

(iii) The charges that the individual may have to pay.

(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

(f) Standard: Home health hotline. The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advance directives requirements.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 57 FR 8203, Mar. 6, 1992; 60 FR 33293, June 27, 1995]

484.12 Condition of participation: Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.

(a) Standard: Compliance with Federal, State, and local laws and regulations. The HHA and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of HHAs, an agency not subject to licensure is approved by the licensing authority as meeting the standards established for licensure.

(b) Standard: Disclosure of ownership and management information. The HHA must comply with the requirements of Part 420, Subpart C of this chapter. The HHA also must disclose the following information to the State survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The name and address of all persons with an ownership or control interest in the HHA as defined in 420.201, 420.202, and 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent or a managing employee of the HHA as defined in 420.201, 420.202, and 420.206 of this chapter.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(c) Standard: Compliance with accepted professional standards and principles. The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

42 CFR Part 484—Subpart C—Furnishing of Services

484.30 Condition of participation: Skilled nursing services.

The HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care.

(a) Standard: Duties of the registered nurse. The registered nurse makes the initial evaluation visit, regularly reevaluates the patient's nursing needs, initiates the plan of care and necessary revisions, furnishes those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, counsels the patient and family in meeting nursing and related needs, participates in in-service programs, and supervises and teaches other nursing personnel.

(b) Standard: Duties of the licensed practical nurse. The licensed practical nurse furnishes services in accordance with agency policies, prepares clinical and progress notes, assists the physician and registered nurse in performing specialized procedures, prepares equipment and materials for treatments observing aseptic technique as required, and assists the patient in learning appropriate self-care techniques.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

484.32 Condition of participation: Therapy services.

Any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs.

(a) Standard: Supervision of physical therapy assistant and occupational therapy assistant. Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in in-service programs.

(b) Standard: Supervision of speech therapy services. Speech therapy services are furnished only by or under supervision of a qualified speech pathologist or audiologist.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

484.34 Condition of participation: Medical social services.

If the agency furnishes medical social services, those services are given by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of care. The social worker assists the physician and other team members in understanding the significant social and emotional factors related to the health problems, participates in the development of the plan of care, prepares clinical and progress notes, works with the family, uses appropriate community resources, participates in discharge planning and inservice programs, and acts as a consultant to other agency personnel.

484.36 Condition of participation: Home health aide services.

Home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care. For home health services furnished (either directly or through arrangements with other organizations) after August 14, 1990, the HHA must use individuals who meet the personnel qualifications specified in 484.4 for "home health aide."

(a) Standard: Home health aide training—

(1) Content and duration of training. The aide training program must address each of the following subject areas through classroom and supervised practical training totalling at least 75 hours, with at least 16 hours devoted to supervised practical training. The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training.

(i) Communications skills.

(ii) Observation, reporting and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and knowledge of emergency procedures.

The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy and his or her property.

(ix) Appropriate and safe techniques in personal hygiene and grooming that include—

(A) Bed bath.

(B) Sponge, tub, or shower bath.

(C) Shampoo, sink, tub, or bed.

(D) Nail and skin care.

(E) Oral hygiene.

(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

(xiii) Any other task that the HHA may choose to have the home health aide perform.

"Supervised practical training" means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse.

(2) Conduct of training—

(i) Organizations. A home health aide training program may be offered by any organization except an HHA that, within the previous 2 years has been found—

(A) Out of compliance with requirements of this paragraph (a) or paragraph (b) of this section;

(B) To permit an individual that does not meet the definition of "home health aide" as specified in 484.4 to furnish home health aide services (with the exception of licensed health professionals and volunteers);

(C) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of the HCFA or the State);

(D) Has been assessed a civil monetary penalty of not less than $5,000 as an intermediate sanction;

(E) Has been found to have compliance deficiencies that endanger the health and safety of the HHA's patients and has had a temporary management appointed to oversee the management of the HHA;

(F) Has had all or part of its Medicare payments suspended; or

(G) Under any Federal or State law within the 2-year period beginning on October 1, 1988—

(1) Has had its participation in the Medicare program terminated;

(2) Has been assessed a penalty of not less than $5,000 for deficiencies in Federal or State standards for HHAs;

(3) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;

(4) Had operated under a temporary management that was appointed to oversee the operation of

the HHA and to ensure the health and safety of the HHA's patients; or

(5) Was closed or had it's residents transferred by the State.

(ii) Qualifications for instructors. The training of home health aides and the supervision of home health aides during the supervised practical portion of the training must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care. Other individuals may be used to provide instruction under the supervision of a qualified registered nurse.

(3) Documentation of training. The HHA must maintain sufficient documentation to demonstrate that the requirements of this standard are met.

(b) Standard: Competency evaluation and in-service training—

(1) Applicability. An individual may furnish home health aide services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this paragraph. The HHA is responsible for ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.

(2) Content and frequency of evaluations and amount of inservice training.

(i) The competency evaluation must address each of the subjects listed in paragraph (a)(1) (ii) through (xiii) of this section.

(ii) The HHA must complete a performance review of each home health aide no less frequently than every 12 months.

(iii) The home health aide must receive at least 12 hours of in-service training during each 12-month period. The in-service training may be furnished while the aide is furnishing care to the patient.

(3) Conduct of evaluation and training—

(i) Organizations. A home health aide competency evaluation program may be offered by any organization except as specified in paragraph (a)(2)(i) of this section. The in-service training may be offered by any organization.

(ii) Evaluators and instructors. The competency evaluation must be performed by a registered nurse. The in-service training generally must be supervised by a registered nurse who possesses a minimum of 2 years of nursing experience at least 1 year of which must be in the provision of home health care.

(iii) Subject areas. The subject areas listed at paragraphs (a)(1) (iii), (ix), (x), and (xi) of this section must be evaluated after observation of the aide's performance of the tasks with a patient. The other subject areas in paragraph (a)(1) of this section may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(4) Competency determination.

(i) A home health aide is not considered competent in any task for which he or she is evaluated as "unsatisfactory". The aide must not perform that task without direct supervision by a licensed nurse until after he or she receives training in the task for which he or she was evaluated as "unsatisfactory" and passes a subsequent evaluation with "satisfactory".

(ii) A home health aide is not considered to have successfully passed a competency evaluation if the aide has an "unsatisfactory" rating in more than one of the required areas.

(5) Documentation of competency evaluation. The HHA must maintain documentation which demonstrates that the requirements of this standard are met.

(6) Effective date. The HHA must implement a competency evaluation program that meets the requirements of this paragraph before February 14, 1990. The HHA must provide the preparation necessary for the individual to successfully complete the competency evaluation program. After August 14, 1990,

the HHA may use only those aides that have been found to be competent in accordance with 484.36(b).

(c) Standard: Assignment and duties of the home health aide—

(1) Assignment. The home health aide is assigned to a specific patient by the registered nurse. Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.

(2) Duties. The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law. The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered. Any home health aide services offered by an HHA must be provided by a qualified home health aide.

(d) Standard: Supervision.

(1) If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit required by paragraph (d)(2) of this section. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy, occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate therapist.

(2) The registered nurse (or another professional described in paragraph (d)(1) of this section) must make an on-site visit to the patient's home no less frequently than every 2 weeks.

(3) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy or speech-language pathology services, the registered nurse must make a supervisory visit to the patient's home no less frequently than every 62 days. In these cases, to ensure that the aide is properly caring for the patient, each supervisory visit must occur while the home health aide is providing patient care.

(4) If home health aide services are provided by an individual who is not employed directly by the HHA (or hospice), the services of the home health aide must be provided under arrangements, as defined in section 1861(w)(1) of the Act. If the HHA (or hospice) chooses to provide home health aide services under arrangements with another organization, the HHA's (or hospice's) responsibilities include, but are not limited to—

(i) Ensuring the overall quality of the care provided by the aide;

(ii) Supervision of the aide's services as described in paragraphs (d)(1) and (d)(2) of this section; and

(iii) Ensuring that home health aides providing services under arrangements have met the training requirements of paragraphs (a) and (b) of this section.

(e) Personal care attendant: Evaluation requirements—

(1) Applicability. This paragraph applies to individuals who are employed by HHAs exclusively to furnish personal care attendant services under a Medicaid personal care benefit.

(2) Rule. An individual may furnish personal care services, as defined in 440.170 of this chapter, on behalf of an HHA after the individual has been found competent by the State to furnish those services for which a competency evaluation is required by paragraph (b) of this section and which the individual is required to perform. The individual need not be determined competent in those services listed in paragraph (a) of this section that the individual is not required to furnish.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991; 56 FR 51334, Oct. 11, 1991; 59 FR 65498, Dec. 20, 1994; 60 FR 39123, Aug. 1, 1995]

484.38 Condition of participation: Qualifying to furnish outpatient physical therapy or speech pathology services.

An HHA that wishes to furnish outpatient physical therapy or speech pathology services must meet all the pertinent conditions of this part and also meet the additional

health and safety requirements set forth in 485.711, 485.713, 485.715, 485.719, 485.723, and 485.727 of this chapter to implement section 1861(p) of the Act.

[54 FR 33367, Aug. 14, 1989, as amended at 60 FR 2329, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995]

484.48 Condition of participation: Clinical records.

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services. In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

(a) Standards: Retention of records. Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations. If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.

(b) Standards: Protection of records. Clinical record information is safe-guarded against loss or unauthorized use. Written procedures govern use and removal of records and the conditions for release of information. Patient's written consent is required for release of information not authorized by law.

[54 FR 33367, Aug. 14, 1989, as amended at 60 FR 65498, Dec. 20, 1994]

484.52 Condition of participation: Evaluation of the agency's program.

The HHA has written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses the extent to which the agency's program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

(a) Standard: Policy and administrative review. As a part of the evaluation process the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient. Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

(b) Standard: Clinical record review. At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 62day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

CFR Part 488—Survey, Certification, and Enforcement Procedures

42 CFR Part 488—Subpart A—General Procedures

488.6 Other national accreditation programs for hospitals and other providers and suppliers.

(a) In accordance with the requirements of this subpart, a national accreditation program for hospitals; psychiatric hospitals; SNFs; HHAs; ASCs; RHCs; CORFs; hospices; screening mammography services; rural primary care hospitals; or clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy, occupational therapy or speech pathology services may provide reasonable assurance to HCFA that it requires the providers or suppliers it accredits to meet requirements that are at least as stringent as the Medicare conditions when taken as a whole. In such a case, HCFA may deem the providers or suppliers the program accredits to be in compliance with the appropriate Medicare conditions. These providers and suppliers are subject to validation surveys under 488.7 of this subpart. HCFA will publish notices in the FEDERAL REGISTER in accordance with 488.8(b) identifying the programs and deeming authority of any national accreditation program and the providers or suppliers it accredits. The notice will describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. (See 488.5 for requirements concerning hospitals accredited by JCAHO or AOA.)

(b) Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c) (1) A provider or supplier deemed to meet program requirements under paragraph (a) of this section must authorize its accreditation organization to release to HCFA and the State survey agency a copy of its most current accreditation survey, together with any information related to the survey that HCFA may require (including corrective action plans).

(2) HCFA may determine that a provider or supplier does not meet the Medicare conditions on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(3) Upon written request, HCFA may disclose the survey and information related to the survey—

(i) Of any HHA; or

(ii) Of any other provider or supplier specified at paragraph (a) of this section if the accreditation survey and related survey information relate to an enforcement action taken by HCFA.

[58 FR 61840, Nov. 23, 1993]

42 CFR Part 488—Subpart A—General Procedures

Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs

SOURCE: 57 FR 34012, July 31, 1992, unless otherwise noted.

488.201 Reconsideration.

(a) Right to reconsideration.

(1) A national accreditation organization dissatisfied with a determination that its accreditation requirements do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements is entitled to a reconsideration as provided in this subpart.

(2) A State dissatisfied with a determination that the requirements it imposes on laboratories in that State and under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements is entitled to a reconsideration as provided in this subpart.

(b) Eligibility for reconsideration. HCFA will reconsider any determination to deny, remove or not renew the approval of deeming authority to private accreditation organizations, or any determination to deny, remove or not renew the approval of a State laboratory program for the purpose of exempting the State's laboratories from CLIA requirements, if the accreditation organization or State files a written request for a reconsideration in accordance with paragraphs (c) and (d) of this section.

(c) Manner and timing of request for reconsideration.

(1) A national accreditation organization or a State laboratory program described in paragraph (b), dissatisfied with a determination with respect to its deeming authority, or, in the case of a State, a determination with respect to the exemption of the laboratories in the State from CLIA requirements, may request a reconsideration of the determination by filing a request with HCFA either directly by its authorized officials or through its legal representative. The request must be filed within 60 days of the receipt of notice of an adverse determination or nonrenewal as provided in subpart A of part 488 or subpart E of part 493, as applicable.

(2) Reconsideration procedures are available after the effective date of the decision to deny, remove, or not renew the approval of an accreditation organization or State laboratory program.

(d) Content of request. The request for reconsideration must specify the findings or issues with which the accreditation organization or State disagrees and the reasons for the disagreement.

[57 FR 34012, July 31, 1992, as amended at 58 FR 61843, Nov. 23, 1993]

488.203 Withdrawal of request for reconsideration.

A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

488.205 Right to informal hearing.

In response to a request for reconsideration, HCFA will provide the accreditation organization or the State laboratory program the opportunity for an informal hearing as described in 488.207 that will—

(a) Be conducted by a hearing officer appointed by the Administrator of HCFA; and

(b) Provide the accreditation organization or State laboratory program the opportunity to present, in writing or in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority or the exemption of a State's laboratories from CLIA requirements.

488.207 Informal hearing procedures.

(a) HCFA will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(b) The informal reconsideration hearing will be conducted in accordance with the following procedures—

(1) The hearing is open to HCFA and the organization requesting the reconsideration, including—

(i) Authorized representatives;

(ii) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

(iii) Legal counsel;

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action;

(3) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissable under the usual rules of court procedures;

(4) Either party may call witnesses from among those individuals specified in paragraph (b)(1) of this section; and

(5) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

488.209 Hearing officer's findings.

(a) Within 30 days of the close of the hearing, the hearing officer will present the findings and recommendations to the accreditation organization or State laboratory program that requested the reconsideration.

(b) The written report of the hearing officer will include—

(1) Separate numbered findings of fact; and

(2) The legal conclusions of the hearing officer.

488.211 Final reconsideration determination.

(a) The hearing officer's decision is final unless the Administrator, within 30 days of the hearing officer's decision, chooses to review that decision.

(b) The Administrator may accept, reject or modify the hearing officer's findings.

(c) Should the Administrator choose to review the hearing officer's decision, the Administrator will issue a final reconsideration determination to the accreditation organization or State laboratory program on the basis of the hearing officer's findings and recommendations and other relevant information.

(d) The reconsideration determination of the Administrator is final.

(e) A final reconsideration determination against an accreditation organization or State laboratory program will be published by HCFA in the FEDERAL REGISTER.

Part 489—Provider Agreements and Supplier Approvals

42 CFR Part 489—Subpart A—General Provisions

489.1 Statutory basis.

This part implements section 1866 of the Social Security Act. Section 1866 specifies the terms of provider agreements, the grounds for terminating a provider agreement, the circumstances under which payment for new admissions may be denied, and the circumstances under which payment may be withheld for failure to make timely utilization review. The following other sections of that Act are also pertinent.

(a) Section 1861 defines the services covered under Medicare and the providers that may be reimbursed for furnishing those services.

(b) Section 1864 provides for the use of State survey agencies to ascertain whether certain entities meet the conditions of participation.

(c) Section 1871 authorizes the Secretary to prescribe regulations for the administration of the Medicare program.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 24492, July 3, 1986]

489.2 Scope of part.

(a) Subpart A of this part sets forth the basic requirements for submittal and acceptance of a provider agreement under Medicare. Subpart B of this part specifies the basic commitments and limitations that the provider must agree to as part of an agreement to provide services. Subpart C specifies the limitations on allowable charges to beneficiaries for deductibles, coinsurance, copayments, blood, and services that must be part of the provider agreement. Subpart D of this part specifies how incorrect collections are to be handled. Subpart F sets forth the circumstances and procedures for denial of payments for new admissions and for withholding of payment as an alternative to termination of a provider agreement.

(b) The following providers are subject to the provisions of this part:

(1) Hospitals.

(2) Skilled nursing facilities (SNFs).

(3) Home health agencies (HHAs).

(4) Clinics, rehabilitation agencies, and public health agencies.

(5) Comprehensive outpatient rehabilitation facilities (CORFs).

(6) Hospices.

(7) Rural primary care hospitals (RPCHs).

(8) Community mental health centers (CMHCs).

(c) (1) Clinics, rehabilitation agencies, and public health agencies may enter into provider agreements only for furnishing outpatient physical therapy, and speech pathology services.

(2) CMHCs may enter into provider agreements only to furnish partial hospitalization services.

[45 FR 22937, Apr. 4, 1980, as amended at 47 FR 56297, Dec. 15, 1982; 48 FR 56036, Dec. 15, 1983; 51 FR 24492, July 3, 1986; 58 FR 30676, May 26, 1993; 59 FR 6578, Feb. 11, 1994]

489.3 Definitions.

For purposes of this part—

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Provider agreement means an agreement between HCFA and one of the providers specified in 489.2(b) to provide services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act.

[48 FR 39837, Sept. 1, 1983, as amended at 51 FR 24492, July 3, 1986; 54 FR 5373, Feb. 2, 1989; 59 FR 56250, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

489.10 Basic requirements.

(a) Any of the providers specified in 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter.

(b) In order to participate in the Medicare program, the provider must meet the applicable civil rights requirements of:

(1) Title VI of the Civil Rights Act of 1964, as

implemented by 45 CFR part 80, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under, any program or activity receiving Federal financial assistance (section 601);

(2) Section 504 of the Rehabilitation Act of 1973, as implemented by 45 CFR part 84, which provides that no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subject to discrimination under any program or activity receiving Federal financial assistance;

(3) The Age Discrimination Act of 1975, as implemented by 45 CFR part 90, which is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Age Discrimination Act also permits federally assisted programs and activities, and recipients of Federal funds, to continue to use certain age distinctions, and factors other than age, that meet the requirements of the Age Discrimination Act and 45 CFR part 90; and

(4) Other pertinent requirements of the Office of Civil Rights of HHS.

(c) In order for a hospital, SNF, HHA, or hospice to be accepted, it must also meet the advance directives requirements specified in subpart I of this part.

(d) The State survey agency will ascertain whether the provider meets the conditions of participation or requirements (for SNFs) and make its recommendations to HCFA.

[58 FR 61843, Nov. 23, 1993, as amended at 59 FR 6578, Feb. 11, 1994]

489.11 Acceptance of a provider as a participant.

(a) Action by HCFA. If HCFA determines that the provider meets the requirements, it will send the provider—

(1) Written notice of that determination; and

(2) Two copies of the provider agreement.

(b) Action by provider. If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to HCFA, together with a written statement indicating whether it has been adjudged insolvent or bankrupt in any State or Federal court, or whether any insolvency or bankruptcy actions are pending.

(c) Notice of acceptance. If HCFA accepts the agreement, it will return one copy to the provider with a written notice that—

(1) Indicates the dates on which it was signed by the provider's representative and accepted by HCFA;

(2) Specifies the effective date of the agreement; and

[45 FR 22937, Apr. 4, 1980, as amended at 59 FR 56251, Nov. 10, 1994]

489.12 Decision to deny an agreement.

(a) Bases for denial. HCFA may refuse to enter into an agreement for any of the following reasons:

(1) Principals of the prospective provider have been convicted of fraud (see 420.204 of this chapter);

(2) The prospective provider has failed to disclose ownership and control interests in accordance with 420.206 of this chapter; or

(3) The prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(b) [Reserved]

(c) Compliance with civil rights requirements. HCFA will not enter into a provider agreement if the provider fails to comply with civil rights requirements set forth in 45 CFR parts 80, 84, and 90, subject to the provisions of 489.10.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 34833, Sept. 30, 1986; 54 FR 4027, Jan. 27. 1989; 59 FR 6578, Feb. 11, 1994; 59 FR 56251, Nov. 10, 1994]

489.13 Effective date of agreement.

(a) All Federal requirements are met on the date of the survey. The agreement is effective on the date the on-site survey is completed if, on the date of the survey, the provider meets all Federal health and safety conditions of participation or requirements (for SNFs), and any other requirements imposed by HCFA.

(b) All Federal requirements are not met on the date

of the survey. If the provider fails to meet any of the requirements specified in paragraph (a) of this section, the agreement will be effective on the earlier of the following dates:

(1) The date on which the provider meets all requirements.

(2) Except for SNFs, the date on which the provider is found to meet all conditions of participation and submits a plan of correction acceptable to HCFA for lower-level deficiencies or an approvable waiver request, or both.

(3) The date on which a SNF—

(i) Is in substantial compliance, as defined in 488.301; and

(ii) Submits, if applicable, an approvable waiver request.

[59 FR 56251, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

489.18 Change of ownership or leasing: Effect on provider agreement.

(a) What constitutes change of ownership—

(1) Partnership. In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law, constitutes change of ownership.

(2) Unincorporated sole proprietorship. Transfer of title and property to another party constitutes change of ownership.

(3) Corporation. The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.

(4) Leasing. The lease of all or part of a provider facility constitutes change of ownership of the leased portion.

(b) Notice to HCFA. A provider who is contemplating or negotiating a change of ownership must notify HCFA.

(c) Assignment of agreement. When there is a change of ownership as specified in paragraph (a) of this section, the existing provider agreement will automatically be assigned to the new owner.

(d) Conditions that apply to assigned agreements. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Any existing plan of correction.

(2) Compliance with applicable health and safety standards.

(3) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C, of this chapter.

(4) Compliance with civil rights requirements set forth in 45 CFR Parts 80, 84, and 90.

(e) Effect of leasing. The provider agreement will be assigned to the lessee only to the extent of the leased portion of the facility.

[45 FR 22937, Apr. 4, 1980, as amended at 59 FR 56251, Nov. 10, 1994]

42 CFR Part 489—Subpart B—Essentials of Provider Agreements

489.20 [Amended] Basic commitments.
[Amended by: 60 FR 63123—12/08/95—MEDICARE PROGRAM; PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 1996; PAYMENT POLICIES AND RELATIVE VALUE UNIT ADJUSTMENTS; FINAL RULE AND NOTICE] The provider agrees to the following:

(a) To limit its charges to beneficiaries and to other individuals on their behalf, in accordance with provisions of subpart C of this part.

(b) To comply with the requirements of subpart D of this part for the return or other disposition of any amounts incorrectly collected from a beneficiary or any other person in his or her behalf.

(c) To comply with the requirements of 420.203 of this chapter when it hires certain former employees of intermediaries.

(d) In the case of a hospital or an RPCH that furnishes services to Medicare beneficiaries, either to furnish directly or to make arrangements (as defined in 409.3 of this chapter) for all Medicare-covered services to inpatients of a hospital or an RPCH except the following:

(1) Physicians' services that meet the criteria of 405.550(b) of this chapter for payment on a reasonable charge basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act, that are furnished after December 31, 1990.

(3) Certified nurse-midwife services, as defined in section 1861(ff) of the Act, that are furnished after December 31, 1990.

(4) Qualified psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(5) Services of an anesthetist, as defined in 410.69 of this chapter.

(e) In the case of a hospital or RPCH that furnishes inpatient hospital services or inpatient RPCH services for which payment may be made under Medicare, to maintain an agreement with a PRO for that organization to review the admissions, quality, appropriateness, and diagnostic information related to those inpatient services. The requirement of this paragraph (e) applies only if, for the area in which the hospital or RPCH is located, there is a PRO that has a contract with HCFA under part B of title XI of the Act.

(f) To maintain a system that, during the admission process, identifies any primary payers other than Medicare, so that incorrect billing and Medicare overpayments can be prevented.

(g) To bill other primary payers before billing Medicare except when the primary payer is a liability insurer and except as provided in paragraph (j) of this section.

(h) If the provider receives payment for the same services from Medicare and another payer that is primary to Medicare, to reimburse Medicare any overpaid amount within 60 days.

(i) If the provider receives, from a payer that is primary to Medicare, a payment that is reduced because the provider failed to file a proper claim—

(1) To bill Medicare for an amount no greater than would have been payable as secondary payment if the primary insurer's payment had been based on a proper claim; and

(2) To charge the beneficiary only:

(i) The amount it would have been entitled to charge if it had filed a proper claim and received payment based on such a claim; and

(ii) An amount equal to any third party payment reduction attributable to failure to file a proper claim, but only if the provider can show that—

(A) It failed to file a proper claim solely because the beneficiary, for any reason other than mental or physical incapacity, failed to give the provider the necessary information; or

(B) The beneficiary, who was responsible for filing a proper claim, failed to do so for any reason other than mental or physical incapacity.

(j) In the State of Oregon, because of a court decision, and in the absence of a reversal on appeal or a statutory clarification overturning the decision,

hospitals may bill liability insurers first. However, if the liability insurer does not pay "promptly," as defined in 411.50 of this chapter, the hospital must withdraw its claim or lien and bill Medicare for covered services.

(k) In the case of home health agencies that provide home health services to Medicare beneficiaries under subpart E of part 409 and subpart C of part 410 of this chapter, to offer to furnish catheters, catheter supplies, ostomy bags, and supplies related to ostomy care to any individual who requires them as part of their furnishing of home health services.

(l) In the case of a hospital as defined in 489.24(b) to comply with 489.24.

(m) In the case of a hospital as defined in 489.24(b), to report to HCFA or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of 489.24(d).

(n) In the case of inpatient hospital services, to participate in any health plan contracted for under 10 U.S.C. 1079 or 1086 or 38 U.S.C. 613, in accordance with 489.25.

(o) In the case of inpatient hospital services, to admit veterans whose admission has been authorized under 38 U.S.C. 603, in accordance with 489.26.

(p) In the case of a hospital that participates in the Medicare program, to comply with 489.27 by giving each beneficiary a notice about his or her discharge rights at or about the time of the individual's admission.

(q) In the case of a hospital as defined in 489.24(b)—

(1) To post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area), a sign (in a form specified by the Secretary) specifying rights of individuals under Section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and

(2) To post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital participates in the Medicaid program under a State plan approved under title XIX.

(r) In the case of a hospital as defined in 489.24(b) (including both the transferring and receiving hospitals), to maintain—

(1) Medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer;

(2) A list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition; and

(3) A central log on each individual who comes to the emergency department, as defined in 489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

[45 FR 22937, Apr. 4, 1980, as amended at 48 FR 39837, Sept. 1, 1983; 49 FR 323, Jan. 3, 1984; 54 FR 41747, Oct. 11, 1989; 57 FR 36018, Aug. 12, 1992; 58 FR 30677, May 26, 1993; 59 FR 32120, June 22, 1994]

EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, in 489.20, paragraphs (l) through (r) were added. Paragraphs (m), (r)(2) and (r)(3) contain information collection and recordkeeping requirements and will not become effective until approved by the Office of Management and Budget. A document will be published in the FEDERAL REGISTER once approval has been obtained.

489.21 [Amended] Specific limitations on charges. [Amended by: 60 FR 63123—12/08/95—MEDICARE PROGRAM; PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 1996; PAYMENT POLICIES AND RELATIVE VALUE UNIT ADJUSTMENTS; FINAL RULE AND NOTICE]

Except as specified in subpart C of this part, the provider agrees not to charge a beneficiary for any of the following:

(a) Services for which the beneficiary is entitled to have payment made under Medicare.

(b) Services for which the beneficiary would be entitled to have payment made if the provider—

(1) Had in its files the required certification and

recertification by a physician relating to the services furnished to the beneficiary;

(2) Had furnished the information required by the intermediary in order to determine the amount due the provider on behalf of the individual for the period with respect to which payment is to be made or any prior period;

(3) Had complied with the provisions requiring timely utilization review of long stay cases so that a limitation on days of service has not been imposed under section 1866(d) of the Act (see subpart K of part 405 and part 482 of this chapter for utilization review requirements); and

(4) Had obtained, from the beneficiary or a person acting on his or her behalf, a written request for payment to be made to the provider, and had properly filed that request. (If the beneficiary or person on his or her behalf refuses to execute a written request, the provider may charge the beneficiary for all services furnished to him or her.)

(c) Inpatient hospital services furnished to a beneficiary who exhausted his or her Part A benefits, if HCFA reimburses the provider for those services.

(d) Custodial care and services not reasonable and necessary for the diagnosis or treatment of illness or injury, if—

(1) The beneficiary was without fault in incurring the expenses; and

(2) The determination that payment was incorrect was not made until after the third year following the year in which the payment notice was sent to the beneficiary.

(e) Inpatient hospital services for which a beneficiary would be entitled to have payment made under Part A of Medicare but for a denial or reduction in payments under regulations at 412.48 of this chapter or under section 1886(f) of the Act.

(f) Items and services furnished to a hospital inpatient (other than physicians' services as described in 405.550(b) of this chapter or the services of an anesthetist as described in 405.553(b)(4) of this chapter) for which Medicare payment would be made if furnished by the hospital or by other providers or suppliers under arrangements made with them by the hospital. For this purpose, a charge by another provider or supplier for such an item or service is treated as a charge by the hospital for the item or service, and is also prohibited.

(g) Items and services furnished in connection with the implantation of cardiac pacemakers or pacemaker leads when HCFA denies payment for those devices under 409.19 or 410.64 of this chapter.

[49 FR 324, Jan. 3, 1984, as amended at 51 FR 22052, June 17, 1986; 52 FR 27765, July 23, 1987]

489.22 Special provisions applicable to prepayment requirements.

(a) A provider may not require an individual entitled to hospital insurance benefits to prepay in part or in whole for inpatient services as a condition of admittance as an inpatient, except where it is clear upon admission that payment under Medicare, Part A cannot be made.

(b) A provider may not deny covered inpatient services to an individual entitled to have payment made for those services on the ground of inability or failure to pay a requested amount at or before admission.

(c) A provider may not evict, or threaten to evict, an individual for inability to pay a deductible or a coinsurance amount required under Medicare.

(d) A provider may not charge an individual for

(1) its agreement to admit or readmit the individual on some specified future date for covered impatient services; or

(2) for failure to remain an inpatient for any agreed-upon length of time or for failure to give advance notice of departure from the provider's facilities.

489.24 Special responsibilities of Medicare hospitals in emergency cases.

(a) General. In the case of a hospital that has an emergency department, if any individual (whether or not eligible for Medicare benefits and regardless of ability to pay) comes by him or herself or with another person to the emergency department and a request is made on the individual's behalf for examination or treatment of a medical condition by qualified medical personnel (as determined by the hospital in its rules and regulations), the hospital must provide for an appropriate medical screening examination within the capability of the hospital's emergency department, including

ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examinations must be conducted by individuals determined qualified by hospital by-laws or rules and regulations and who meet the requirements of 482.55 concerning emergency services personnel and direction.

(b) Definitions. As used in this subpart—

Capacity means the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. Capacity encompasses such things as numbers and availability of qualified staff, beds and equipment and the hospital's past practices of accommodating additional patients in excess of its occupancy limits.

Comes to the emergency department means, with respect to an individual requesting examination or treatment, that the individual is on the hospital property (property includes ambulances owned and operated by the hospital, even if the ambulance is not on hospital grounds). An individual in a nonhospital-owned ambulance on hospital property is considered to have come to the hospital's emergency department. An individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital's emergency department, even if a member of the ambulance staff contacts the hospital by telephone or telemetry communications and informs the hospital that they want to transport the individual to the hospital for examination and treatment. In such situations, the hospital may deny access if it is in "diversionary status," that is, it does not have the staff or facilities to accept any additional emergency patients. If, however, the ambulance staff disregards the hospital's instructions and transports the individual on to hospital property, the individual is considered to have come to the emergency department. Emergency medical condition means—

(i) A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part; or

(ii) With respect to a pregnant woman who is having contractions—

(A) That there is inadequate time to effect a safe transfer to another hospital before delivery; or

(B) That transfer may pose a threat to the health or safety of the woman or the unborn child.

Hospital includes a rural primary care hospital as defined in section 1861(mm)(1) of the Act.

Hospital with an emergency department means a hospital that offers services for emergency medical conditions (as defined in this paragraph) within its capability to do so.

Labor means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor unless a physician certifies that, after a reasonable time of observation, the woman is in false labor.

Participating hospital means

(i) a hospital or

(ii) a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Stabilized means, with respect to an "emergency medical condition" as defined in this section under paragraph (i) of that definition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility or, with respect to an "emergency medical condition" as defined in this section under paragraph

(ii) of that definition, that the woman has delivered the child and the placenta.

To stabilize means, with respect to an "emergency medical condition" as defined in this section under paragraph (i) of that definition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility or that, with respect to an "emergency medical condition" as defined in this section under paragraph (ii) of that definition, the woman has delivered the child and the placenta.

Transfer means the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who

(i) has been declared dead, or

(ii) leaves the facility without the permission of any such person.

(c) Necessary stabilizing treatment for emergency medical conditions—

(1) General. If any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—

(i) Within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition; or

(ii) For transfer of the individual to another medical facility in accordance with paragraph (d) of this section.

(2) Refusal to consent to treatment. A hospital meets the requirements of paragraph (c)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) refuses to consent to the examination and treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

(3) Delay in examination or treatment. A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (c) in order to inquire about the individual's method of payment or insurance status.

(4) Refusal to consent to transfer. A hospital meets the requirements of paragraph (c)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (d) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) refuses to consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

(d) Restricting transfer until the individual is stabilized—

(1) General. If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b)

of this section), the hospital may not transfer the individual unless—

(i) The transfer is an appropriate transfer (within the meaning of paragraph (d)(2) of this section); and

(ii) (A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer;

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or rules and regulations) has signed a certification described in paragraph (d)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which—

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(ii) The receiving facility—

(A) Has available space and qualified personnel for the treatment of the individual; and

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (d)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (f) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

(3) A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (d)(1)(ii)(C) of this section because the

physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.

(e) Recipient hospital responsibilities. A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.

(f) Termination of provider agreement. If a hospital fails to meet the requirements of paragraph (a) through (e) of this section, HCFA may terminate the provider agreement in accordance with 489.53.

(g) Consultation with Peer Review Organizations (PROs)—

(1) General. Except as provided in paragraph (g)(3) of this section, in cases where a medical opinion is necessary to determine a physician's or hospital's liability under section 1867(d)(1) of the Act, HCFA requests the appropriate PRO (with a contract under Part B of title XI of the Act) to review the alleged section 1867(d) violation and provide a report on its findings in accordance with paragraph (g)(2)(iv) and (v) of this section. HCFA provides to the PRO all information relevant to the case and within its possession or control. HCFA, in consultation with the OIG, also provides to the PRO a list of relevant questions to which the PRO must respond in its report.

(2) Notice of review and opportunity for discussion and additional information. The PRO shall provide the physician and hospital reasonable notice of its review, a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. When a PRO receives a request for consultation under paragraph (g)(1) of this section, the following provisions apply—

(i) The PRO reviews the case before the 15th calendar day and makes its tentative findings.

(ii) Within 15 calendar days of receiving the case, the PRO gives written notice, sent by certified mail, return receipt requested, to the physician or the hospital (or both if applicable).

(iii) (A) The written notice must contain the following information:

(1) The name of each individual who may have been the subject of the alleged violation.

(2) The date on which each alleged violation occurred.

(3) An invitation to meet, either by telephone or in person, to discuss the case with the PRO, and to submit additional information to the PRO within 30 calendar days of receipt of the notice, and a statement that these rights will be waived if the invitation is not accepted. The PRO must receive the information and hold the meeting within the 30-day period.

(4) A copy of the regulations at 42 CFR 489.24.

(B) For purposes of paragraph (g)(2)(iii)(A) of this section, the date of receipt is presumed to be 5 days after the certified mail date on the notice, unless there is a reasonable showing to the contrary.

(iv) The physician or hospital (or both where applicable) may request a meeting with the PRO. This meeting is not designed to be a formal adversarial hearing or a mechanism for discovery by the physician or hospital. The meeting is intended to afford the physician and/or the hospital a full and fair opportunity to present the views of the physician and/or hospital regarding the case. The following provisions apply to that meeting:

(A) The physician and/or hospital has the right to have legal counsel present during that meeting. However, the PRO may control the scope, extent, and manner of any questioning or any other presentation by the attorney. The PRO may also have legal counsel present.

(B) The PRO makes arrangements so that, if requested by HCFA or the OIG, a verbatim transcript of the meeting may be generated. If HCFA or OIG requests a transcript, the affected physician and/or the affected hospital may request that HCFA provide a copy of the transcript.

(C) The PRO affords the physician and/or the hospital an opportunity to present, with the assistance of counsel, expert testimony in either oral or written form on the medical issues presented. However, the PRO may reasonably limit the number of witnesses and length of such testimony if such testimony is irrelevant or repetitive. The physician and/or hospital, directly or through counsel, may disclose patient records to potential expert witnesses without violating any non-disclosure requirements set forth in part 476 of this chapter.

(D) The PRO is not obligated to consider any additional information provided by the physician and/or the hospital after the meeting, unless, before the end of the meeting, the PRO requests that the physician and/or hospital submit additional information to support the claims. The PRO then allows the physician and/or the hospital an additional period of time, not to exceed 5 calendar days from the meeting, to submit the relevant information to the PRO.

(v) Within 60 calendar days of receiving the case, the PRO must submit to HCFA a report on the PRO's findings. HCFA provides copies to the OIG and to the affected physician and/or the affected hospital. The report must contain the name of the physician and/or the hospital, the name of the individual, and the dates and times the individual arrived at and was transferred (or discharged) from the hospital. The report provides expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there were any medical utilization or quality of care issues involved in the case.

(vi) The report required under paragraph (g)(2)(v) of this section should not state an opinion or conclusion as to whether section 1867 of the Act or 489.24 has been violated.

(3) If a delay would jeopardize the health or safety of individuals or when there was no screening examination, the PRO review described in this section is not required before the OIG may impose civil monetary penalties or an exclusion in accordance with section 1867(d)(1) of the Act and 42 CFR part 1003 of this title.

(4) If the PRO determines after a preliminary review that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, as defined by paragraph (b) of this section, then the PRO may, at its discretion, return the case to HCFA and not meet the requirements of paragraph (g) except for those in paragraph (g)(2)(v).

(h) Release of PRO assessments. Upon request, HCFA may release a PRO assessment to the physician and/or hospital, or the affected individual, or his or her representative. The PRO physician's identity is confidential unless he or she consents to its release. (See 476.132 and 476.133 of this chapter.)

[59 FR 32120, June 22, 1994]

EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, 489.24 was added. Paragraphs (d) and (g) contain information collection and recordkeeping requirements and will not become effective until

approved by the Office of Management and Budget. A document will be published in the FEDERAL REGISTER once approval has been obtained.

489.25 Special requirements concerning CHAMPUS and CHAMPVA programs.

For inpatient services, a hospital that participates in the Medicare program must participate in any health plan contracted under 10 U.S.C. 1079 or 1086 (Civilian Health and Medical Program of the Uniformed Services) and under 38 U.S.C. 613 (Civilian Health and Medical Program of the Veterans Administration) and accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full, less applicable deductible, patient cost-share, and noncovered items. Hospitals must meet the requirements of 32 CFR part 199 concerning program benefits under the Department of Defense. This section applies to inpatient services furnished to beneficiaries admitted on or after January 1, 1987.

[59 FR 32123, June 22, 1994]

489.26 Special requirements concerning veterans.

For inpatient services, a hospital that participates in the Medicare program must admit any veteran whose admission is authorized by the Department of Veterans Affairs under 38 U.S.C. 603 and must meet the requirements of 38 CFR part 17 concerning admissions practices and payment methodology and amounts. This section applies to services furnished to veterans admitted on and after July 1, 1987.

[59 FR 32123, June 22, 1994]

489.27 [Revised] Beneficiary notice of discharge rights.

[Revised by: 61 FR 27443—5/31/96—MEDICARE PROGRAM; CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 1997 RATES]

[Amended by: 61 FR 46165—08/30/96—MEDICARE PROGRAM; CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 1997 RATES]

A hospital that participates in the Medicare program must furnish each Medicare beneficiary, or an individual acting on his or her behalf, the notice of discharge rights HCFA supplies to the hospital to implement section 1886(a)(1)(M) of the Act. The hospital must furnish the statement at or about the time of admission. The hospital must be able to demonstrate compliance with this requirement. This provision is effective with admissions beginning on or after July 22, 1994.

[59 FR 32123, June 22, 1994]

42 CFR Part 489—Subpart C—Allowable Charges

489.30 Allowable charges: Deductibles and coinsurance.

(a) Part A deductible and coinsurance. The provider may charge the beneficiary or other person on his or her behalf:

(1) The amount of the inpatient hospital deductible or, if less, the actual charges for the services;

(2) The amount of inpatient hospital coinsurance applicable for each day the individual is furnished inpatient hospital services after the 60th day, during a benefit period; and

(3) The posthospital SNF care coinsurance amount.

(4) In the case of durable medical equipment (DME) furnished as a home health service, 20 percent of the customary charge for the service.

(b) Part B deductible and coinsurance.

(1) The basic allowable charges are the $75 deductible and 20 percent of the customary (insofar as reasonable) charges in excess of that deductible.

(2) For hospital outpatient services, the allowable deductible charges depend on whether the hospital can determine the beneficiary's deductible status.

(i) If the hospital is unable to determine the deductible status, it may charge the beneficiary its full customary charges up to $75.

(ii) If the beneficiary provides official information as to deductible status, the hospital may charge only the unmet portion of the deductible.

(3) In either of the cases discussed in paragraph (b)(2) of this section, the hospital is required to file with the intermediary, on a form prescribed by HCFA, information as to the services, charges, and amounts collected.

(4) The intermediary must reimburse the beneficiary if reimbursement is authorized and credit the expenses to the beneficiary's deductible if the deductible has not yet been met.

(5) In the case of DME furnished as a home health service under Medicare Part B, the coinsurance is 20 percent of the customary (insofar as reasonable) charge for the services, with the following exception: If the DME is used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for comparable new equipment, no coinsurance is required.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 41350, Nov. 14, 1986]

489.31 Allowable charges: Blood.

(a) Limitations on charges.

(1) A provider may charge the beneficiary (or other person on his or her behalf) only for the first three pints of blood or units of packed red cells furnished under Medicare Part A during a calendar year, or furnished under Medicare Part B during a calendar year.

(2) The charges may not exceed the provider's customary charges.

(3) The provider may not charge for any whole blood or packed red cells in any of the circumstances specified in 409.87(c)(2) of this chapter.

(b) Offset for excessive charges. If the charge exceeds the cost to the provider, that excess will be deducted from any Medicare payments due the provider.

[56 FR 23022, May 20, 1991, as amended at 57 FR 36018, Aug. 12, 1992]

489.32 Allowable charges: Noncovered and partially covered services.

(a) Services requested by beneficiary. If services furnished at the request of a beneficiary (or his or her representative) are more expensive than, or in excess of, services covered under Medicare—

(1) A provider may charge the beneficiary an amount that does not exceed the difference between—

(i) The provider's customary charges for the services furnished; and

(ii) The provider's customary charges for the kinds and amounts of services that are covered under Medicare.

(2) A provider may not charge for the services unless they have been requested by the beneficiary (or his or her representative) nor require a beneficiary to request services as a condition of admission.

(3) To avoid misunderstanding and disputes, a provider must inform any beneficiary who requests a service for which a charge will be made that there will be a specified charge for that service.

(b) Services not requested by the beneficiary. For special provisions that apply when a provider customarily furnishes more expensive services, see 413.35 of this chapter.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 34833, Sept. 30, 1986]

489.34 Allowable charges: Hospitals participating in State reimbursement control systems or demonstration projects.

A hospital receiving payment for a covered hospital stay under either a State reimbursement control system approved under 1886(c) of the Act or a demonstration project authorized under section 402(a) of Pub. L. 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Pub. L. 92603 (42 U.S.C. 1395b-1 (note)) and that would otherwise be subject to the prospective payment system set forth in part 412 of this chapter may charge a beneficiary for noncovered services as follows:

(a) For the custodial care and medically unnecessary services described in 412.42(c) of this chapter, after the conditions of 412.42(c)(1) through (c)(4) are met; and

(b) For all other services in accordance with the applicable rules of this subpart C.

[54 FR 41747, Oct. 11, 1989]

489.35 Notice to intermediary.

The provider must inform its intermediary of any amounts collected from a beneficiary or from other persons on his or her behalf.

42 CFR Part 489—Subpart D—Handling of Incorrect Collections

489.40 Definition of incorrect collection.

(a) As used in this subpart, "incorrect collections" means any amounts collected from a beneficiary (or someone on his or her behalf) that are not authorized under subpart C of this part.

(b) A payment properly made to a provider by an individual not considered entitled to Medicare benefits will be deemed to be an "incorrect collection" when the individual is found to be retroactively entitled to benefits.

489.41 Timing and methods of handling.

(a) Refund. Prompt refund to the beneficiary or other person is the preferred method of handling incorrect collections.

(b) Setting aside. If the provider cannot refund within 60 days from the date on the notice of incorrect collection, it must set aside an amount, equal to the amount incorrectly collected, in a separate account identified as to the individual to whom the payment is due. This amount incorrectly collected must be carried on the provider's records in this manner until final disposition is made in accordance with the applicable State law.

(c) Notice to, and action by, intermediary.

(1) The provider must notify the intermediary of the refund or setting aside required under paragraphs (a) and (b) of this section.

(2) If the provider fails to refund or set aside the required amounts, they may be offset against amounts otherwise due the provider.

489.42 Payment of offset amounts to beneficiary or other person.

(a) In order to carry out the commitment to refund amounts incorrectly collected, HCFA may determine that amounts offset in accordance with 489.41 are to be paid directly to the beneficiary or other person from whom the provider received the incorrect collection, if:

(1) HCFA finds that the provider has failed, following written request, to refund the amount of the incorrect collection to the beneficiary or other person; and

(2) The provider agreement has been terminated in accordance with the provisions of subpart E of this part.

(b) Before making a determination to make payment under paragraph (a) of this section, HCFA will give written notice to the provider

(1) explaining that an incorrect collection was made and the amount;

(2) requesting the provider to refund the incorrect collection to the beneficiary or other person; and

(3) advising of HCFA's intention to make a determination under paragraph (a) of this section.

(c) The notice will afford an authorized official of the provider an opportunity to submit, within 20 days from the date on the notice, written statement or evidence with respect to the incorrect collection and/or offset amounts. HCFA will consider any written statement or evidence in making a determination.

(d) Payment to a beneficiary or other person under the provisions of paragraph (a) of this section:

(1) Will not exceed the amount of the incorrect collection; and

(2) May be considered as payment made to the provider.

42 CFR Part 489—Subpart E—Termination of Agreement and Reinstatement After Termination

489.52 Termination by the provider.

(a) Notice to HCFA.

(1) A provider that wishes to terminate its agreement must send HCFA written notice of its intent.

(2) The notice may state the intended date of termination which must be the first day of a month.

(b) Termination date.

(1) If the notice does not specify a date, or the date is not acceptable to HCFA, HCFA may set a date that will not be more than 6 months from the date on the provider's notice of intent.

(2) HCFA may accept a termination date that is less than 6 months after the date on the provider's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) A cessation of business is deemed to be a termination by the provider, effective with the date on which it stopped providing services to the community.

(c) Public notice.

(1) The provider must give notice to the public at least 15 days before the effective date of termination.

(2) The notice must be published in one or more local newspapers and must—

(i) Specify the termination date; and

(ii) Explain to what extent services may continue after that date, in accordance with the exceptions set forth in 489.55.

489.53 Termination by HCFA.

Basis for termination of agreement with any provider.

HCFA may terminate the agreement with any provider if HCFA finds that any of the following failings is attributable to that provider:

(1) It is not complying with the provisions of title XVIII and the applicable regulations of this chapter or with the provisions of the agreement.

(2) It places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

(3) It no longer meets the appropriate conditions of participation or requirements (for SNFs and NFs) set forth elsewhere in this chapter.

(4) It fails to furnish information that HCFA finds necessary for a determination as to whether payments are or were due under Medicare and the amounts due.

(5) It refuses to permit examination of its fiscal or other records by, or on behalf of HCFA, as necessary for verification of information furnished as a basis for payment under Medicare.

(6) It failed to furnish information on business transactions as required in 420.205 of this chapter.

(7) It failed at the time the agreement was entered into or renewed to disclose information on convicted individuals as required in 420.204 of this chapter.

(8) It failed to furnish ownership information as required in 420.206 of this chapter.

(9) It failed to comply with civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

(10) In the case of a hospital or a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has reason to believe it may have received an individual transferred by another hospital in violation of 489.24(d), the hospital failed to report the incident to HCFA or the State survey agency.

(11) In the case of a hospital requested to furnish inpatient services to CHAMPUS or CHAMPVA beneficiaries or to veterans, it failed to comply with 489.25 or 489.26, respectively.

(12) It failed to furnish the notice of discharge rights as required by 489.27.

(13) It refuses to permit photocopying of any records or other information by, or on behalf

of HCFA, as necessary to determine or verify compliance with participation requirements.

(14) In the case of a rural primary care hospital as defined in part 485, subpart F of this chapter, the rural primary care hospital maintains an average length of stay for inpatients in its most recent 12-month cost reporting period that is in excess of 72 hours. In determining the length of stay of a rural primary care hospital for purposes of this paragraph, HCFA does not take into account periods of stay in excess of 72 hours that occurred because transfer to a hospital was precluded because of inclement weather or other emergency conditions.

(b) Termination of provider agreement. In the case of a hospital or rural primary care hospital that has an emergency department, as defined in 489.24(b), HCFA may terminate the provider agreement if—

(1) The hospital fails to comply with the requirements of 489.24 (a) through (e), which require the hospital to examine, treat, or transfer emergency medical condition cases appropriately, and require that hospitals with specialized capabilities or facilities accept an appropriate transfer; or

(2) The hospital fails to comply with 489.20(m), (q), and (r), which require the hospital to report suspected violations of 489.24(d), to post conspicuously in emergency departments or in a place or places likely to be noticed by all individuals entering the emergency departments, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments, (that is, entrance, admitting area, waiting room, treatment area), signs specifying rights of individuals under this subpart, to post conspicuously information indicating whether or not the hospital participates in the Medicaid program, and to maintain medical and other records related to transferred individuals for a period of 5 years, a list of on-call physicians for individuals with emergency medical conditions, and a central log on each individual who comes to the emergency department seeking assistance.

(c) Notice of termination—

(1) Timing: Basic rule. Except as provided in 488.456 of this chapter, HCFA gives the provider notice of termination at least 15 days before the effective date of termination of the provider agreement.

(2) Immediate jeopardy deficiencies. For a provider or supplier with deficiencies that pose immediate jeopardy to residents' or patients' health or safety, HCFA gives notice of termination at least 2 days before the effective date of termination of the provider agreement.

(3) Content of notice. The notice states the reasons for, and the effective date of, the termination, and explains the extent to which services may continue after that date, in accordance with 489.55.

(4) Notice to public. HCFA concurrently gives notice of the termination to the public.

(d) Appeal by the provider. A provider may appeal the termination of its provider agreement by HCFA in accordance with part 498 of this chapter.

[51 FR 24492, July 3, 1986, as amended at 52 FR 22454, June 12, 1987; 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 59 FR 32123, June 22, 1994; 59 FR 56251, Nov. 10, 1994; 60 FR 45851, Sept. 1, 1995; 60 FR 50119, Sept. 28, 1995]

489.54 Termination by the OIG.

(a) Basis for termination.

(1) The OIG may terminate the agreement of any provider if the OIG finds that any of the following failings can be attributed to that provider.

(i) It has knowingly and willfully made, or caused to be made, any false statement or representation of a material fact for use in an application or request for payment under Medicare.

(ii) It has submitted, or caused to be submitted, requests for Medicare payment of amounts that substantially exceed the costs it incurred in furnishing the services for which payment is requested.

(iii) It has furnished services that the OIG has determined to be substantially in excess of the needs of individuals or of a quality that fails to meet professionally recognized standards of health care. The

OIG will not terminate a provider agreement under paragraph (a) if HCFA has waived a disallowance with respect to the services in question on the grounds that the provider and the beneficiary could not reasonably be expected to know that payment would not be made. (The rules for determining such lack of knowledge are set forth in 405.330 through 405.334 of this chapter.)

(b) Notice of termination. The OIG will give the provider notice of termination at least 15 days before the effective date of termination of the agreement, and will concurrently give notice of termination to the public.

(c) Appeal by the provider. A provider may appeal a termination of its agreement by the OIG in accordance with subpart O of part 405 of this chapter.

(d) Other applicable rules. The termination of a provider agreement by the OIG is subject to the additional procedures specified in 1001.105 through 1001.109 of this title for notice and appeals.

[51 FR 24492, July 3, 1986, as amended at 51 FR 34788, Sept. 30, 1986]

489.55 Exceptions to effective date of termination.

Payment is available for up to 30 days after the effective date of termination for—

(a) Inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who was admitted before the effective date of termination; and

(b) Home health services and hospice care furnished under a plan established before the effective date of termination.1

1 For termination before July 18, 1984, payment was available through the calendar year in which the termination was effective.

[50 FR 37376, Sept. 13, 1985]

489.57 Reinstatement after termination.

When a provider agreement has been terminated by HCFA under 489.53, or by the OIG under 489.54, a new agreement with that provider will not be accepted unless HCFA or the OIG, as appropriate, finds—

(a) That the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur; and

(b) That the provider has fulfilled, or has made satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilities of its previous agreement.

[51 FR 24493, July 3, 1986]

42 CFR Part 489—Subpart I—Advance Directives

SOURCE: 57 FR 8203, Mar. 6, 1992, unless otherwise noted.

489.100 Definition.

For purposes of this part, advance directive means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.

489.102 Requirements for providers.

(a) Hospitals, rural primary care hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care (and for Medicaid purposes, providers of personal care services), and hospices must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the provider and are required to:

(1) Provide written information to such individuals concerning—

(i) An individual's rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Providers are to update and disseminate amended information as soon as possible, but no later than 90 days from the effective date of the changes to State law; and

(ii) The written policies of the provider or organization respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience. At a minimum, a provider's statement of limitation should:

(A) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(B) Identify the state legal authority permitting such objection; and

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(2) Document in the individual's medical record whether or not the individual has executed an advance directive;

(3) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(4) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives. The provider must inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

(5) Provide for education of staff concerning its policies and procedures on advance directives; and

(6) Provide for community education regarding issues concerning advance directives that may include material required in paragraph (a)(1) of this section, either directly or in concert with other providers and organizations. Separate community education materials may be developed and used, at the discretion of providers. The same written materials do not have to be provided in all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. A

provider must be able to document its community education efforts.

(b) The information specified in paragraph (a) of this section is furnished:

(1) In the case of a hospital, at the time of the individual's admission as an inpatient.

(2) In the case of a skilled nursing facility at the time of the individual's admission as a resident.

(3) (i) In the case of a home health agency, in advance of the individual coming under the care of the agency. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(ii) In the case of personal care services, in advance of the individual coming under the care of the personal care services provider. The personal care provider may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(4) In the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program.

(c) The providers listed in paragraph (a) of this section—

(1) Are not required to provide care that conflicts with an advance directive.

(2) Are not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(d) Prepaid or eligible organizations (as specified in sections 1833(a)(1)(A) and 1876(b) of the Act) must meet the requirements specified in 417.436 of this chapter.

(e) If an adult individual is incapacitated at the time of admission or at the start of care and is unable to receive information (due to the incapacitating conditions or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the provider may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The provider is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

[57 FR 8203, Mar. 6, 1992, as amended at 59 FR 45403, Sept. 1, 1994; 60 FR 33294, June 27, 1995]

489.104 Effective dates.

These provisions apply to services furnished on or after December 1, 1991 payments made under section 1833(a)(1)(A) of the Act on or after December 1, 1991, and contracts effective on or after December 1, 1991. Pt. 491

CFR Part 493—Laboratory Requirements

42 CFR Part 493—Subpart A—General Provisions

SOURCE: 57 FR 7139, Feb. 28, 1992, unless otherwise noted.

493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in 493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

493.2 Definitions.

As used in this part, unless the context indicates otherwise Accredited institution means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Accredited laboratory means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by HCFA in accordance with this part;

Adverse action means the imposition of a principal or alternative sanction by HCFA.

ALJ stands for Administrative Law Judge.

Alternative sanctions means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with "intermediate sanctions" as used in section 1846 of the Act.

Analyte means a substance or constituent for which the laboratory conducts testing.

Approved accreditation organization for laboratories means a private, nonprofit accreditation organization that has formally applied for and received HCFA's approval based on the organization's compliance with this part.

Approved State laboratory program means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received HCFA approval based on the State's compliance with this part.

Authorized person means an individual authorized under State law to order tests or receive test results, or both.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA means the Clinical Laboratory Improvement Amendments of 1988.

CLIA certificate means any of the following types of certificates issued by HCFA or its agent:

(1) Certificate of compliance means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with 493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) Certificate for provider-performed microscopy (PPM) procedures means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with 493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in 493.15(c).

(3) Certificate of accreditation means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by HCFA (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with 493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) Certificate of registration or registration certificate means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with 493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by HCFA or its agent; or in accordance with 493.57 to an entity that is accredited by an approved accreditation organization.

(5) Certificate of waiver means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with 493.37, to a laboratory to perform only the waived tests listed at 493.15(c).

CLIA-exempt laboratory means a laboratory that has been licensed or approved by a State where HCFA has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by HCFA in accordance with subpart E of this part.

Condition level deficiency means noncompliance with one or more condition level requirements.

Condition level requirements means any of the requirements identified as "conditions" in subparts G through Q of this part.

Credible allegation of compliance means a statement or documentation that—

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

Dentist means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

Equivalency means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by HCFA, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as

(1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and

(2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

HCFA agent means an entity with which HCFA arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, nonprofit organization other than an approved accreditation organization, a component of HHS, or any other governmental component HCFA approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State's exemption request, the State survey agency is not the HCFA agent.

HHS means the Department of Health and Human Services, or its designee.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

Intentional violation means knowing and willful noncompliance with any CLIA condition.

Kit means all components of a test that are packaged together.

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or

other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Midlevel practitioner means a nurse midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

Party means a laboratory affected by any of the enforcement procedures set forth in this subpart, by HCFA or the OIG, as appropriate.

Performance characteristic means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

Performance specification means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

Physician means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

Principal sanction means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

Prospective laboratory means a laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIA certificates.

Rate of disparity means the percentage of sample validation inspections for a specific accreditation organization or State where HCFA, the State survey agency or other HCFA agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

EXAMPLE: Assume the State survey agency, HCFA or other HCFA agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more condition level requirements out of compliance. HCFA reviews the validation and accreditation organization's or State's inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

Referee laboratory means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

Reference range means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

Sample in proficiency testing means the material contained in a vial, on a slide, or other unit that contains

material to be tested by proficiency testing program participants. When possible, samples are of human origin.

State includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

State licensure means the issuance of a license to, or the approval of, a laboratory by a State laboratory program as meeting standards for licensing or approval established under State law.

State survey agency means the State health agency or other appropriate State or local agency that has an agreement under section 1864 of the Social Security Act and is used by HCFA to perform surveys and inspections.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

Target value for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group ("peer" group) may be used. If the method group is less than 10 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

Unsatisfactory proficiency testing performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

Unsuccessful participation in proficiency testing means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at 493.855.

Unsuccessful proficiency testing performance means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

Validation review period means the one year time period during which HCFA conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

[57 FR 7139, Feb. 28, 1992, as amended at 57 FR 7236, Feb. 28, 1992; 57 FR 34013, July 31, 1992; 57 FR 35761, Aug. 11, 1992; 58 FR 5220, Jan. 19, 1993; 58 FR 48323, Sept. 15, 1993; 60 FR 20043, Apr. 24, 1995]

493.3 Applicability.

(a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it -

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is CLIA-exempt.

(b) Exception. These rules do not apply to components or functions of -

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the National Institutes on Drug Abuse (NIDA), in which drug testing is performed which meets NIDA guidelines and regulations. However, all other testing conducted by a NIDA-certified laboratory is subject to this rule.

(c) Federal laboratories. Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993; 60 FR 20043, Apr. 24, 1995]

493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in 493.2:

(1) Certificate of registration or registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate of compliance.

(5) Certificate of accreditation.

[60 FR 20043, Apr. 24, 1995]

493.15 Laboratories performing waived tests.

(a) Requirement. Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) Criteria. Test systems are simple laboratory examinations and procedures which -

(1) Are cleared by FDA for home use;

(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:

(1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:

(i) Bilirubin;

(ii) Glucose;

(iii) Hemoglobin;

(iv) Ketone;

(v) Leukocytes;

(vi) Nitrite;

(vii)pH;

(viii) Protein;

(ix) Specific gravity; and

(x) Urobilinogen.

(2) Fecal occult blood;

(3) Ovulation tests - visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests—visual color comparison tests;

(5) Erythrocyte sedimentation rate—non-automated;

(6) Hemoglobin—copper sulfate—non-automated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

(8) Spun microhematocrit; and

(9) Hemoglobin by single analyte instruments with selfcontained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

(d) Revisions to criteria for test categorization and the list of waived tests. HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.

(e) Laboratories eligible for a certificate of waiver must—

(1) Follow manufacturers' instructions for performing the test; and

(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993]

493.17 Test categorization.

(a) Categorization by criteria. Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

NOTE: A score of "2" will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of "1" and "3."

(1) Knowledge.

(i) Score 1.

(A) Minimal scientific and technical knowledge is required to perform the test; and

(B) Knowledge required to perform the test may be obtained through on-the-job instruction.

(ii) Score 3. Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing.

(2) Training and experience.

(i) Score 1.

(A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and

(B) Limited experience is required to perform the test.

(ii) Score 3.

(A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; or

(B) Substantial experience may be necessary for analytic test performance.

(3) Reagents and materials preparation.

(i) Score 1.

(A) Reagents and materials are generally stable and reliable; and

(B) Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions.

(ii) Score 3.

(A) Reagents and materials may be labile and may require special handling to assure reliability; or

(B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.

(4) Characteristics of operational steps.

(i) Score 1. Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

(ii) Score 3. Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.

(5) Calibration, quality control, and proficiency testing materials.

(i) Score 1.

(A) Calibration materials are stable and readily available;

(B) Quality control materials are stable and readily available; and

(C) External proficiency testing materials, when available, are stable.

(ii) Score 3.

(A) Calibration materials, if available, may be labile;

(B) Quality control materials may be labile, or not available; or

(C) External proficiency testing materials, if available, may be labile.

(6) Test system troubleshooting and equipment maintenance.

(i) Score 1.

(A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and

(B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.

(ii) Score 3.

(A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or

(B) Maintenance requires special knowledge, skills, and abilities.

(7) Interpretation and judgment.

(i) Score 1.

(A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and

(B) Resolution of problems requires limited independent interpretation and judgment; and

(ii) Score 3.

(A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and

(B) Resolution of problems requires extensive interpretation and judgment.

(b) Revisions to the criteria for categorization. The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(c) Process for device/test categorization utilizing the scoring system under 493.17(a).

(1) (i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both HCFA and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations:

(A) When categorizing previously uncategorized new technology;

(B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and

(C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75.

(ii) Test categorization will be effective as of the notification to the applicant.

(2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, HCFA, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization.

(3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

(4) If a laboratory test system, assay or examination does not appear on the lists of tests in the FEDERAL REGISTER notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant.

(5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993]

493.19 Provider-performed microscopy (PPM) procedures.

(a) Requirement. To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this section.

(b) Criteria. Procedures must meet the following specifications:

(1) The examination must be personally performed by one of the following practitioners:

(i) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.

(ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(iii) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

(2) The procedure must be categorized as moderately complex.

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.

(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result.

(5) Control materials are not available to monitor the entire testing process.

(6) Limited specimen handling or processing is required.

(c) Provider-performed microscopy (PPM) examinations. A laboratory may qualify to perform tests under this section if it restricts PPM examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others:

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.

(2) All potassium hydroxide (KOH) preparations.

(3) Pinworm examinations.

(4) Fern tests.

(5) Post-coital direct, qualitative examinations of vaginal or cervical mucous.

(6) Urine sediment examinations.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

(9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

(d) Revisions to criteria and the list of PPM procedures.

(1) The CLIAC conducts reviews upon HHS' request and recommends to HHS revisions to the criteria for categorization of procedures.

(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the FEDERAL REGISTER as a notice with an opportunity for public comment.

(e) Laboratory requirements. Laboratories eligible to perform PPM examinations must -

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and P of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

[60 FR 20044, Apr. 24, 1995]

493.20 Laboratories performing tests of moderate complexity.

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to waived tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity including the subcategory of PPM procedures.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, P, and Q of this part. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must

meet the inspection requirements at 493.1777.

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, M, and P of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in 493.15(e) and 493.1775.

[60 FR 20044, Apr. 24, 1995]

493.25 Laboratories performing tests of high complexity.

(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in 493.17(a).

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, P, and Q of this part.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, P, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at 493.1777.

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, M, and P are not applicable to the waived tests. However, the laboratory must comply with the requirements in 493.15(e) and 493.1775.

[57 FR 7139, Feb. 28, 1992, as amended at 60 FR 20044, Apr. 24, 1995]

42 CFR Part 493—Subpart B—Certificate of Waiver

SOURCE: 57 FR 7142, Feb. 28, 1992, unless otherwise noted.

493.35 Application for a certificate of waiver.

(a) Filing of application. Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in 493.15 must file a separate application for each laboratory location.

(b) Exceptions.

(1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) Application format and contents. The application must—

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes;

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) Access requirements. Laboratories that perform one or more waived tests listed in 493.15(c) and no other tests must meet the following conditions:

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and 493.15(e);

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

(ii) To evaluate complaints from the public.

(iii) On a random basis to determine whether the laboratory is performing tests not listed in 493.15.

(iv) To collect information regarding the appropriateness of waiver of tests listed in 493.15.(e) Denial of application. If HHS determines that the application for a certificate of waiver is to be denied, HHS will—

(1) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with the procedures set forth in subpart R of this part;

(2) Notify a laboratory that has its application for a certificate of waiver denied that it cannot operate as a laboratory under the PHS Act

unless the denial is overturned at the conclusion of the administrative appeals process provided by subpart R; and

(3) Notify the laboratory that it is not eligible for payment under the Medicare and Medicaid programs.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993;60 FR 20044, Apr. 24, 1995]

493.37 Requirements for a certificate of waiver.

(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of 493.35.

(b) Laboratories issued a certificate of waiver—

(1) Are subject to the requirements of this subpart and 493.15(e) of subpart A of this part; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.

(c) Laboratories must remit the certificate of waiver feespecified in subpart F of this part.

(d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(e)

(1) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination resulting in HHS action to revoke, suspend, or limit the laboratory's certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for appeal as provided in subpart R of this part.

(2) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate of waiver or reissued certificate of waiver until a decision is made by an administrative law judge, as specified in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(3) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(f) A laboratory seeking to renew its certificate of waivermust—

(1) Complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate; and

(2) Meet the requirements of 493.35 and 493.37.

(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not listed in the waiver test category must meet the requirements set forth in subpart C or subpart D of this part, as applicable.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993;60 FR 20045, Apr. 24, 1995]

493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in 493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under 493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

(b) Within 30 days of any change(s) in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

[57 FR 7142, Feb. 28, 1992, as amended at 60 FR 20045, Apr. 24, 1995]

CFR Part 498—Appeals Procedures for Determinations that Affect Participation In the Medicare Program

42 CFR Part 498—Subpart A—General Provisions

498.1 [Amended] Statutory basis.
[Amended by: 61 FR 32347—6/24/96—MEDICARE AND MEDICAID PROGRAMS; PROVIDER APPEALS: TECHNICAL AMENDMENTS]

(a) Section 1869(c) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Section 1128 (a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

(e) Section 1862(d) of the Act provides for the exclusion of individuals or entities that submit false claims, bill excessive charges or furnish substandard care.

(f) HFCA is responsible for implementing section 1869(c) of the Act, and section 1866 (b)(2), except subparagraphs (D), (E), and (F). The OIG is responsible for implementing the other cited sections.

(g) Although sections 1866 and 1869 of the Act are silent regarding appeal rights for suppliers and practitioners, the rules in this part include procedures for review of determinations that affect those two groups.

(h) Section 1128A of the Act provides that HCFA will not collect a civil money penalty while a SNF or NF has a final administrative decision pending on the noncompliance that led to the imposition of the civil money penalty.

[52 FR 22446, June 12, 1987, as amended at 59 FR 56251, Nov. 10, 1994]

498.2 [Amended] Definitions.
[Amended by: 61 FR 32347—6/24/96—MEDICARE AND MEDICAID PROGRAMS; PROVIDER APPEALS: TECHNICAL AMENDMENTS]

As used in this part—

Affected party means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and "party" means the affected party or HCFA (or the OIG), as appropriate. ALJ stands for Administrative Law Judge.

Appeals Council or Council means the Appeals Council of the Office of Hearings and Appeals of the Social Security Administration.

OHA stands for the Social Security Administration's Office of Hearings and Appeals.

OIG stands for the Department's Office of the Inspector General.

Provider means a hospital, rural primary care hospital (RPCH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), or hospice, that has in effect an agreement to participate in Medicare, a nursing facility (NF), or intermediate care facility for the mentally retarded (ICF/MR) that has in effect an agreement to participate in Medicaid, or a clinic, rehabilitation agency, or public health agency that has a similar agreement but only to furnish outpatient physical therapy or outpatient speech pathology services, and "prospective provider" means any of the listed entities that seeks to participate in Medicare as a provider.

Supplier means an independent laboratory, supplier of portable X-ray services, rural health clinic (RHC), Federally qualified health center (FQHC), ambulatory surgical center (ASC), organ procurement organization (OPO), or end-stage renal disease (ESRD) treatment facility that is approved by HCFA as meeting the conditions

for coverage of its services, and prospective supplier means any of the listed entities that seeks to be approved for coverage of its services under Medicare.

(However, for purposes of the sanctions and penalties that may be imposed by the OIG, the term supplier has the meaning specified in 1001.2 of this title.)

[52 FR 22446, June 12, 1987, as amended at 53 FR 6551, March 1, 1988; 57 FR 24984, June 12, 1992; 58 FR 30677, May 26, 1993; 59 FR 6579, Feb. 11, 1994; 59 FR 56251, Nov. 10, 1994]

498.3 [Amended] Scope and applicability. [Amended by: 61 FR 32347—6/24/96—MEDICARE AND MEDICAID PROGRAMS; PROVIDER APPEALS: TECHNICAL AMENDMENTS]

(a) Scope. This part sets forth procedures for reviewing initial determinations that HCFA makes with respect to the matters specified in paragraph (b) of this section and that the OIG makes with respect to matters specified in paragraph (c) of this section.

(b) Initial determinations by HCFA. HCFA makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(3) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(4) Whether a prospective supplier meets the appropriate conditions for coverage of its services, as set forth in part 405 (subpart M, N, Q, or U), part 416, part 485, subpart D, or part 491 of this chapter).

(5) Whether the services of a supplier continue to meet the conditions for coverage.

(6) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services as set forth in subpart D of part 486 of this chapter and 410.22 of this chapter, respectively.

(7) Except for SNFs and NFs, the termination of a provider agreement in accordance with 489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with 405.2404 of this chapter, or the termination of a Federally qualified health center agreement in accordance with 405.2400 of this chapter.

(8) The cancellation of the approval of a Medicaid SNF or NF by HCFA under section 1910(b) of the Act.

(9) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospitalbased or independent.

(10) Whether to deny payment under 409.19 or 409.64 of this chapter, pertaining to cardiac pacemakers and the pacemaker registry.

(11) Whether a hospital, skilled nursing facility, home health agency, or hospice program meets or contimues to meet the advance directives requirements specified in subpart I of part 489 of this chapter.

(12) Except as provided at 498.3(d)(11) for SNFs and NFs, the finding of noncompliance leading to the imposition of enforcement actions specified in 488.406 of this chapter, but not the determination as to which remedy to impose. The scope of review on the imposition of a civil money penalty is specified in 488.438(e) of this chapter.

(13) The level of noncompliance found by HCFA in a SNF or NF only if a successful challenge on this issue would affect the range of civil money penalty amounts that HCFA could collect.

(c) Initial determinations by the OIG. The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with part 1001, subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with part 1001, subpart B of this title.

(3) The imposition of sanctions in accordance with part 1004 of this title.

(d) Administrative actions that are not initial determinations. Administrative actions other than those specified in paragraphs (b) and (c) of this section

are not initial determinations and thus are not subject to this part.

Administrative actions that are not initial determinations include, but are not limited to, the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions of participation or the conditions for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution—

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF that is not in substantial compliance with the requirements, the finding that the SNF's or NF's deficiencies pose immediate jeopardy to residents' health or safety, except as provided in paragraph (b)(13) of this section.

(11) For SNFs and NFs, the imposition of State monitoring or loss of nurse aide training.

(12) Except as provided in paragraph (b)(13) of this section, a determination by HCFA concerning the level of noncompliance in an SNF or NF.

(13) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(14) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements.

(e) Exclusion of civil rights issues. The procedures in this subpart do not apply to the adjudication of issues relating to a provider's compliance with civil rights requirements that are set forth in part 489 of this chapter. Those issues are handled through the Department's Office of Civil Rights.

[52 FR 22446, June 12, 1987, as amended at 52 FR 27765, July 23, 1987; 53 FR 6551, March 1, 1988; 53 FR 6649, March 2, 1988; 54 FR 5373, Feb. 2, 1989; 56 FR 8854, Mar. 1, 1991; 56 FR 48879,

Sept. 26, 1991; 57 FR 8204, Mar. 6, 1992; 57 FR 34021, July 31, 1992; 57 FR 43925, Sept. 23, 1992; 59 FR 56251, Nov. 10, 1994; 60 FR 2330, Jan. 9, 1995; 60 FR 50120, Sept. 28, 1995]

498.5 Appeal rights.

(a) Appeal rights of prospective providers.

(1) Any prospective provider dissatisfied with an initial determination or revised initial determination that it does not qualify as a provider may request reconsideration in accordance with 498.22(a).

(2) Any prospective provider dissatisfied with a reconsidered determination under paragraph (a)(1) of this section, or a revised reconsidered determination under 498.30, is entitled to a hearing before an ALJ.

(b) Appeal rights of providers. Any provider dissatisfied with an initial determination to terminate its provider agreement is entitled to a hearing before an ALJ.

(c) Appeal rights of providers and prospective providers. Any provider or prospective provider dissatisfied with a hearing decision may request Appeals Council review and has a right to seek judicial review of the Council's decision.

(d) Appeal rights of prospective suppliers.

(1) Any prospective supplier dissatisfied with an initial determination or a revised initial determination that its services do not meet the conditions for coverage may request reconsideration in accordance with 498.22(a).

(2) Any prospective supplier dissatisfied with a reconsidered determination under paragraph (d)(1) of this section, or a revised reconsidered determination under 498.30, is entitled to a hearing before an ALJ.

(e) Appeal rights of suppliers. Any supplier dissatisfied with an initial determination that the services subject to the determination no longer meet the conditions for coverage, is entitled to a hearing before an ALJ.

(f) Appeal rights of suppliers and prospective suppliers.

(1) Any supplier or prospective supplier dissatisfied with the hearing decision may request Departmental Appeals Board review of the ALJ's decision.

(2) Suppliers and prospective suppliers do not have a right to judicial review except as provided in paragraph (i) of this section.

(g) Appeal rights for certain practitioners. A physical therapist in independent practice or a chiropractor dissatisfied with a determination that he or she does not meet the requirements for coverage of his or her services has the same appeal rights as suppliers have under paragraphs (d), (e) and (f) of this section.

(h) Appeal rights for nonparticipating hospitals that furnish emergency services. A nonparticipating hospital dissatisfied with a determination or decision that it does not qualify to elect to claim payment for all emergency services furnished during a calendar year has the same appeal rights that providers have under paragraph (a), (b), and (c) of this section.

(i) Appeal rights for suspended or excluded practitioners, providers, or suppliers.

(1) Any practitioner, provider, or supplier who has been suspended, or whose services have been excluded from coverage in accordance with 498.3(c)(2), or has been sanctioned in accordance with 498.3(c)(3), is entitled to a hearing before an ALJ.

(2) Any suspended or excluded practitioner, provider, or supplier dissatisfied with a hearing decision may request Departmental Appeals Board review and has a right to seek judicial review of the Board's decision by filing an action in Federal district court.

(j) Appeal rights for Medicaid ICFs/MR terminated by HCFA.

(1) Any Medicaid ICF/MR that has had its approval cancelled by HCFA in accordance with 498.3(b)(8) has a right to a hearing before an ALJ, to request Departmental Appeals Board review of the hearing decision, and to seek judicial review of the Board's decision.

(2) The Medicaid agreement remains in effect until the period for requesting a hearing has expired or, if the facility requests a hearing, until a hearing decision is issued, unless HCFA—

(i) Makes a written determination that continuation of provider status for the SNF or ICF constitutes an immediate and serious threat to the health and safety of patients

and specifies the reasons for that determination; and

(ii) Certifies that the facility has been notified of its deficiencies and has failed to correct them.

[52 FR 22446, June 12, 1987, as amended at 57 FR 43925, Sept. 23, 1992; 59 FR 56252, Nov. 10, 1994]

498.10 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with HCFA, the ALJ, or the Appeals Council.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

498.11 Authority of representatives.

(a) A representative appointed and qualified in accordance with 498.10 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

498.13 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with 498.10 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

498.15 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Council review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Appeals Council, as appropriate.

498.17 Filing of briefs with the ALJ or Appeals Council, and opportunity for rebuttal.

(a) Filing of briefs and related documents. If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and one copy to the ALJ or the Appeals Council, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) Opportunity for rebuttal.

(1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and one copy with the ALJ or the Council and furnish a copy to the other party.

(2) The ALJ or the council will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

42 CFR Part 498—Subpart B—Initial, Reconsidered, and Revised Determinations

498.20 Notice and effect of initial determinations.

(a) Notice of initial determination.

(1) General rule. HCFA or the OIG, as appropriate, mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to reconsideration, if applicable, or to a hearing.

(2) Special rules: Independent laboratories and suppliers of portable x-ray services. If HCFA determines that an independent laboratory or a supplier of portable x-ray services no longer meets the conditions for coverage of some or all of its services, the notice—

(i) Specifies an effective date of termination of coverage that is at least 15 days after the date of the notice;

(ii) Is also sent to physicians, hospitals, and other parties that might use the services of the laboratory or supplier; and

(iii) In the case of laboratories, specifies the categories of laboratory tests that are no longer covered.

(3) Special rules: Nonparticipating hospitals that elect to claim payment for emergency services. If HCFA determines that a nonparticipating hospital no longer qualifies to elect to claim payment for all emergency services furnished in a calendar year, the notice—

(i) States the calendar year to which the determination applies;

(ii) Specifies an effective date that is at least 5 days after the date of the notice; and

(iii) Specifies that the determination applies to services furnished, in the specified calendar year, to patients accepted (as inpatients or outpatients) on or after the effective date of the determination.

(4) Other special rules. Additional rules pertaining, for example, to content and timing of notice, notice to the public and to other entities, and time allowed for submittal of additional information, are set forth elsewhere in this chapter, as follows:

Part 405 Subpart X—for rural health clinics.

Part 416—for ambulatory surgical centers.

Part 489—for providers, when their provider agreements have been terminated.

Part 1001, Subpart B—for excluded or suspended providers, suppliers, physicians, or practitioners.

Part 1001, Subpart C—for providers, when their provider agreements are terminated by the OIG.

Part 1004—for sanctioned providers and practitioners.

(b) Effect of initial determination. An initial determination is binding unless it is—

(1) Reconsidered in accordance with 498.24;

(2) Reversed or modified by a hearing decision in accordance with 498.78; or

(3) Revised in accordance with 498.32 or 498.100.

498.22 Reconsideration.

(a) Right to reconsideration. HCFA reconsiders any initial determination that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section.

(None of the determinations made by the OIG are subject to reconsideration.)

(b) Request for reconsideration: Manner and timing. The affected party specified in paragraph (a) of this section, if dissatisfied with the initial determination may request reconsideration by filing the request—

(1) With HCFA or with the State survey agency;

(2) Directly or through its legal representative or other authorized official; and

(3) Within 60 days from receipt of the notice of initial determination, unless the time is extended in accordance with paragraph (d) of this section. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later.

(c) Content of request. The request for reconsideration must state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement.

(d) Extension of time to file a request for reconsideration.

(1) If the affected party is unable to file the request within the 60 days specified in paragraph (b) of this section, it may file a written request with HCFA, stating the reasons why the request was not filed timely.

(2) HCFA will extend the time for filing a request for reconsideration if the affected party shows good cause for missing the deadline.

498.23 Withdrawal of request for reconsideration.

A request for reconsideration is considered withdrawn if the requestor files a written withdrawal request before HCFA mails the notice of reconsidered determination, and HCFA approves the withdrawal request.

498.24 Reconsidered determination.

When a request for reconsideration has been properly filed in accordance with 498.22, HCFA—

(a) Receives written evidence and statements that are relevant and material to the matters at issue and are submitted within a reasonable time after the request for reconsideration;

(b) Considers the initial determination, the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other written evidence submitted under paragraph (a) of this section, taking into account facts relating to the status of the prospective provider or supplier subsequent to the initial determination; and

(c) Makes a reconsidered determination, affirming or modifying the initial determination and the findings on which it was based.

498.25 Notice and effect of reconsidered determination.

(a) Notice.

(1) HCFA mails notice of a reconsidered determination to the affected party.

(2) The notice gives the reasons for the determination.

(3) If the determination is adverse, the notice specifies the conditions or requirements of law or regulations that the affected party fails to meet, and informs the party of its right to a hearing.

(b) Effect. A reconsidered determination is binding unless—

(1) HCFA or the OIG, as appropriate, further revises the revised determination; or

(2) The revised determination is reversed or modified by a hearing decision.

42 CFR Part 498—Subpart C—Reopening of Initial or Reconsidered Determinations

498.30 Limitation on reopening.

An initial or reconsidered determination that a prospective provider is a provider or that a hospital qualifies to elect to claim payment for all emergency services furnished in a calendar year may not be reopened. HCFA or the OIG, as appropriate, may on its own initiative, reopen any other initial or reconsidered determination, within 12 months after the date of notice of the initial determination.

498.32 Notice and effect of reopening and revision.

(a) Notice.

(1) HCFA or the OIG, as appropriate, gives the affected party notice of reopening and of any revision of the reopened determination.

(2) The notice of revised determination states the basis or reason for the revised determination.

(3) If the determination is that a supplier or prospective supplier does not meet the conditions for coverage of its services, the notice specifies the conditions with respect to which the affected party fails to meet the requirements of law and regulations, and informs the party of its right to a hearing.

(b) Effect. A revised determination is binding unless

(1) The affected party requests a hearing before an ALJ; or

(2) HCFA or the OIG further revises the revised determination.

42 CFR Part 498—Subpart D—Hearings

498.40 Request for hearing.

(a) Manner and timing of request.

(1) An affected party entitled to a hearing under 498.5 may file a request for a hearing with HCFA or the OIG, as appropriate, or with OHA.

(2) The affected party or its legal representative or other authorized official must file the request in writing within 60 days from receipt of the notice of initial, reconsidered, or revised determination unless that period is extended in accordance with paragraph (c) of this section. (Presumed date of receipt is determined in accordance with 498.22(b)(3)).

(b) Content of request for hearing. The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for contending that the findings and conclusions are incorrect.

(c) Extension of time for filing a request for hearing. If the request was not filed within 60 days—

(1) The affected party or its legal representative or other authorized official may file with the ALJ a written request for extension of time stating the reasons why the request was not filed timely.

(2) For good cause shown, the ALJ may extend the time for filing the request for hearing.

498.42 Parties to the hearing.

The parties to the hearing are the affected party and HCFA or the OIG, as appropriate.

498.44 Designation of hearing official.

(a) The Associate Commissioner for Hearings and Appeals, or his or her delegate designates an ALJ or a member or members of the Appeals Council to conduct the hearing.

(b) If appropriate, the Associate Commissioner or the delegate may substitute another ALJ or another member or other members of the Appeals Council to conduct the hearing.

(c) As used in this part, "ALJ" includes a member or members of the Appeals Council who are designated to conduct a hearing.

498.45 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Appeals Council as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

498.47 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion,the ALJ may adjourn the prehearing conference and reconvene at a later date.

498.48 Notice of prehearing conference.

(a) Timing of notice. The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 days before the scheduled date.

(b) Content of notice. The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) Additional issues. Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

498.49 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the HCFA or OIG representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

498.50 Record, order, and effect of prehearing conference.

(a) Record of prehearing conference.

(1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) Order and opportunity to object.

(1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 days to file objections to the order.

(3) After the 10 days have elapsed, the ALJ settles the order.

(c) Effect of prehearing conference. The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

498.52 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

498.53 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

498.54 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the preceedings is made and a separate decision issued with respect to each affected party.

498.56 Hearing on new issues.

(a) Basic rules.

(1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if HCFA or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) Time limits. The ALJ will not consider any issue that arose on or after any of the following dates:
(1) The effective date of the termination of a provider agreement.
(2) The date on which it is determined that a supplier no longer meets the conditions for coverage of its services.
(3) The effective date of the notice to a hospital of its failure to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished to Medicare beneficiaries during the calendar year.
(4) The effective date of the suspension, or of the exclusion from coverage of services furnished by a suspended or excluded practitioner, provider, or supplier.
(5) With respect to Medicaid SNFs or ICFs surveyed under section 1910(c) of the Act—
(i) The completion date of the survey or resurvey that is the basis for a proposed cancellation of approval; or
(ii) If approval was cancelled before the hearings, because of immediate and serious threat to patient health and safety, the effective date of cancellation.

(c) Notice and conduct of hearing on new issues.
(1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with 498.52.
(2) After giving notice, the ALJ will, except as provided in paragraph (d) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(d) Remand to HCFA or the OIG. At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (c) of this section, the ALJ may remand the case to HCFA or the OIG for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct HCFA or the OIG to return the case to the ALJ for further proceedings.

[52 FR 22446, June 12, 1987, as amended at 53 FR 31335, Aug. 18, 1988]

498.58 Subpoenas.

(a) Basis for issuance. The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) Timing of request by a party. The party must file a written request for a subpoena with the ALJ at least 5 days before the date set for the hearing.

(c) Content of request. The request must:
(1) Identify the witnesses or documents to be produced;
(2) Describe their addresses or location with sufficient particularity to permit them to be found; and
(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) Method of issuance. Subpoenas are issued in the name of the Secretary, who pays the cost of issuance and the fees and mileage of any subpoenaed witnesses.

498.60 [Amended] Conduct of hearing.
[Amended by: 61 FR 32347—6/24/96—MEDICARE AND MEDICAID PROGRAMS; PROVIDER APPEALS: TECHNICAL AMENDMENTS]

(a) Participants in the hearing. The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) Hearing procedures.
(1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.
(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.
(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

498.61 [Amended] Evidence.

[Amended by: 61 FR 32347—6/24/96—MEDICARE AND MEDICAID PROGRAMS; PROVIDER APPEALS: TECHNICAL AMENDMENTS]

(a) Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

(b) In civil money penalty cases, HCFA's conclusions as to a SNF's or NF's level of noncompliance must be upheld unless clearly erroneous.

[59 FR 56252, Nov. 10, 1994]

498.62 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

498.63 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with 498.17.

498.64 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

498.66 Waiver of right to appear and present evidence.

(a) Waiver procedures.

(1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) Effect of waiver. If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) HCFA or the OIG shows good cause for requiring the presentation of oral evidence.

(c) Dismissal for failure to appear. If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with 498.69.

(d) Hearing without oral testimony. When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) Handling of briefs and related statements. If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with 498.17.

498.68 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

498.69 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 days after the ALJ sends a "show cause" notice, with a showing of good cause.

498.70 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either

entirely or as to any stated issue, under any of the following circumstances:

(a) Res judicata. There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) No right to hearing. The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) Hearing request not timely filed. The affected party did not file a hearing request timely and the time for filing has not been extended.

498.71 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in 498.72.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Appeals Council.

498.72 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 days from receipt of the notice of dismissal and shows good cause for vacating the dismissal. (Date of receipt is determined in accordance with 498.22(b)(3).)

498.74 [Changes] Administrative Law Judge's decision.

[Changes: 61 FR 32347—6/24/96—MEDICARE AND MEDICAID PROGRAMS; PROVIDER APPEALS: TECHNICAL AMENDMENTS]

(a) Timing, basis and content. As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) Notice and effect. A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Appeals Council within the stated time period, and the Council reviews the case;

(2) The Appeals Council denies the request for review and the party seeks judicial review by filing an action in a Federal district court;

(3) The decision is revised by an ALJ or the Appeals Council; or

(4) The decision is a recommended decision directed to the Council.

498.76 Removal of hearing to Appeals Council.

(a) At any time before the ALJ receives oral testimony, the Council may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Council conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

498.78 Remand by the Administrative Law Judge.

(a) If HCFA or the OIG requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to HCFA or the OIG for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

42 CFR Part 498—Subpart E—Appeals Council Review

498.80 Right to request Appeals Council review of Administrative Law Judge's decision or dismissal.
Either of the parties has a right to request Appeals Council review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

498.82 Request for Appeals Council review.

(a) Manner and time of filing.
  (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Appeals Council.
  (2) The requesting party or its representative or other authorized official must file the request with the OHA within 60 days from receipt of the notice of decision or dismissal, unless the Council, for good cause shown by the requesting party, extends the time for filing. The rules set forth in 498.40(c) apply to extension of time for requesting Appeals Council review. (The date of receipt of notice is determined in accordance with 498.22(c)(3).)

(b) Content of request for review. A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

498.83 Appeals Council action on request for review.

(a) Request by HCFA or the OIG. The Appeals Council may dismiss, deny, or grant a request made by HCFA or the OIG for review of an ALJ decision or dismissal.

(b) Request by the affected party. The Council will grant the affected party's request for review unless it dismisses the request for one of the following reasons:
  (1) The affected party requests dismissal of its request for review.
  (2) The affected party did not file timely or show good cause for late filing.
  (3) The affected party does not have a right to review.
  (4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Council review, or judicial review, as appropriate.

(c) Effect of dismissal. The dismissal of a request for Appeals Council review is binding and not subject to further review.

(d) Review panel. If the Council grants a request for review of the ALJ's decision, the review will be conducted by a panel of at least two members of the Council, designated by the Chairperson or Deputy Chairperson, and one individual designated by the Secretary from the US Public Health Service.

498.85 Procedures before the Appeals Council on review.
The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Appeals Council to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with 498.17.

498.86 Evidence admissible on review.

(a) The Appeals Council may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Council considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Council that additional relevant evidence is available, the Council will require that it be produced.

(c) Before additional evidence is admitted into the record—
  (1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and
  (2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Council, a transcript is prepared and made available to any party upon request.

498.88 Decision or remand by the Appeals Council.

(a) When the Appeals Council reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Council may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Council.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Council in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Council, certifies the case to the Council with a recommended decision.

(d) The parties have 20 days from the date of a notice of a recommended decision to submit to the Council any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-day period, the Council issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Council does not remand the case to an ALJ, the following rules apply:

(1) The Council's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Council receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Council's decision is mailed to each party.

498.90 [Revised] Effect of Appeals Council decision. [Revised: 61 FR 32347—6/24/96—MEDICARE AND MEDICAID PROGRAMS; PROVIDER APPEALS: TECHNICAL AMENDMENTS]

(a) The decision of the Appeals Council is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a district court of the United States; or

(2) The Council reopens and revises its decision in accordance with 498.102.

(b) (1) When HCFA imposes a civil money penalty on a SNF or NF, the decision of the Appeals Council is final upon issuance.

(2) Judicial review of an Appeals Council decision concerning the imposition of a civil money penalty on a SNF or NF is available in the appropriate United States Court of Appeals.

(c) Section 498.5 specifies the circumstances under which an affected party has a right to seek judicial review.

[52 FR 22446, June 12, 1987, as amended at 60 FR 50120, Sept. 28, 1995]

498.95 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Appeals Council decision and is entitled to judicial review must commence civil action within 60 days from receipt of the notice of the Council's decision (as determined under 498.22(c)(3)), unless the Council extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Council before the 60-day period ends.

(c) For good cause shown, the Council may extend the time for commencing civil action.

42 CFR Part 498—Subpart F—Reopening of Decisions Made by Administrative Law Judges or the Appeals Council

498.100 Basis, timing, and authority for reopening an ALJ or Council decision.

(a) Basis and timing for reopening. An ALJ of Appeals Council decision may be reopened, within 60 days from the date of the notice of decision, upon the motion of the ALJ or the Council or upon the petition of either party to the hearing.

(b) Authority to reopen.

(1) A decision of the Appeals Council may be reopened only by the Appeals Council.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Appeals Council. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

498.102 Revision of reopened decision.

(a) Revision based on new evidence. If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Appeals Council—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Council revision.

(b) Basis for revised decision and right to review.

(1) If a revised decision is necessary, the ALJ or the Appeals Council, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Appeals Council may review that revised decision at the request of either party or on its own motion.

498.103 Notice and effect of revised decision.

(a) Notice. The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Appeals Council review of an ALJ revised decision, or to judicial review of a Council reviewed decision.

(b) Effect—

(1) ALJ revised decision. An ALJ revised decision is binding unless it is reviewed by the Appeals Council.

(2) Appeals Council revised decision. A Council revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in 498.95.CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

Professional Certification for
Home Care & Hospice Executives

Candidate Information Handbook

SEPTEMBER 1998

Sponsored by Home Care University, an affiliate of
The National Association for Home Care
519 C Street, NE
Washington, DC 20002

HOMECARE UNIVERSITY

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

Professional Certification for
Home Care & Hospice Executives

Candidate Information Handbook

SEPTEMBER 1998

Sponsored by Home Care University, an affiliate of
The National Association for Home Care
519 C Street, NE
Washington, DC 20002

HOMECARE UNIVERSITY