The original documents are located in Box 12, folder "Health - Home Health Care (3)" of the Sarah C. Massengale Files at the Gerald R. Ford Presidential Library.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

TO: See Below

DATE: JAN 15 1976

FROM: Executive Secretary

SEQUENCE No. SRS - 13

DOCUMENT No. 1 of 1
(FINALS ONLY)

SUBJECT: SRS - Final Regulations -- Home Health Services - Part 249--Services and Payment in Medical Assistance Programs - Title XIX of the Social Security Act - Chapter II, Title 45

Attached is a copy of SRS' Action Memorandum dated January 14, 1976, with accompanying Federal Register document. Please indicate your conconcurrence by signing the Action Memorandum in the space provided within 5 working days. If additional time is needed for review of this document, please notify Miss Howell by telephone (extension 57770).

Please discuss questions you have about these proposed regulations with operating agency personnel before submitting memoranda of comment. If issues cannot be resolved, nonconcurrence memoranda addressed to the Secretary are then appropriate.

Please return your concurrence (or nonconcurrence memorandum) to Miss Howell, Room 5139-B, North Building, for association with the docket file.

Simultaneous routing of this Federal Register document submitted to the Secretary is being made to expedite clearance and approval in the Office of the Secretary.

Attachments

Addressees:
General Counsel
Assistant Secretary, Comptroller
Assistant Secretary (Planning and Evaluation)
Assistant Secretary (Legislation)
Assistant Secretary for Administration and Management
Commissioner of Social Security
Assistant Secretary (Health)
Assistant Secretary (Public Affairs)
Assistant Secretary (Human Development)
Mr. Peter Franklin, Special Assistant to the Secretary

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
SOCIAL AND REHABILITATION SERVICE
Office of the Administrator

TO : The Secretary
Through: U_____
ES_____

DATE: JAN 14 1976

FROM : Acting Administrator
Social and Rehabilitation Service

SUBJECT: Final Medicaid Regulations on Home Health Services - ACTION

PURPOSE

To revise regulations in order to increase use of home health services under the Medicaid program where home care is appropriate and necessary with respect to the recipient's condition. The revisions broaden the types of agencies eligible to provide services and clarify the required and optional services made available by States.

BACKGROUND

Under existing Medicaid home health services regulations:

(1) Provider participation has been restricted to those which meet Medicare requirements. One such requirement is that they must provide skilled nursing services and one other service such as physical therapy. This has meant that some agencies, such as small public health departments and visiting nurse associations, have been unable to participate if they cannot offer the second service. Also, the requirement has served as a deterrent to creation of new agencies.

Another requirement under Medicare (by statute) is that proprietary agencies must be licensed under State law and, if the State has not enacted such a law, a proprietary agency cannot be a provider for Medicare in that State. This restriction has been carried over into Medicaid by regulation.

(2) There is ambiguity as to the minimum set of home health services which States must provide under a State plan. It has been interpreted that the States are required to provide only one of the specified services (nursing, home health aide, supplies and equipment), when in fact it was intended that all of these were required to be available.

Another problem has been that some States have adopted the Medicare requirement that a patient must be in need of "skilled" nursing or other professional services. Thus, a person who does not require "skilled" services but for example, only home health aide services, was regarded as not eligible for home health services. Some States also limited eligibility by applying inappropriate requirements of post-hospitalization or pre-institutionalization.

A GAO report on home health services recommended that SRS clarify the services for which FFP is available and encourage States to make greater use of them. In line with these recommendations and as part of the Department's effort to develop alternatives to institutional care, SRS published proposed regulations on August 21, 1975, containing the following revisions:

(1) Clarification of required and optional services. The proposal specified that States must make available nursing services, home health aide services, and medical supplies, equipment and appliances suitable for use in the home. At State option, physical, occupational, or speech therapy may be provided to home health care patients even though not generally provided to all recipients under the State plan.

(2) Expansion of the types of agencies qualified to provide services and specification of standards they must meet:

(a) Instead of the limitation to agencies providing primarily skilled nursing plus a therapeutic service, the proposal permitted agencies offering only nursing or only home health aide services to qualify if they meet the prescribed standards. (The latter are basically the Medicare standards adapted to permit these agencies to qualify).

(b) The proposal also permitted proprietary agencies to participate if they meet the standards, not restricting their participation to States which have enacted a licensing law.

(3) Clarification of recipient eligibility. As indicated above, there has been some confusion as to whether recipients must be determined to need skilled care or to require admittance to institutions.

COMMENTS

Almost 1300 comments were received, covering both the major issues of types of agencies to be included and different standards for Medicaid and Medicare, and virtually every provision of the proposed regulations. There were also hearings held by the subcommittees of the Senate and House Committees on Aging, and a meeting convened by SRS with State, Congressional, consumer and provider representatives.

TYPES OF AGENCIES

The major controversy arose over the proposal to permit proprietary agencies to be Medicaid providers if they meet the Federal standards, whether or not the State has a licensing law.

Comments indicated primarily (a) a misunderstanding that States could not continue to regulate home health agencies, and (b) a strong concern that proprietary agencies would not provide quality services, since their overriding interest is in returning a profit to their owners or stockholders; that they would employ inadequately trained and supervised staff, which might lead to patient abuse; and that they would "corner the market" of paying patients, thus driving out of business voluntary agencies which depend on payment from some percentage of patients. Also, some of those basically in favor of allowing for-profit agencies to participate expressed concern about the Federal and State capacity for monitoring and standards enforcement.

With respect to State licensing laws, the regulations do not limit State action in any way--States are free to require licensing and to establish standards higher than the Federal requirements. The regulations establish Federal standards which all agencies must meet. Additional requirements are then properly a matter for State legislative and regulatory action. This is appropriate in light of the silence on this subject in the Medicaid statute as contrasted with the specific provisions enacted for Medicare.

The Department also believes that home health services should not be subject to a restriction which is not applied in the case of any other Medicaid service, and that there should not be discrimination against one type of provider-rather, the same standards should be used for all.

With respect to the second comment, SRS recognizes a legitimate concern. However, it is regarded as inappropriate to bar all proprietary agencies (in States which do not enact licensing laws) because of the possible abuse by some. To lessen the potential that these results will ensue, SRS will make home health services one of its four top priorities for monitoring against fraud and abuse and will assist States in establishing effective systems for this purpose.

Another issue centered on the proposal to allow single-service agencies to become Medicaid providers. Comments expressed concern that use of a single-service agency would lead to fragmentation of care and poor quality service.

ONLY NURSING SERVICE AGENCIES

In the final regulation, the "single-service" agency provision has been changed to allow only nursing service agencies to qualify, since SRS believes that these agencies are best qualified to provide the coordination of services that may be needed by many recipients. Home health aide agencies have been eliminated from the regulation as single-service providers since they are usually not equipped to perform such coordination.

DIFFERING STANDARDS FOR MEDICARE AND MEDICAID

The proposal contained a standard for Medicaid agencies not participating in Medicare--that is, proprietary and single-service agencies which the Department wishes to include in Medicaid in order to increase availability of services. The proposed standard was the Medicare rule, modified to allow such agencies to participate.

There was much misunderstanding of the extent of the differences and of the need for a separate Medicaid standard. In the final regulations the Medicare standards have been adopted by cross-reference and the necessary exceptions (for proprietary and single-service agencies, etc.,) have been listed. This should clarify that the Medicare-Medicaid standards are the same wherever possible.

Other comments have been considered and appropriate changes made, as explained in the preamble.

PRESS RELEASE

A draft press release is attached (Tab B).

INFLATIONARY IMPACT STATEMENT

It has been determined that an inflationary impact statement is not necessary.

RECOMMENDATION

That you approve the final regulations (Tab A) for publication in the Federal Register.

JOHN A. SVAHN
John A. Svahn

Enclosure
Tab A - Final Regulations
Tab B - Press Release
Tab C - Previous Action Memo

Prepared by: SRS/MSA, MOSchnoor x50397, 1/13/76

(Contact: Ilse C. Sandmann, x58822)

CONCUR _____
Asst. Secretary (Legislation) DATE _____

TITLE 45 - PUBLIC WELFARE
CHAPTER II - SOCIAL AND REHABILITATION SERVICE
(ASSISTANCE PROGRAMS)
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 249 - SERVICES AND PAYMENT IN MEDICAL ASSISTANCE PROGRAMS

Home Health Services

Notice of proposed rule making was published August 21, 1975 (40 FR 36702) revising existing regulations on the provision of home health services under State plans for medical assistance (title XIX, Social Security Act). The purpose of the proposed revisions was to remove certain restrictions and ambiguities which prevented full realization of the benefits of such services. The basis for the proposal was the Department's desire to increase the availability of home health services to Medicaid recipients and to encourage their use in appropriate cases as one alternative to institutionalization.

In the summary, the proposed revisions would:

- permit certain types of qualified health service agencies, in addition to those which meet Medicare standards, to provide home health services under Medicaid programs;

- prescribe the standards which those agencies must meet, which parallel those for Medicare but are appropriately adjusted for differing needs under Medicaid;

- permit proprietary agencies to participate if they meet the standards, subject to any licensing law of the State;

- clarify that States must make available under the State plan the three main types of services needed in home care: nursing, home

health aide, and supplies and equipment, and also permit them to provide various therapies as home health services;

- clarify the Medicaid recipients to whom home health services must be available, specify the requirements for a physician's determination of medical needs recorded in a plan of care and periodically reviewed, and clarify that Medicare requirements relating to need for "skilled" care or to post-hospitalization do not apply under Medicaid.

Nearly 1300 comments were received from a broad range of interested parties: members of Congress, private citizens, national health and welfare organizations, consumer and senior citizen groups, public and private providers and provider organizations, State and local agencies, etc. The comments themselves represented a broad range of opinion from approval of the changes to strong objections in whole or in part. Evidence of widespread interest was also presented by the holding of public hearings on October 28, 1975 by subcommittees of the Senate and House Committees on Aging, and by the convening of an all-day session on the major issues to which the Department invited State, congressional, consumer and provider representatives.

The greatest controversy arose over the proposal to drop from Medicaid the restrictions on proprietary agency participation applied by statute under Medicare, thus allowing their participation in the Medicaid program on the same basis and under the same standards as nonprofit agencies. Another major issue was the establishment of standards differing in some respects from Medicare's, including the provision for single service agencies to participate in Medicaid

(those offering only nursing or only home health aide services). In addition, however, there were questions and suggestions on virtually every detail of the proposed regulations. All comments have been analyzed and given careful consideration in developing the final regulations, and numerous clarifications have been made. The major comments and the Department's responses are listed below:

1. Participation of proprietary agencies.

Under Medicare, for-profit agencies may qualify as home health providers only if licensed by the State; if the State does not have a licensing law, they may not be certified under the program. This provision, statutory for Medicare, had been adopted by regulation for Medicaid. The Department's proposal would allow proprietary agencies to qualify as Medicaid providers if they met the standards prescribed in the regulations; however, States could still require licensing if they wished. Comments indicated primarily (a) a misunderstanding that States could not continue to regulate home health agencies, and (b) a strong concern that proprietary agencies would not provide quality services, since their overriding interest is in returning a profit to their owners or stockholders; that they would employ inadequately trained and supervised staff, which might lead to patient abuse; and that they would "corner the market" of paying patients, thus driving out of business voluntary agencies which depend on payment from some percent-

age of patients--the net result leaving poor persons refused service by the profit-making agencies and deprived of any other source of help. Also, some of those basically in favor of allowing for-profit agencies to participate expressed concern about the Federal and State capacity for monitoring and standards enforcement.

With respect to State licensing laws, the regulations do not limit State action in any way--States are free to require licensing and to establish standards higher than the Federal requirements. States may also impose certificate-of-need requirements and other procedures designed to control the establishment and operation of home health agencies. What the regulations do is to establish Federal standards which all agencies must meet. Additional requirements are then properly a matter for State legislative and regulatory action. This is appropriate in light of the silence on this subject in the Medicaid statute as contrasted with the specific provisions enacted for Medicare.

The Department also believes that home health services should not be subject to a restriction which is not applied in the case of any other Medicaid service, and that there should not be discrimination against one type of provider-rather, the same standards should be used for all.

With respect to the second comment, the Department recognizes a very legitimate concern among a number of interested parties, particularly in light of the abuses perpetrated by some profitmaking agencies in the nursing home field. However, it is regarded as inappropriate, to bar all proprietary agencies (in States which do not enact licensing laws) because of the possible abuse by some. To lessen the potential that these results will ensue, the Social and Rehabilitation Service will make home health services one of its four top priorities for monitoring against fraud and abuse and will assist States in establishing effective systems for this purpose.

2. Establishment of separate standards for Medicare and Medicaid.

Again, some comments reflected misunderstanding of the extent of the differences and of the need for a separate Medicaid standard. As explained in the Notice of Proposed Rule Making, using Medicare standards in total has restricted the participation of a number of agencies which can offer quality services to Medicaid recipients, for example, agencies which offer only a single service. In cases where a recipient needs only one type of home health service, he should be able to receive it from such an agency (provided it meets all other prescribed standards) and to have reimbursement provided to the agency by the Medicaid program. Although Medicare restrictions such as the requirement for providing skilled nursing plus one other service are imposed by statute, no similar restriction appears in the Medicaid statute and thus regulatory changes can be made as appropriate.

In the final regulation, the "single-service" agency provision has been changed to allow only nursing service agencies to qualify, since the Department believes that these agencies are best qualified to provide the coordination of services that may be needed by many recipients. Home health aide agencies have been eliminated from the regulation as single--service providers since they are usually not equipped to perform such coordination and since the regulation requires supervision of home health aides by qualified nursing personnel; therefore

the agency should be able to offer nursing service in a home health program.

To clarify that the only variations from Medicare standards are those necessary to permit additional types of agencies to participate in Medicaid, the final regulation has adopted the Medicare standards in 20 CFR 405.1201-1230 with certain exceptions.

3. Definition of home health services (§249.10(b)(7)).

This paragraph specifies the required and optional services to be provided under State Medicaid plans. Comments included the following:

(a) Clarify when services may be provided in an intermediate care facility.

This has been done by giving an example. Guidelines will also elaborate on this provision.

(b) Change the 90-day physician's review to the Medicare requirement of 60 days.

This has been done by adopting the Medicare standard.

(c) With respect to use of a "solo" nurse in the absence of a qualified agency: drop the requirement, make it optional, clarify when no agency is considered "available", require public hearings prior to such a finding, clarify "direction" by a physician.

The requirement has been retained since it is necessary for the provision of services in certain areas, primarily rural, where no agency meeting the standard is available to give home health services. Approximately 23 States now make use of this provision and the Department considers it essential for all States to have such arrangements in effect. However, the requirement has been strengthened by restricting its applicability to use of registered nurses.

The non-availability of an agency has been clarified by changing the wording to "no such agency exists in the area". The Department considers that holding of public hearings would be an undue administrative burden on State agencies and unnecessary as a control. The wording on 'direction" by a physician has been deleted and replaced by more specific language.

(d) Clarify whether the home health agency itself must furnish the medical supplies, equipment and appliances required by §249.10(b)(7)(i)(C).

It is intended that these items be supplied by direct prescription of the physician and not necessarily by the home health agency. It is the State's responsibility to make payment for any such item. Guidelines will elaborate on this provision.

(e) Many commenters suggested that a variety of other services--nutrition, homemaker, social services--should be required and that the therapy services listed as optional should be mandated.

The Department recognizes that many of these services would enhance the benefits gained from home health services. However, with respect to some of the suggested services, there is no statutory basis for mandating them under State Medicaid programs, or for authorizing payment for them whether mandated or optional. The therapy services have been retained as optional since it is felt that in the light of current fiscal restraints, this should be a State decision. Such services are optional in State Medicaid programs for provison to any recipient as well as under home health programs.

4. Definition of a medical rehabilitation facility (§249.150 (a)(3))

Comments pointed out an inconsistency between the specification that the major portion of services be provided in the facility and the fact that home health services are provided in the patient's residence.

The inconsistent wording has been deleted.

5. Subcontracting provisions (§249.150(c)(2); now 20 CFR 405.1221(h))

Suggestions included: require licensing of subcontractors; require liability coverage for them; require contracting with Medicare agencies.

The Department believes the first is a State prerogative; the second is a responsibility of the provider agency; and the third is impractical and inappropriate for Federal regulations.

6. Disclosure of ownership of agency (§249.150(b)(2)(vii))

Respondents suggested that all ownership interests be disclosed, rather than limiting the requirement to interests of 10 percent or more.

The Department believes that the additional reporting and review requirements for ownership interests of less than 10 percent would not be justified by any benefit gained. Ownership of less than this amount does not present strong stock manipulation possibilities leading to fraudulent activities, which the disclosure requirement is designed to inhibit.

7. Administrator or director (§ 249.150(c)(4); now 20 CFR 405.1221(c))

Question was raised about the difficulty of recruiting such a person in rural areas or for small agencies; clarification of the qualifications required was requested.

The Medicare standards specify that the administrator or director may also perform the function of the supervising physician or nurse, thus eliminating the need for two persons to perform these functions separately in a small agency. Guidelines will explain more fully the types of acceptable qualifications.

8. Supervising physician or nurse (§249.150(c)(5); now 20 CFR 405.1221(d))

Clarification was requested relating to the "supervision" exercised over members of other disciplines and as to when professionals other than the M.D. or R.N. would be supervising.

This will be clarified in guidelines.

9. Personnel policies (§249.150(b)(2)(iii))

It was requested that minimum qualifications be prescribed and that staffing requirements be set.

Minimum qualifications were included in the proposed rule making and have been retained. It is not appropriate to prescribe staffing ratios for all home health agencies at the Federal level. Suggested patterns will be included in guides.

10. Advisory committee (§249.150(d))

Suggestions were to drop the requirement as ineffective; to strengthen it by requiring entirely outside composition, increasing the number of consumers, or adding social workers; to eliminate the requirement for a physician; and to leave monitoring up to the State.

The requirement has now been replaced by adopting the Medicare provision for review, by a group of professional persons, of the agency's policies and program (20 CFR 405.1222).

11. Review of drug program (§249.150(a)(2)(viii))

The wording "agency staff" should be changed; only a physician or R.N. should perform review of the patient's medication. The wording now requires review by the R.N., who reports problems to the physician.

12. Initial evaluation visits (§249.150(e) and (f); now 20 CFR 405.1224(a))

Respondents pointed out an apparent contradiction between the requirement for such a visit, and the wording "as appropriate /a visit is made/".

The Medicare standard clarifies that an initial evaluation visit is required.

It was also suggested that the R.N. could not make this visit where therapy services are involved.

The R.N. can and should make the initial visit, for over-

all evaluation of the patient's needs, and development with the physician and other disciplines of the total plan of care. This in no way interferes with the performance of treatment procedures by another discipline.

13. Licensed practical nurse services (§249.150; now 20 CFR 405.1224(b))

"Under supervision" should be defined--does it mean on the premises? How often is the LPN's performance reviewed? On-premises supervision is not required; this and other questions on supervision will be clarified in guides.

14. Therapy services (§249.150.(h); now 20 CFR 405.1225))

Suggestions included changes in terminology, specifications as to what the orders shall include, and provision for therapists to act as single-service providers.

The terminology change has been made in §249.10(b)(7)(i)(D)). Specifications for therapy orders are contained in 20 CFR 1223(a). The Department believes that single-service providers should be restricted to nursing agencies, since this appears to be the best way of assuring coordination of care to meet the total needs of the patient, and of avoiding fragmentation.

15. Home health aide services §249.10(b)(7) and §249.150(a)(2)(ix))

Comments were:

(a) Such services should not be mandated.

The Department believes it essential to include these in a truly effective home health program.

(b) Require certification of agencies by the National Council of Homemaker- Home Health Aide Agencies or require that the Council's standards be met.

The Department believes that the Federal regulations should contain the minimum standards and that it would be inappropriate to require certification by an outside organization. However, a number of the Council's standards with respect to training aides have been adopted in the regulations.

(c) Aides should be required to complete a State-approved medication administration course.

Since the aide's duties involve assisting the patient with medication that is ordinarily self-administered, completion of such a course is not considered necessary. However, the content of the required home health aide

training has been amended to include training in providing such assistance.

(d) Supervision should be changed from monthly to biweekly or to every two weeks for the first two months of care and then monthly.

The first suggestion has been adopted by using the Medicare standards.

(e) Training should be strengthened by increasing the hours or enlarging the content, specifying the qualifications of the trainer, requiring State approval of the course, and requiring in-service training on a quarterly basis.

One commenter suggested substitution of experience for training.

The content of the required course has been strengthened with respect to additional subject matter. Trainer qualifications have been specified. It is not felt appropriate for the Federal regulations to specify State approval, although States may wish to impose this. The suggestion regarding in-service training has been accepted. Substitution of experience is not acceptable since it would be extremely difficult to determine whether the specific experience provided the knowledge and skill intended to be gained from the training.

16. Records (§249.150(a)(2)(x))

(a) Require 5-year retention as in Medicare.

For Federal grant-in-aid programs including Medicaid, the Department must follow the general regulations in

45 CFR Part 74, Administration of Grants. The rule in Part 74 is 3 years' retention; however States may set longer retention periods.

(b) The requirement should specify review of records closed within the quarter.

Medicare standards require quarterly review of both active and closed records.

(c) A requirement for review of 10 per cent of records is too burdensome for large agencies.

Medicare standards do not specify a percentage.

(d) For hospital-based agencies, the regulations should recognize that some of the requirements, including record review, may be otherwise met as part of the hospital's administrative functioning.

The regulations do not preclude meeting some of the requirements in this manner provided all of the specifications are fulfilled.

17. Utilization control (§249.150(a)(2)(xi))

Comments ranged from approval to objections as impractical, costly or vague. There was some misunderstanding that the two specified procedures (record review and evaluation studies) had to be performed by home health agency--established teams.

There were suggestions to have the State appoint teams or to let each provider design its own control procedures.

Finally, it was suggested that a copy of the recommendations resulting from evaluation studies be sent to the governing body.

Under 45 CFR 250.18, State title XIX agencies must have a utilization control program covering each item of service provided under the State plan, including home health services. They must also provide for evaluation of the necessity for and quality and timeliness of services, and for a post-payment review system which includes development of provider and recipient profiles and exceptions criteria. The specific provisions in the home health regulations are intended as partial amplification of these requirements. In the final regulations, changes have been made to specify that the State agency must provide for establishing the teams (in any appropriate manner), to change the record review requirement to one performed on a sampling basis, to require in-home visits as a safeguard in detecting fraud, abuse or over-utilization, to delete the requirement for a physician on the team in view of the difficulty of securing their participation in certain areas, to clarify the conflict-of-interest requirements, and to incorporate the suggestion concerning copies of the recommendations.

18. Certification procedures (§249.151)

(a) Concern was expressed about the lack of capacity to enforce the requirements and monitor agencies, and about

the need for a cost control mechanism. It was suggested that a certificate of need provision be required.

It is recognized that there are fiscal constraints on States' ability to enforce and monitor; however, it is essential that this be made a priority in Medicaid programs both to realize the full benefits of home health services and to avoid fraud and over-utilization. The utilization control requirement represents one cost control mechanism; the Department will assist in developing others. As indicated above, States may impose certificate of need requirements.

(b) Many respondents suggested clarifying the terminology used; this has been done.

(c) It was suggested that a requirement for prompt transfer of patients when an agency loses certification be added; this has been accepted.

(d) Concern was expressed that the requirements are too loose and give unlimited time to agencies to comply. The survey agency is responsible for specifying the time considered appropriate for an agency to correct its deficiencies. Ordinarily this will not exceed 60 days.

In addition, provider agreements between the State Medicaid agency and the home health agency are time-limited under the regulation to one year, or less if the latter is found deficient in meeting standards; therefore home health agencies cannot have unlimited time to meet requirements.

Chapter II, Title 45, Code of Federal Regulations, is amended as follows:

1. Section 249.10 is amended by revising paragraphs (a)(4) and (b)(7) to read as set forth below:

§ 249.10 Amount, duration, and scope of medical assistance.

(a) * * *

* * * * *

(4) Provide for the inclusion of home health services which, as a minimum, shall include nursing services, home health aide services, and medical supplies, equipment and appliances as specified in paragraph (b)(7) of this section. Under this requirement, home health services must be provided to all categorically needy individuals 21 years of age or over; to all categorically needy individuals under 21 years of age if the State plan provides for skilled nursing facility services for such individuals; and to all corresponding groups of medically needy individuals to whom skilled nursing facility services are available under the plan. Eligibility of any individual to receive home health services available under the plan shall not depend upon his need for, or discharge from, institutional care.

* * * * *

(b) * * *

* * * * *

(7) *Home health services.* (i) This term means the following services and items provided to a recipient in his place of residence. Such residence does not include a hospital, skilled nursing facility or intermediate care facility, except that these services and items may be furnished as home health services to a recipient in an intermediate care facility if they are not furnished by the facility as intermediate care services. Any such service or item provided to a recipient of home health services must be ordered by his physician as part of a written plan of care which is reviewed by his physician at least every ~~90~~ days. Those services listed in paragraphs (A), (B) and (C) are required to be made available by the State as home health services; those listed in paragraph (D) may be provided as home health services at State option.

(A) Nursing service, as defined in the State Nurse Practice Act, provided by a qualified agency or, in the case where no such agency ~~is available~~ to provide nursing services, by a registered nurse ~~or licensed practical nurse~~ who is currently licensed to practice in the State ~~and who is under the direction of the patient's physician.~~

(B) Home health ~~aid~~ services provided by a qualified agency.

required to be

(for example, short-term registered nurse service during an acute illness to avoid transfer to a skilled nursing facility).

60

on a part-time or intermittent basis

exists in the area

, receives written orders from the patient's physician, documents the care and services provided and has had orientation to home care and record keeping from a health department nurse.

aide

(C) Medical supplies, equipment and appliances suitable for use in the home.

(D) Physical therapy, occupational therapy or speech ~~therapy~~ provided by a qualified agency or by a facility licensed by the State to provide medical rehabilitation services. — pathology and audiology services

(ii) In order to participate under a State title XIX plan as an agency qualified to provide home health services, such agency must meet the conditions and standards set forth in § 249.150 of this chapter, as determined in accordance with the applicable provisions for the certification and execution of valid provider agreements under § 249.151 of this chapter.

2. A new § 249.150 is added to Part 249, as set forth below:

§ 249.150 Standards for agencies qualified to provide home health services.

(a) *Type of agencies qualified to provide home health services.* The requirement to provide home health services under State plans for medical assistance is specified in § 249.10(a)(4) of this chapter; the services included are defined in § 249.10(b)(7). This section describes the agencies which qualify to provide the nursing, home health aide and therapy services specified in § 249.10(b)(7).

(1) Home health services may be provided under the title XIX State plan by any agency which is certified under title XVIII of the Act to provide such services and which executes a valid provider agreement with the title XIX State agency.

(2) Home health services may also be provided under the title XIX State plan ~~by a public or private agency or subdivision thereof (e.g., the home care unit of a hospital) which is primarily engaged in providing medical or health care services, of which one must be nursing, or home health aide services, and which meets the standards set forth in this section; and~~ — by an agency which meets the requirements set forth in 20 CFR 405.1201-1230 except as described in this paragraph; and

which executes a valid ~~provided~~ agreement with the title XIX agency. — provider

Exceptions to the requirements of 20 CFR 405.1201-1230 are:

(i) The definition of a home health agency contained in section 1861(o) of the Act, which is cited in §405.1201(a), is revised in the following respects for purposes of this paragraph (a)(2):

(A) A home health agency may be a public or private agency or organization or subdivision thereof;

(B) The agency is one primarily engaged in providing medical or health care services, of which one must be nursing, and which executes a valid provider agreement with the State title XIX agency;

(C) Private organizations which are nonprofit organizations exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954 are eligible to participate under title XIX if they meet the remaining requirements of §§405.1201-1230, subject to the revisions herein.

(ii) The definition of "nonprofit agency" in §405.1202(e) is not applicable under this paragraph.

(iii) The definitions of occupational therapist, occupational therapy assistant, physical therapist, physical therapy assistant, social worker, and speech pathologist or audiologist, in §405.1202(f), (g), (i),(j), (t), and (u) are replaced by those in 20 CFR 405.1101(m)(n), (q), (r) (s) and (t).

(iv) The exclusion of proprietary organizations appearing in §405.1220 is deleted in that section and wherever else it appears.

(v) The requirements that agencies must provide "skilled" nursing services and that they must provide at least one other therapeutic service, which appear in §405.1221(a), are deleted in that paragraph and wherever else they appear.

(vi) The reference in §405.1221(a) to a "place of residence" is amplified as described in §249.10(b)(7)(i) of this chapter.

(vii) The requirement for disclosure of ownership information in §405.1221(b) is replaced by a requirement that the governing body or designated person so functioning shall supply to the State survey agency full and complete information as to the identity:

(A) Of each person who has any direct or indirect ownership interest of 10 percentum or more in the agency or who is the owner (in whole or in part) of any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the agency or by any of the property or assets of the agency;
(B) Of each officer and director of the corporation if the agency is organized as a corporation;
(C) Of each partner if the agency is organized as a partnership; and promptly report any changes to the State survey agency which would affect the current accuracy of the information supplied under this paragraph.

shall

(viii) The statement in §405.1223(c) that "agency staff" shall check a patient's medication is changed to require review by a licensed nurse.

(ix) The statement in 20 CFR 405.1227 relating to training of home health aides is replaced by the following requirements:

(A)

~~(3) *Training.*~~ All home health aides shall receive basic orientation and training consisting of not less than 40 hours. The training will include as a minimum content in each of the following areas:

(1) ~~(i)~~ Basic techniques of personal care and rehabilitation;

(2) ~~such as the activities of daily living;~~

(3) ~~(ii)~~ Health ~~and~~ hygiene, and household tasks essential to health;

(4) ~~(iii)~~ Food preparation and nutrition;

(5) ~~(iv)~~ Interpersonal relationships meeting the social, emotional, and physical needs of patients; The ill, disabled and aging adult;

(6) ~~(v) Basic household management;~~

(7) ~~(vi)~~ Mental health and mental illness;

(8) ~~(vii)~~ Child care.

(9) ~~(viii)~~ Accident prevention;

~~(ix)~~ Assisting patients to take own medications.

(B)

~~(4) *In-service education.*~~ There shall be continuing in-service programs on a regularly scheduled basis, but at least quarterly with on-the-job training during supervisory visits and more often as needed.

(C) Only persons with teaching experience and knowledge of the subject shall be responsible for training and in-service education.

(x) The retention period for clinical records specified in §405.1228(a) is changed to 3 years for purposes of this paragraph.

(xi) The evaluation requirements in §405.1229 are replaced by the following requirement for utilization control:

~~(k) *Utilization control.*~~ The agency shall participate in a program of utilization control of services as prescribed by the title XIX State agency pursuant to § 250.18 of this chapter~~ which, as a minimum, shall include provisions for:~~ As a minimum, the utilization control program shall include establishment by the State title XIX agency of a team or teams of professional persons to perform the functions of patient record review and home health evaluation studies as specified in this paragraph.

(A)

~~(1)~~ Review of patient records~~ by a~~ team of professional persons (at least a ~~physician~~, public health nurse and one additional health professional)~~ not in~~ on a sampling basis shall be performed

No reviewer may participate in the review of the records for patients in wh e care he is directly involved. The team shall also make in-home visits on a sampling basis. The purpose of the review and visits is

~~volved in the direct care of the individual patient, for each 90-day period of service with respect to any patient receiving continued services during such period, in order~~ to make recommendations to the agency providing service as to the necessity for continued service, the adequacy of the plan of care and the appropriateness of continued service~~ and~~.

(B)

~~(2)~~ A continuing program of home health evaluation studies~~ by a team of~~ professional persons (which may be the same team as specified in~~ paragraph (k)(1) of this section~~), which shall identify and analyze trends, problems and patterns of care and make recommendations to the State title XIX agency~~ for~~ improvement of the quality of home health care.

shall be carried out subparagraph ix(A) of this paragraph (a)(2) and to the governing body of the home health agency

(xii) The special standards set forth in the appendix to Subpart L of Part 405 are not applicable under this paragraph unless so specified by the State title XIX agency.

(3) Therapy services may be provided as home health services by an agency specified in paragraph (a) (1) or (2) of this section, or by a facility licensed by the State to provide medical rehabilitation services, and which meets the other conditions set forth in this paragraph. Such a rehabilitation facility must be operated under competent medical supervision and is one which provides therapy services for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of (i) medical evaluation and services, and (ii) psychological, social, or vocational evaluation and services. ~~The major portion of the required evaluation and services must be furnished within the facility and the~~ facility must be operated either in connection with a hospital or as a facility in which all medical and related health services are prescribed by, or are under the general direction of, persons licensed to practice medicine or surgery in the State.

The

(b)

~~(1)~~ *Determination of qualifications.* The determination that an agency providing home health services meets the conditions and standards for participation shall be made in accordance with the applicable provisions for certification and the execution of valid provider agreements set forth in § 249.151 of this chapter.

3. A new § 249.151 is added to Part 249 set forth below:

§ 249.151 Home health agencies: Requirements for agencies qualifying as home health service providers.

(a) *Certification of agencies not participating under title XVIII.* Prior to the execution of a provider agreement and participation in the title XIX program as a provider of home health services, the State survey agency designated under § 250.100 of this chapter shall survey the home health agency and certify as to whether it is found to be in compliance with the conditions and standards set forth in § 249.150 (a) (2) ~~and (j)~~.

(1) The findings of the State survey agency with respect to each of the standards shall be adequately documented. Where the State survey agency certifies that a provider agency is not in compliance with the standards, such documentation shall include, in addition to the description of the specific deficiencies which resulted in the agency's finding, a report of all consultation which has been undertaken in an effort to assist the provider to comply with the standards, a report of the provider's responses with respect to the consultation, and the State agency's assessment of the prospects for such improvements as to enable the provider to achieve compliance with the standards within a reasonable period of time.

(2) If a provider is certified by the State survey agency to be in compliance with the standards or to be in compliance except for deficiencies not adversely affecting the health and safety of patients the following information will be incorporated into the finding:

(i) A statement of the deficiencies which were found, and

(ii) A description of further action which is required to remove the deficiencies, and

(iii) A time-phased plan of correction developed by the provider and concurred in by the State survey agency, and

(iv) A scheduled time for a resurvey of the ~~agency~~ to be conducted by the State survey agency within 90 days following the completion of the survey.

(3) If, on the basis of the State certification that ~~an agency~~ meets standards, and such other information as it possesses, the State title XIX agency executes a provider agreement with the provider agency, the information described in paragraph (a) (2) of this section will be incorporated into a notice to the provider.

with the State title XIX agency

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State survey

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and submitted to the State survey agency within 10 days of the provider's receipt of the deficiency report

follow-up visit or

provider

survey agency

a provider

(4) Initial certifications and recertifications by the State survey agency to the effect that a provider is in compliance with all the standards will be for a period of 12 months. State survey agencies may visit or resurvey providers more frequently where necessary to evaluate correction of deficiencies, ascertain continued compliance, or accommodate to periodic or cyclical survey programs. The State survey agency shall evaluate such reports as may pertain to the health and safety requirements and, as necessary, take appropriate action to achieve compliance or certify to the State title XIX agency that compliance has not been achieved. A State finding and certification that a provider is no longer in compliance will supersede the State's previous certification. survey agency

(5) The State survey agency will certify that a provider is not or is no longer in compliance with the standards where the deficiencies are of such character as to substantially limit the provider's capacity to render adequate care or which adversely affect the health and safety of patients.

(6) If a provider is found to be deficient with respect to one or more of the standards, it may participate in the State title XIX program only if the provider has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the State survey agency. The existing deficiencies noted either individually or in combination must neither jeopardize the health and safety of patients nor be of such character as to seriously limit the provider's capacity to render adequate care.

(7) If it is determined during a survey that a provider is not in compliance with one or more of the standards in accordance with paragraph (a)(6), it will be granted a reasonable time to achieve compliance. The amount of time will depend upon the nature of the deficiency and the State survey agency's judgment as to the provider's capabilities to provide adequate and safe care. Ordinarily a provider will be expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies but the State survey agency may grant additional time in individual situations, if in its judgment it is not reasonable to expect compliance within 60 days, e.g., a provider must obtain the approval of its governing body, or engage in competitive bidding.

(b) *Execution of provider agreements with all agencies providing home health services.* (1) The State agency shall not execute a provider agreement, under this section, with an agency providing home health services unless the agency is certified to provide such services under title XVIII of the Act, or is certified as meeting the standards specified in § 249.150 of this chapter in accordance with the applicable provisions of this section.

(2) (i) The term of an agreement may not exceed a period of one year and the effective date of such agreement may not be earlier than the date of certification. (ii) Execution of a provider agreement shall be for the term and in accordance with the provisions of certification determined by the survey agency, except that the ~~single~~ State agency for good cause based on adequate and documented evidence may elect to execute a provider agreement for a term less than the full period of certification, or may elect not to execute a provider agreement, or may cancel a provider agreement for participation by ~~an~~ agency certified under the State plan. (iii) Notwithstanding the provisions of this paragraph the single State agency may extend such term for a period not exceeding two months where the survey agency has notified the single State agency in writing prior to the expiration of a provider agreement that the health and safety of the patients will not be jeopardized thereby, and that such extension is necessary to prevent irreparable harm to such agency or hardship to the individuals being furnished items or services or that it is impracticable within such provider agreement period to determine whether such agency is complying with the provisions and requirements under the program. An extension of the provider agreement for more than two months may be granted if it is necessary to implement the State survey agency's determination under paragraph (a)(7) of this section to allow the provider additional time to correct deficiencies.

(iv) Any ~~agency~~ whose agreement has been cancelled or otherwise terminated

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may not be issued another agreement until the reasons which caused the cancellation or termination have been removed and reasonable assurance provided the ~~survey agency~~ State that they will not recur.

(3) With respect to home health agencies certified to participate under title XVIII of the Act, the term of a provider agreement between such agency and the State title XIX agency shall be subject to the same terms and conditions and be coterminous with the period of participation specified by the Secretary under title XVIII. Upon notification that an agreement with ~~an agency~~ a provider under title XVIII has been terminated or cancelled, the State title XIX agency will take the same action under title XIX as of the effective date of the title XVIII action.

When an agreement is cancelled or otherwise terminated, the State title XIX agency must take prompt action to provide alternate sources of care.

(c) *Disallowance of Federal financial participation when agency is found not to meet all requirements for certification.* A provider agreement between the title XIX State agency and an agency specified in § 249.150(a)(2) of this chapter shall not be considered valid evidence that such agency meets all requirements for certification pursuant to § 249.150, if the Secretary establishes on the basis of on-site validation surveys, other Federal reviews, State certification records, or such other reports as he may prescribe, that:

(1) The survey agency failed to apply the Federal standards for the certification of such agency as required under § 249.150 of this chapter;

(2) The survey agency failed to follow the rules and procedures for certification set forth under § 249.151 of this chapter;

(3) The survey agency failed to use the Federal standards and such forms, methods and procedures as are established under § 250.100(c)(1) of this chapter; or

(4) The terms and conditions of a provider agreement do not meet the requirements of this section.

States upon request shall receive a reconsideration of any disallowances of Federal financial participation resulting from the Secretary's determination under these provisions, in accordance with section 1116(d) of the Act, and § 201.14 of this chapter.

(Sec. 1102, 49 Stat. 647 (42 U.S.C. 1302))

Effective Date: The regulations in this section shall be effective 90 days following date of publication in the Federal Register.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program)

DATED: JAN 14 1976

JOHN A. SVAHN

Acting Administrator, Social and Rehabilitation Service

APPROVED: _____

Secretary

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
SOCIAL AND REHABILITATION SERVICE
Office of the Administrator

TO : The Secretary
Through: U
ES

AUG 4 1975

FROM : Acting Administrator
Social and Rehabilitation Service

SUBJECT: Proposed Medicaid Regulations on Home Health Services - ACTION

Purpose

To revise regulations in order to increase use of home health services under the Medicaid program where home care is appropriate and necessary with respect to the recipient's condition. The revisions broaden the types of agencies eligible to provide services and clarify the required and optional services to be available by States.

Background

Under existing Medicaid home health services regulations (Tab E);

(1) Provider participation has been restricted to those which meet Medicare requirements, i.e., they must provide skilled nursing services and one other service such as physical therapy. This has meant that agencies, such as visiting nurse associations, have been unable to participate if they cannot offer the second service. Also, the requirement has served as a deterrent to creation of new agencies.

(2) There is ambiguity as to the minimum set of home health services which States must provide under a State plan. It has been interpreted that the States are required to provide only one of the specified services (nursing, home health aide, supplies and equipment), when in fact it was intended that all of these were required to be available.

Another problem has been that some States have adopted the Medicare definition of home health services as those which can be performed only by an R.N. or L.P.N. This has resulted in a person who did not require "skilled" services but for example, only home health aide services, not being eligible for home health services. Some States also limited eligibility by applying inappropriate requirements of post-hospitalization or pre-institutionalization.

...

A GAO report on home health services recommended that SRS clarify the services for which FFP is available and encourage States to make greater use of them. In line with these recommendations and as part of the Department's effort to develop alternatives to institutional care, SRS has developed a proposed revision of the regulations as outlined below.

Proposed Revisions

(1) Clarification of required and optional services. The proposal now specifies that States must make available, as determined necessary by the recipient's physician and included in the plan of care, nursing services, home health aide services, and medical supplies, equipment and appliances suitable for use in the home. At State option, physical, or occupational or speech therapy may be provided to home health care patients even though not generally provided to all recipients under the State plan (§249.10(b)(7), page 2).

(2) Expansion of the types of agencies qualified to provide services and specification of standards they must meet. Instead of the limitation to agencies providing primarily skilled nursing plus a therapeutic service, the regulations would permit agencies offering nursing or home health aide services to qualify if they meet the prescribed standards. The latter are basically the Medicare standards for home health agencies, appropriately adapted to reflect inclusion of additional provider types (§249.150, page 3).

(3) Clarification of recipient eligibility. As indicated above, there has been some confusion as to whether recipients must be determined to need skilled care or to require admittance to long-term care. The revision incorporates into regulations an explanation of entitlement previously issued as policy interpretation. §249.10 (a)(4), page 1)

(4) Specification of certification procedures for agencies offering home health services. These are based on Medicare procedures. (§249.151, page 18)

Discussion of Issues

An earlier version of these regulations was circulated by OS/ES to appropriate offices and agencies in the Department and was also reviewed by a committee of State representatives through APWA. Discussions and written comments have indicated that a variety of

opinions exist on what revisions should be made, although there is general agreement on the value of increasing the use of these services. The regulations at Tab A reflects most of the suggestions received on the detail of the provisions; it also contains the SRS position on the two major issues involved in revising the current rules. Those issues concern participation by proprietary agencies on the same basis as voluntary and non-profit agencies, and eligibility of single-service agencies to provide home health services. They are discussed at Tab B.

Recommendation

That you decide the issues described under Tab B, and approve the Notice of Proposed Rule Making at Tab A for publication in the Federal Register. We believe that, in the light of the GAO report and Congressional interest in expanding home health services, it is urgent to publish a Notice for comment by States, provider and recipient groups, and others, and that additional comments from DHEW staff should be considered during the public notice period.

JOHN A. SVAHN

John A. Svahn

Enclosures
Tab A - Notice of Proposed Rule Making
Tab B - Discussion of Issues
Tab C - Inflationary Impact Statement
Tab D - Press Release
Tab E - Current Medicaid Regulations

Prepared by: SRS/MSA, MOSchnoor, 5/02/75, x50397

Done

L-H

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

January 16, 1976

TO:

GC, C, P, L, A, SSA, H, HD and Mr. Peter Franklin

SUBJECT: Press Release for SRS' Regulations----
Home Health Services (Sequence No.
SRS-13, 1 of 1----Staffed by ES 1/15/76

Attached is SRS' press release for the subject regulations routed to you yesterday.

Please associate with regulations file now in your offices.

Mary Frances Howell

Mary Frances Howell
Regulations Coordinator

Attachment

cc: ESW, Room 5614 North Building

HEW NEWS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social and Rehabilitation Service
KELSO--(202)--245-0620
KAPLAN--(202)--245-0347

More health care organizations can provide home health services for Medicaid patients under a regulation issued by HEW's Social and Rehabilitation Service.

The regulation, published today in the Federal Register, permits profit-making agencies which meet Federal and State Standards to provide home health services under Medicaid. It also permits small visiting nurses associations, providing only nursing services, to participate.

Further, the regulation clarifies who is eligible for home health care as well as the kinds of services States are required to make available under the title of home health services.

Among them are nursing services, home health aide services, and the furnishing of suitable medical supplies, equipment, and appliances (in accordance with a patient's needs as determined by his physician.) Physical and occupational therapy, as well as speech therapy, can be offered as home health services at a State option whether or not they are available to all Medicaid recipients under a State plan.

The regulation adopts the Medicare standards for home health agencies, with appropriate modifications, as standards for health care organizations and profit-making agencies participating in Medicaid.

(more)

Under the regulation, profit-making agencies will be able to participate in Medicaid home health services programs if they meet those standards, subject to State licensing laws.

In proposing the regulation last August, HEW said that many Medicaid patients would prefer to be taken care of at home rather than in an institution, if possible. HEW also noted that home health care for some patients can be provided at lower cost, to the benefit of both patient and taxpayer.

# # #