DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 440

[MB–071–F]

RIN 0938–AH00

Medicaid Program; Coverage of Personal Care Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule specifies the revised requirements for Medicaid coverage of personal care services furnished in a home or other location as an optional benefit, effective for services furnished on or after October 1, 1994. In particular, this final rule specifies that personal care services may be furnished in a home or other location by any individual who is qualified to do so. This rule conforms the Medicaid regulations to the provisions of section 13601(a)(5) of the Omnibus Budget Reconciliation Act of 1993, which added section 1905(a)(24) to the Social Security Act. Additionally, we are making two minor changes to the Medicaid regulations concerning home health services.

EFFECTIVE DATE: November 10, 1977.

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SUPPLEMENTARY INFORMATION:

I. Background

Under section 1902(a)(10) of the Social Security Act (the Act), States with Medicaid programs must provide certain basic services to Medicaid recipients. Section 1905(a) of the Act defines the required and optional services that are provided as medical assistance. Before the enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90, Public Law 101–508), a State had the option to elect to cover personal care services under its Medicaid State plan. Although not specifically mentioned in section 1905(a) of the Act, personal care services could be covered under section 1905(a)(22) of the Act (redesignated as section 1905(a)(25) of the Act on November 5, 1990), under which a State may furnish any additional services specified by the Secretary and recognized under State law. In regulations at 42 CFR 440.170(f), the Secretary specified that personal care services may be covered.

Section 4721 of OBRA '90 amended section 1905(a)(7) of the Act to include personal care services as part of the home health services benefit and to impose certain conditions on the provision of personal care services, effective for services furnished on or after October 1, 1994. This amendment would have had a significant effect since, under section 1902(a)(10)(D) of the Act, home health services are a mandatory benefit for all Medicaid recipients eligible for nursing facility services under the State plan. Thus, had section 1905(a)(7) of the Act not been further amended (as discussed below) before the effective date of section 4721 of OBRA '90, personal care services would have become a mandatory benefit for all recipients eligible for nursing facility services, effective October 1, 1994.

Before the provisions of OBRA '90 became effective, the Omnibus Budget Reconciliation Act of 1993 (OBRA '93, Public Law 103–66) was enacted on August 10, 1993. Section 13601(a)(1) of OBRA '93 amended section 1905(a)(7) of the Act to remove personal care services from the definition of home health services. Additionally, section 13601(a)(5) of OBRA '93 added a new paragraph (24) to section 1905(a) of the Act, to include payment for personal care services under the definition of medical assistance. Under section 1905(a)(24) of the Act, personal care services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for persons with mental retardation (ICF/MR), or institution for mental disease is an optional benefit for which States may provide medical assistance payments. The statute specifies that personal care services must be: (1) Authorized for an individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State; (2) provided by an individual who is qualified to provide such services and who is not a member of the individual's family; and (3) furnished in a home or other location. This amendment was effective October 1, 1994. Therefore, as a result of the legislative changes made by OBRA '93, personal care services continue to be an optional State plan benefit, and are now authorized under section 1905(a)(24) of the Act, effective for services furnished on or after October 1, 1994.

II. Issuance of the Proposed Rule

A. Personal Care Services in a Home or Other Location (§ 440.167)

On March 8, 1996, we published in the **Federal Register** a proposed rule that specified that personal care services may be furnished in a home or other location by any individual who is qualified to do so (61 FR 9405). Throughout the preamble to the proposed rule, we emphasized our main goal in implementing the statutory provisions regarding personal care services. Specifically, our objective was to provide States maximum flexibility in tailoring their Medicaid programs to meet the needs of recipients while also setting guidelines so that States that choose to offer the personal care services benefit furnish quality services in an effective manner.

In the preamble to the proposed rule, we stated that as historically used in the Medicaid program, personal care services means services related to a patient's physical requirements, such as assistance with eating, bathing, dressing, personal hygiene, activities of daily living, bladder and bowel requirements, and taking medications (61 FR 9406). These services primarily involve ''hands on'' assistance by a personal care attendant with a recipient's physical dependency needs (as opposed to purely housekeeping services). We noted that although personal care services may be similar to or overlap some services furnished by home health aides, skilled services that may be performed only by a health professional are not considered personal care services. Alternatively, services that require a lower level of skill such as personal care services may also be provided by home health aides under the home health benefit. We did not propose to include the above description of personal care services in the regulations. The specific changes we proposed to the regulations are set forth below:

The existing regulations at § 440.170 specify that personal care services in a recipient's home means services prescribed by a physician in accordance with the recipient's plan of treatment, and furnished by an individual who is (1) qualified to provide the services, (2) supervised by a registered nurse, and (3) not a member of the recipient's family. The existing regulations do not provide for personal care services furnished in settings other than the recipient's home. To conform the regulations to the provisions of section 1905(a)(24) of the Act, we proposed to add a new § 440.167, ''Personal care services in a home or other location.'' We proposed

that personal care services are services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for persons with mental retardation, or institution for mental disease, that are: (1) Authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State; (2) provided by an individual who is qualified to provide such services and who is not a member of the individual's family; and (3) furnished in a home, and if the State chooses, in another location.

Since section 1905(a)(24) of the Act does not require that the services be supervised by a registered nurse, we proposed that we would not require such supervision in new § 440.167. In addition, we proposed that States that elect to offer the personal care services benefit must, at a minimum, cover personal care services provided in the home, but also have the option to cover personal care services provided in other locations. We set forth a detailed discussion of alternatives that we considered in implementing the provision of OBRA '93 that allows States to cover personal care services provided outside the home (61 FR 9406).

We proposed to leave to the State's option the decision of whether personal care services are to be authorized by a physician in accordance with a plan of treatment, or otherwise authorized in accordance with a service plan approved by the State. Similarly, we proposed to permit States to determine, through development of provider qualifications, which individuals are qualified to provide personal care services (other than family members).

Section 1905(a)(24)(B) of the Act specifies that, for Medicaid purposes, personal care services may not be furnished by a member of the individual's family. To provide for more clarity and consistency in this regard, we proposed to define family members under new § 440.167(b) as spouses of recipients and parents (or stepparents) of minor recipients. Finally, since personal care services are now an optional benefit under section 1905(a)(24) of the Act, we proposed to remove existing § 440.170(f), which provides for coverage of personal care services in a recipient's home as part of any other medical care or remedial care recognized under State law and specified by the Secretary.

B. Proposed Changes Concerning Home Health Services (§ 440.70)

We proposed several changes to the regulations concerning home health services. Specifically, we proposed to revise § 440.70(b)(3) to provide that the frequency of physician review of a recipient's need for medical supplies, equipment, and appliances suitable for use in the home under the home health benefit would be determined on a case-by-case basis depending on the nature of the item prescribed (rather than every 60 days, as provided for in the existing regulations). Absent changes in a recipient's condition, we do not believe that a recipient's need for medical equipment necessitates routine inclusion in a plan of care reviewed every 60 days by a physician.

Additionally, existing § 440.70(d) defines a home health agency for purposes of Medicaid reimbursement as a public or private agency or organization, or part of an agency or organization, that meets requirements for participation in Medicare. We proposed to revise this definition to indicate that in order to participate in Medicaid, the agency must meet Medicare requirements for participation as well as any additional standards the State may wish to apply that are not in conflict with Federal requirements. Finally, we proposed a technical change to § 440.70(c) to remove an obsolete reference to subparts F and G of part 442.

III. Discussion of Public Comments and Departmental Responses

We received 73 timely comments in response to the proposed rule. A summary of these comments and our responses follow.

Comment: Many commenters disagreed with our proposal to eliminate the requirement that personal care services be supervised by a registered nurse. The commenters indicated that the registered nurse is the only medical contact many (mostly elderly) beneficiaries have and that the nurse is instrumental in identifying health needs that require immediate attention by a health care professional.

Response: Section 1905(a)(24) of the Act, as added by OBRA ''93, does not specify that personal care services must be supervised by a registered nurse. Therefore, we proposed to remove the requirement from the existing regulations. While we believe that it was clearly the intent of Congress to eliminate this requirement from the statute, we agree with the commenters that there may be situations in which individuals providing personal care services need supervision. However, while some individuals' conditions may dictate a need for nurse supervision, many individuals receiving personal care services are either capable of directing their own care or have needs that are not based on a ''medical'' condition (for example, individuals with mental retardation). Additionally, a stable, physically disabled beneficiary without cognitive impairments may not need supervision of his or her personal care attendant. In some cases, supervision of personal care services by a registered nurse may be unnecessary, but the services of a case manager may be appropriate to oversee the individual's needs. We note that case management services could be reimbursed as either administrative costs or, as applicable, targeted case management services under Medicaid. Our revision to the regulations does not prohibit the supervision of a registered nurse; rather, it allows States to make the determination of when supervision of personal care services is necessary and what type of professional is qualified to supervise the personal care attendant. Therefore, we believe that the need for supervision, whether by a registered nurse or another individual, should be made on a case-by-case basis by the State.

Comment: A few commenters were concerned that we did not define ''qualified'' personal care providers. Others suggested that we require States to establish criteria for determining provider qualifications. In addition, several commenters recommended that, without the nursing supervision requirement, we establish Federal quality assurance standards or minimal standards of training or testing for personal care providers.

Response: We are not establishing provider qualifications for personal care services. Rather, in the interest of maintaining a high level of flexibility in providing personal care services, we suggest that States develop their own provider qualifications and establish mechanisms for quality assurance. While we recognize the importance of provider qualifications and quality assurance, we also firmly believe in allowing States the greatest flexibility in designing their Medicaid programs. There are several methods States may use to ensure that recipients are receiving high quality personal care services. For example, States may opt to screen personal care attendants before they are employed and/or train them afterward or allow the recipient to be the judge of quality through an initial screening. Alternatively, States may require agency providers to train their

employees on the job. State level oversight of overall program compliance standards, case level oversight, attendant training and screening, and recipient complaint and grievance mechanisms are ways in which States can influence the quality of their personal care programs. In this way, States can best address the needs of their target populations (for example, individuals with AIDS or with physical disabilities) and set unique provider qualifications and quality assurance mechanisms. We note that home health aides employed by home health agencies may sometimes provide personal care services. Home health aides that provide only personal care services under Medicaid need only meet the qualifications set forth at § 484.36(e) (and not other qualifications for home health aide services).

Comment: Some commenters disagreed with our proposal that States electing to offer personal care services must cover these services when provided in the home and may also choose to cover personal care services provided in other locations. The commenters believed that we should require States to provide the services in locations outside the home. One commenter stated that we should indicate that assisted living facilities may be considered an individual's home. Other commenters asked that we clarify the meaning of ''other locations.''

Response: In the proposed rule, we set forth a detailed discussion of options we considered for implementing the provision of OBRA '93 that allows States to cover personal care services outside the home (61 FR 9406). We proposed that States electing the personal care services benefit must provide the services in the home but may also choose to provide personal care in locations outside the home. We stated that our main goal in implementing the provision was to afford States maximum flexibility in tailoring their Medicaid programs to meet the needs of their recipients while also expanding the settings in which personal care services may be provided.

We do not believe that adopting the commenters' suggestion that we require States to provide the services in the home *and* in other locations would be appropriate since section 1905(a)(24)(C) of the Act refers to services ''furnished in a home *or* other location.'' We believe that Congress clearly did not intend to impose such a mandate on State Medicaid programs. Moreover, a policy such as the one suggested by the commenters could work against the best interests of recipients if States choose not to offer the personal care services benefit at all because of the expense involved in covering the services both inside and outside the home. In addition, the Medicaid program has always given States latitude in establishing the criteria or conditions under which optional services (such as personal care) may be covered, as long as the services available are sufficient to achieve their purpose. States have the flexibility to define optional services to include less than the full array of services that could be covered under the regulatory definitions, if they so choose. (In accordance with section 1905(r)(5) of the Act, coverage of personal care services outside the home is not optional with respect to those individuals who are eligible for the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program. Personal care services outside the home are mandatory for these individuals when medically necessary under the EPSDT program.)

We note that an individual need not receive personal care services inside the home to be eligible to receive them in another location. Rather, as stated above, a State that opts to furnish personal care services must provide them inside the home to recipients that need them in that setting, but also has the option to provide them in other locations. Thus, depending on whether the State also chooses to provide personal care services outside the home, an individual recipient could receive personal care services inside the home, outside the home or in both locations. We believe that our policy is the most appropriate interpretation of the statute, is in the best interest of recipients, and gives States the discretion necessary to operate their programs in an efficient manner.

With regard to the other issues raised by commenters, States may consider an assisted living facility as an individual's home but we do not believe we need to add this requirement to the regulations. Additionally, ''other locations'' may be any location, as specified by the State, except for the statutorily excluded locations set forth in section 1905(a)(24) of the Act (hospital, nursing facility, or ICF/MR).

Comment: One commenter disagreed with our position that the EPSDT provisions mandate coverage of personal care services outside the home when medically necessary.

Response: As stated above, under section 1905(r)(5) of the Act, the provision of medically necessary personal care services outside the home is not an option but a mandate for individuals eligible under the EPSDT program. The EPSDT benefit includes all medically necessary services described in section 1905(a) of the Act, whether or not such services are covered under the State's Medicaid plan. Therefore, personal care services must be provided outside the home when medically necessary to individuals under the EPSDT program.

Comment: Some commenters disagreed with our proposed definition of personal care services and others believed that we should define the services in regulation. The commenters recommended that we provide a detailed description of the services that can be provided under the personal care services benefit in the regulatory language. One commenter indicated that personal care services should include those that are delegated by a nurse or physician to an unlicensed personal care provider. They also suggested that the definition be revised to delete reference to physical tasks while referring to assistance with both activities of daily living (ADLs) and instrumental activities of daily living (IADLs), including assistance with cognitive tasks and services to prevent an individual from harming himself. One commenter suggested changing the name of the service from personal care services to ''personal assistant services.'' One commenter asserted that assistance with taking medications should not be included as a personal care service.

Response: As stated in the proposed rule, in order to more easily address changes that may occur in the definition and delivery of personal care services and to allow greatest State flexibility, in the near future we plan to publish in a State Medicaid Manual instruction a definition that States may use. As suggested by the commenter, we plan to define the services in terms of assistance with ADLs and IADLs. Services such as those delegated by nurses or physicians to personal care attendants may be provided so long as the delegation is in keeping with State law or regulation and the services fit within the personal care services benefit covered under a State's plan. Services such as assistance with taking medications would be allowed if they are permissible in States' Nurse Practice Acts, although States may need to ensure proper training is provided when necessary. We will not change the name of the service as suggested, as the regulations now are consistent with the statutory language.

Comment: Some commenters were concerned about our proposed definition of ''family member'' for purposes of individuals providing personal care services. A few commenters suggested that we expand the definition to preclude Medicaid

coverage of personal care services provided by children, grandchildren, and legal guardians of recipients. Other commenters believed that parents and spouses should be allowed to provide personal care services. Another commenter recommended that stepparents be allowed to provide personal care services in States where stepparents are not legally responsible for the recipient. Finally, several commenters disagreed with our proposal to allow States to further restrict family members from providing services and indicated that States should be required to limit excluded family members to spouses and parents.

Response: Section 1905(a)(24)(B) of the Act specifies that personal care services may not be furnished by a member of the individual's family. We proposed to define family members as spouses of recipients and parents (or stepparents) of minor recipients. Additionally, we proposed that States could further restrict which family members could qualify as providers by extending the definition to apply to family members other than spouses and parents.

To provide for more clarity and consistency, we have revised the definition of family member at new § 440.167(b) to provide that a family member is a legally responsible relative. Thus, spouses of recipients and parents of minor recipients (including stepparents who are legally responsible for minor children) are included in the definition of family member. This definition is identical to the revised definition that applies to personal care services provided under a home and community-based services waiver.

Congress clearly intended to preclude family members from providing personal care services and we believe our revised definition is the most reasonable interpretation of the term. Furthermore, we have always maintained that spouses and parents are inherently responsible for meeting the personal care needs of their family members, and, therefore, it would not be appropriate to allow Medicaid reimbursement for such services. If stepparents are not legally responsible for the recipient in some States, they could provide personal care services under our revised definition. However, because States can further restrict which family members can qualify as providers by extending the definition to apply to individuals other than those legally responsible for the recipient, States could choose to exclude stepparents regardless of their legal responsibility. In addition, by allowing States to further define ''family members'' for purposes of personal care services, States can tailor their programs to meet their individual needs.

Comment: A few commenters indicated that the personal care services benefit should be a mandatory service that States must provide under their Medicaid programs. One commenter believed that the regulation should specifically allow various methods of delivering personal care services (for example, vouchers, individual providers, consumer-directed agency models, or traditional agency models).

Response: The Medicaid program is a Federal-State program that provides for mandatory services that States must provide and optional services that States may choose to provide. Sections 1902(a)(10)(A) and 1905(a) of the Act define those services that are optional and those that are mandatory. Under section 1905(a)(24) of the Act, personal care services are an optional benefit that States may choose to provide to their Medicaid populations. To mandate that States provide personal care services would require legislative action by Congress. With regard to methods for delivering personal care services, we believe in allowing States the flexibility to determine the best method of providing services and will not specify such methods in a regulation.

Comment: One commenter suggested that we retain the requirement for physician plan of care authorization for personal care services. The commenter believed that eliminating this requirement will lead to fraud and excess spending.

Response: Section 1905(a)(24) of the Act provides that personal care services must be authorized ''by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State.'' In accordance with this section of the Act, we proposed to include this provision in new § 440.167. We believe that the statute clearly indicates Congress' intent to allow States the flexibility to utilize alternative means of plan of care authorization. Further, regarding the commenter's concern that the elimination of the requirement for physician authorization will encourage fraud, we believe that it is in the best interest of States to control spending and to establish methods to prevent providers from engaging in fraudulent activities. Our revisions do not preclude physician authorization of personal care services. Rather, in accordance with the statute, we are allowing States to determine the appropriate method for plan of care authorization. Therefore, we will not continue to require that the plan of care be authorized by a physician.

Comment: One commenter disagreed with our revision to the frequency of review of an individual's plan of care for medical supplies, equipment, and appliances suitable for use in the home under the home health services benefit. The commenter was concerned that our proposal might compromise quality of care and utilization control concerns.

Response: We proposed that § 440.70(b)(3) be revised to provide that physician review of a recipient's need for medical supplies, equipment, and appliances suitable for use in the home under the home health benefit would be required annually instead of every 60 days. The frequency of review on other than an annual basis would be determined by the State on a case-by-case basis depending on the nature of the item prescribed. We have found that, in many cases, once a recipient's need for medical supplies, equipment, and appliances is indicated by a physician, that need is unlikely to change within 60 days. A recipient's need for supplies or pieces of equipment that generally tend to be used on a long-term basis would not be reviewed as frequently as equipment that is usually used only temporarily. For example, review of the need for a wheelchair need not be as frequent as review of the need for an oxygen concentrator. In all cases, a physician's order for the equipment would be required initially, and frequency of further review of a recipient's continuing needs would depend on the type of equipment prescribed. We believe that the requirement for annual review of medical supplies and equipment balances States flexibility in furnishing home health services with providing an appropriate level of oversight. In addition, this may allow a decrease in physicians' paperwork burden, time, and costs.

Comment: Two commenters disagreed with our proposal to revise the definition of a home health agency for purposes of Medicaid reimbursement to indicate that in order to participate in Medicaid, the agency must meet Medicare requirements for participation as well as any additional standards the State may wish to apply that are not in conflict with Federal requirements.

Response: Under this provision a State would have the option of imposing additional standards on home health agencies for participation in Medicaid beyond the Medicare conditions of participation. Our intention in revising the home health agency definition is to afford States greater flexibility in

establishing Medicaid program requirements tailored to their own specific needs. This will enable States to conform existing State and Federal requirements but by no means mandates that additional requirements be established.

Comment: One commenter indicated that our proposed revision to § 440.70(c) would erroneously preclude home health services from being provided to ICF/MR residents regardless of whether those services are not otherwise available.

Response: We proposed to make a technical revision to § 440.70(c) to remove an obsolete reference to subparts F and G of part 442. We agree with the commenter that our proposed revision would have the effect of precluding home health services from being made available to ICF/MR residents even when the services are not otherwise available. We have revised the language in § 440.70(c) to correct this error.

IV. Provisions of the Final Rule

We are adopting the proposed rule as final with some revisions. Specifically:

- We have revised § 440.70(c) to provide that a recipient's place of residence, for home health services, does not include a hospital, nursing facility, or ICF/MR, except for home health services in an ICF/MR that are not required to be provided by the facility under subpart I of part 483. We also have reinstated the example given.
- We have revised the definition of family member at proposed § 440.167(b) to provide that a family member is a legally responsible relative.
- In the proposed rule, we failed to include language currently located in existing § 440.170(f) in new § 440.167. Specifically, the introductory text of existing § 440.170(f) permits States to define personal care services differently for purposes of a section 1915(c) waiver. We have revised new § 440.167 to include this provision.

V. Impact Statement

A. Background

For proposed rules such as this, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless we certify that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of a RFA, States and individuals are not considered small entities. However, providers are considered small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operation of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We are not preparing a rural impact statement since we have determined, and we certify, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

This final rule revises the Medicaid regulations to incorporate the statutory requirements of section 1905(a)(24) of the Act concerning personal care services. In accordance with the statute, we are providing that the services must be: (1) Authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State; (2) provided by an individual who is qualified to provide the services and who is not a member of the individual's family; and (3) furnished in a home or other location.

In general, the provisions of this final rule are prescribed by section 1905(a)(24) of the Act, as added by section 13601(a)(5) of OBRA'93. The most significant change required under the statute is that, as of October 1, 1994, the settings in which States may elect to cover personal care services have been expanded to include locations outside the home. We believe that this statutory provision will increase Medicaid program expenditures regardless of whether or not we promulgate this rule. The primary discretionary aspect of this rule is the requirement that States electing to offer the personal care services benefit must cover the services in the home and may choose to cover them in any other location. As discussed in the proposed rule (61 FR 9406), we considered requiring States that elect to offer the personal care services benefit to cover the services in both the home and other locations. We also considered allowing States to cover the services either in the home or in other locations. However, we believe that the policy in this final rule is the most appropriate interpretation of the statute and gives States the discretion necessary to operate their programs in an efficient manner and in the best interest of their recipients.

As noted above, the major provisions of this final rule are required by the statute. Thus, costs associated with these regulations are the result of legislation, and this rule, in and of itself, has little or no independent effect or burden. However, to the extent that a legislative provision being implemented through rulemaking may have a significant effect on recipients or providers or may be viewed as controversial, we believe that we should address any potential concerns. In this instance, we believe it is desirable to inform the public of our estimate of the substantial budgetary effect of these statutory changes. The statutorily driven costs have been included in the Medicaid budget baseline. In addition, we anticipate that a large number of Medicaid recipients and providers, particularly home health agencies, will be affected. The expansion of settings where personal care services may be furnished represents an expansion of Medicaid benefits that, if exercised by States, will likely have significant effects, particularly on Medicaid recipients. Therefore, the following discussion constitutes a voluntary regulatory flexibility analysis.

B. Impact of New Personal Care Services Provision

1. Overview

This analysis addresses a wide range of costs and benefits of this rule. Whenever possible, we express impact quantitatively. In cases where quantitative approaches are not feasible, we present our best examination of determinable costs, benefits, and associated issues.

It is difficult to predict the economic impact of expanding the settings where personal care services may be covered under Medicaid to locations outside the home. We do not know the exact number and type of personal care services furnished by individual States or how much these services currently cost. Currently, approximately 32 States offer coverage for personal care services, and we do not have cost data from all of those States. States also differ in their definitions of personal care services and rules concerning who may furnish them. Since we do not have a full picture of the scope or cost of the different services, it is difficult for us to quantify the impact these changes will have. Other unknown factors regarding the future provision of personal care services include which States now offering the personal care services benefit will choose to cover services furnished outside the home, how many additional States will opt to offer coverage, how many Medicaid recipients will elect to use these

services in States in which the services have not been covered, and the type and costs of these specific services. We believe that the majority of those individuals who qualify for these services will elect to use this benefit. Thus, although costs to States will rise as they begin to pay for the additional services, there will be substantial benefits to some providers and to Medicaid recipients as described in detail below.

2. Effects Upon Medicaid Recipients

Permitting States that elect to offer the personal care services benefit the option of covering these services in locations outside the home will have a positive effect on recipients. In States where coverage has been provided only for personal care services in the home, this final rule may expand the types of personal care services available and/or the settings where recipients may receive these services. Expansion of personal care services or settings could help improve the quality of life for these recipients as well as for recipients who have not been receiving personal care services. It also could save money for some Medicaid recipients or their families since they would no longer have to pay for these services. No data are available on the number of recipients or family members who are currently paying for these services. However, since only 32 States currently pay for personal care services, we believe that a substantial number of recipients who receive these services are paying for them out of pocket.

3. Effects on Providers

By expanding the range of settings in which Medicaid will cover personal care services, we anticipate that this final rule will increase the demand for such services. We believe this effect will be viewed as beneficial to providers of personal care services. If the increase in demand for such services is sufficient, the number of providers of personal care services may increase.

4. Effects on Medicaid Program Expenditures

This final rule implements the provisions of section 1905(a)(24) of the Act by specifying that personal care services are an optional State plan benefit under the Medicaid program. The rule allows States the option to cover personal care services furnished in a home or other location, effective for services furnished on or after October 1, 1994. Table 1 below provides an estimate of the anticipated additional Medicaid program expenditures associated with furnishing these services outside the home, beginning on October 1, 1997. This estimate was made using various assumptions about increases in utilization by current recipients, adjusted for age, as well as assumptions about the induced utilization that may result from the availability of these services. We have assumed a utilization increase of 5 percent for the aged and 10 percent for the non-aged, and an overall induction factor of 10 percent. Given these assumptions, our estimate based on Federal budget projections is shown in Table 1, which also provides a breakdown of these costs. The first row of figures shows the Federal costs of providing this optional State plan benefit. The second row shows the Federal administrative costs associated with furnishing these services. We estimate the following costs to the Medicaid program:

TABLE 1.—PERSONAL CARE SERVICES OUTSIDE THE HOME

	Federal medicaid cost estimate (in millions) [1]				
	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Services	$185	$440	$545	$685	$855
Admin. Costs	10	15	15	15	20
Total	195	455	560	700	875

[1] Figures are rounded to the nearest $5 million.

5. Effects on States

As stated above, the coverage of personal care services is optional except when such services are medically necessary to correct or ameliorate medical problems found as a result of a screen under the EPSDT program. Many States (approximately 18) currently do not cover optional personal care services. In those States that do offer the personal care services benefit, services furnished outside the home previously could not be covered. Therefore, there may be a substantial economic impact on States that decide to provide coverage for personal care services furnished outside the home. The varying State definitions of personal care services and rules concerning who may furnish them make it difficult to estimate accurately the potential increases in expenditures for those States that choose to expand coverage of personal care services to include services furnished outside the home. However, Table 2 includes estimated costs to States, which are based upon the same data and assumptions used to formulate the Federal expenditures shown in Table 1.

TABLE 2.—PERSONAL CARE SERVICES OUTSIDE THE HOME

	Federal medicaid cost estimate (in millions) [1]				
	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Services	$140	$330	$415	$515	$645
Admin. Costs	5	10	10	20	20
Total	145	340	425	535	665

[1] Figures are rounded to the nearest $5 million.

C. Conclusion

The provisions of this final rule are required by section 1905(a)(24) of the Act. We believe that the provisions of this rule adding personal care services as an optional State plan benefit and expanding the possible settings for covering personal care services to locations outside the home will benefit providers, recipients, and their families.

As shown above in Tables 1 and 2, the costs to the Federal Government and States associated with paying for personal care services furnished outside the home are substantial. There may be some minor offsetting of costs if the number of admissions to nursing facilities decreases as a result of these provisions, but we have no data to determine the potential savings, if any. Regardless of any possible savings, the economic impact of these provisions is attributable to the statutory changes mandated by OBRA '93.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

This final rule has been classified as a major rule subject to congressional review. The effective date is November 10, 1997. If, however, at the conclusion of the congressional review process the effective date has been changed, HCFA will publish a document in the **Federal Register** to establish the actual effective date or to issue a notice of termination of the final rule action.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Section § 440.167 of this final rule contains requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The rule requires States to amend their State plans to specify whether they will cover personal care services and in what locations they will provide the services. Public reporting burden for this collection of information is estimated to be 1 hour per State. A notice will be published in the **Federal Register** when approval is obtained. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should mail them directly to the following:

Health Care Financing Administration, Office of Financial and Human Resources, Management Planning and Analysis Staff, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21255–1850.

Any comments submitted on the information collection requirements must be received by these two offices on or before November 10, 1997, to enable OMB to act promptly on HCFA's information collection approval request.

List of Subjects in 42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR part 440 is amended as set forth below:

PART 440—SERVICES: GENERAL PROVISIONS

1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A—Definitions

2. In § 440.70, the introductory text of paragraphs (a) and (b) are republished and paragraphs (a)(2), (b)(3), (c), and (d) are revised to read as follows:

§ 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) * * *

(2) On his or her physician's orders as part of a written plan of care that the physician reviews every 60 days, except as specified in paragraph (b)(3) of this section.

(b) Home health services include the following services and items. * * *

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

(i) A recipient's need for medical supplies, equipment, and appliances must be reviewed by a physician annually.

(ii) Frequency of further physician review of a recipient's continuing need for the items is determined on a case-by-case basis, based on the nature of the item prescribed;

* * * * *

(c) A recipient's place of residence, for home health services, does not include a hospital, nursing facility, or intermediate care facility for the mentally retarded, except for home health services in an intermediate care facility for the mentally retarded that are not required to be provided by the facility under subpart I of part 483. For example, a registered nurse may provide short-term care for a recipient in an intermediate care facility for the mentally retarded during an acute illness to avoid the recipient's transfer to a 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 and any additional standards legally promulgated by the State that are not in conflict with Federal requirements.

* * * * *

3. A new § 440.167 is added to read as follows:

§ 440.167 Personal care services.

Unless defined differently by a State agency for purposes of a waiver granted under part 441, subpart G of this chapter—

(a) ''Personal care services'' means services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for the mentally retarded, or institution for mental disease that are—

(1) Authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State;

(2) Provided by an individual who is qualified to provide such services and who is not a member of the individual's family; and

(3) Furnished in a home, and at the State's option, in another location.

(b) For purposes of this section, ''family member'' means a legally responsible relative.

§ 440.170, [Amended]

4. § 440.170, paragraph (f) is removed and reserved.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program.)

Dated: June 26, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

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