written plan of care based on an assessment of the individual's health and welfare needs and developed by qualified individuals for each recipient under the waiver. The qualifications of the individual or individuals who will be responsible for developing the individual plan of care must be described. Each plan of care must contain, at a minimum, the medical and other services to be provided, their frequency, and the type of provider to furnish them. Plans of care must be subject to the approval of the Medicaid agency.

- (g) Medicaid agency review. The request must assure that the State agency maintain and exercise its authority to review (at a minimum) a valid statistical sample of each month's plans of care. When the services in a plan do not comport with the stated disabilities and needs of the recipient, the agency must implement immediate corrective action procedures to ensure that the needs of the recipient are adequately addressed.
- (h) *Groups served*. The request must describe the group or groups of individuals to whom the services will be offered.
- (i) Assurances regarding amount expended. The request must assure that the total amount expended by the State under the plan for individuals age 65 or older during a waiver year for medical assistance with respect to NF, home health, private duty nursing, personal care, and home and community-based services described in §§ 440.180 and 440.181 of this subchapter and furnished as an alternative to NF care will not exceed the aggregate projected expenditure limit (APEL) defined in § 441.354.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, §441.351 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

## § 441.352 State assurances.

Unless the Medicaid agency provides the following satisfactory assurances to CMS, CMS will not grant a waiver under this subpart and may terminate a waiver already granted.

(a) Health and welfare. The agency must assure that necessary safeguards

have been taken to protect the health and welfare of the recipients of services by assuring that the following conditions are met:

- (1) Adequate standards for all types of providers that furnish services under the waiver are met. (These standards must be reasonably related to the requirements of the waiver service to be furnished.)
- (2) The standards of any State licensure or certification requirements are met for services or for individuals furnishing services under the waiver.
- (3) All facilities covered by section 1616(e) of the Act, in which home and community-based services are furnished, are in compliance with applicable State standards that meet the requirements of 45 CFR part 1397 for board and care facilities.
- (4) Physician reviews of prescribed psychotropic drugs (when prescribed for purposes of behavior control of waiver recipients) occur at least every 30 days.
- (b) Financial accountability. The agency must assure financial accountability for funds expended for home and community-based services. The State must provide for an independent audit f its waiver program. The performance of a single financial audit, in accordance with the Single Audit Act of 1984 (Pub. L. 98-502, enacted on October 19, 1984), is deemed to satisfy the requirement for an independent audit. The agency must maintain and make available to HHS, the Comptroller General, or other designees, appropriate financial records documenting the cost of services furnished to individuals age 65 or older under the waiver and the State plan, including reports of any independent audits conducted.
- (c) Evaluation of need. The agency must provide for an initial evaluation (and periodic reevaluations) of the need for the level of care furnished in a NF when there is a reasonable indication that individuals age 65 or older might need those services in the near future, but for the availability of home and community-based services. The procedures used to assess level of care for a potential waiver recipient must be at least as stringent as any existing State procedures applicable to individuals

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entering a NF. The qualifications of individuals performing the waiver assessment must be as high as those of individuals assessing the need for NF care, and the assessment instrument itself must be the same as any assessment instrument used to establish level of care of prospective inpatients in NFs. A periodic reevaluation of the level of care must be performed. The period of reevaluation of level of care cannot extend beyond 1 year.

- (d) Expenditures. The agency must assure that the total amount expended by the State for medical assistance with respect to NF, home health, private duty nursing, personal care services, home and community-based services furnished under a section 1915(c) waiver granted under Subpart G of this part to individuals age 65 or older, and the home and community-based services approved and furnished under a section 1915(d) waiver for individuals age 65 or older during a waiver year will not exceed the APEL, calculated in accordance with §441.354.
- (e) Reporting. The agency must assure that it will provide CMS annually with information on the waiver's impact. The information must be consistent with a reasonable data collection plan designed by CMS and must address the waiver's impact on—
- (1) The type, amount, and cost of services furnished under the State plan; and
- (2) The health and welfare of recipients of the services described in §440.181 of this chapter.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.352 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

## §441.353 Supporting documentation required.

The agency must furnish CMS with sufficient information to support the assurances required under §441.352, in order to meet the requirement that the assurances are satisfactory. At a minimum, this information must consist of the following:

(a) Safeguards. A description of the safeguards necessary to protect the health and welfare of recipients.

This information must include:

- (1) A copy of the standards established by the State for facilities (in which services will be furnished) that are covered by section 1616(e) of the Act
- (2) The minimum educational or professional qualifications of the providers of the services.
- (3) A description of the administrative oversight mechanisms established by the State to ensure quality of care.
- (b) Records. A description of the records and information that are maintained by the agency and by providers of services to support financial accountability, information regarding how the State meets the requirement for financial accountability, and an explanation of how the State assures that there is an audit trail for State and Federal funds expended for section 1915(d) home and community-based waiver services. If the State has an approved Medicaid Management Information System (MMIS), this system must be used to process individual claims data and account for funds expended for services furnished under the waiver.
- (c) Evaluation and reevaluation of recipients. A description of the agency's plan for the evaluation and reevaluation of recipients' level of care, including the following:
- (1) A description of who makes these evaluations and how they are made.
- (2) A copy of the evaluation instrument.
- (3) The agency's procedure to assure the maintenance of written documentation on all evaluations and reevaluations and copies of the forms. In accordance with regulations at 45 CFR part 74, written documentation of all evaluations and reevaluations must be maintained for a minimum period of 3 years.
- (4) The agency's procedure to assure reevaluations of need at regular intervals.
- (5) The intervals at which reevaluations occur, which may be no less frequent than for institutionalized individuals at comparable levels of care.
- (6) The procedures and criteria used for evaluation and reevaluation of waiver recipients must be the same or more stringent than those used for individuals served in NFs.