DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 440, and 441

[CMS–2249–P]

RIN 0938–AO53

Medicaid Program: Home and Community-Based State Plan Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Medicaid regulations to define and describe home and community-based State plan services implementing new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 3, 2008.

ADDRESSES: In commenting, please refer to file code CMS–2249–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2249–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2249–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kathy Poisal, (410) 786–5940.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely also will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

On February 8, 2006, the Deficit Reduction Act of 2005 (DRA 2005) (Pub. L. 109–171) was signed into law. Section 6086 of the DRA is entitled ''Expanded Access to Home and Community-Based Services for the Elderly and Disabled.'' Section 6086(a) of the DRA adds a new section 1915(i) to the Social Security Act (the Act) that allows States, at their option, to provide home and community-based services (HCBS) under their regular State Medicaid plans. This option allows States to receive Federal financial participation (FFP) for services that were previously eligible for the funds only under waiver or demonstration projects, including those under sections 1915(c) and 1115 of the Act. Section 1915(i) of the Act sets forth several conditions that States must meet, and actions they must take, if they choose to add State plan HCBS to services available through the State plan. Section 6086(b) of the DRA provides for the Secretary to develop, through the Agency for Healthcare Research and Quality, quality of care measures to assess Medicaid HCBS.

Under section 1915(i) of the Act, States can provide HCBS to individuals who require less than institutional level of care and who would therefore not be eligible for HCBS under 1915(c) waivers. Section 1915(i) of the Act does not link HCBS to institutional level of care or require cost savings over institutional services, permitting States to provide the State Plan HCBS benefit to individuals whether or not they meet an institutional level of care, and based on need for support rather than population characteristics.

Section 1915(i) of the Act does impose other limits not required by section 1915(c) waivers, including a prescribed set of services States may choose to offer, and exclusion of individuals with income above 150 percent of the Federal Poverty Level (FPL). HCBS under the State plan are limited to elderly and disabled individuals.

HCBS are available in some States in demonstration programs under section 1115 of the Act. Each demonstration under section 1115 of the Act is unique with respect to the Medicaid requirements waived, type and scope of services offered and population served, and cannot be generally characterized. Therefore, we are not including HCBS provided under section 1115

demonstrations in this discussion except to note that the section 1115 authority has been used by States to provide services in the home and community. States can also provide Medicaid long-term care services to individuals in the community through the mandatory State plan home health benefit, and the optional State plan personal care services benefit. These services are occasionally referred to as home and community-based, but are not included as HCBS in this discussion. The section 1915(i) benefit does not diminish the State's ability to provide any of these existing community services. States opting to offer State plan HCBS under section 1915(i) of the Act can continue to provide the full array of community services under section 1915(c) waivers, section 1115 demonstration programs, mandatory State plan home health benefits, and the optional State plan personal care services benefit.

Before 1981, the Medicaid program provided limited coverage for long-term care services in non-institutional, community-based settings. Medicaid's complex eligibility criteria and other factors made institutional care much more accessible than care in the community.

Medicaid HCBS were established in 1981 as an alternative to care in Medicaid institutions, by permitting States to waive certain Medicaid requirements upon approval by the Secretary. Section 1915(c) of the Act was added to title XIX by the Omnibus Budget Reconciliation Act of 1981 (OBRA 1981) (Pub. L. 97–35). Programs of HCBS under section 1915(c) of the Act are known as ''waiver programs'', or simply ''waivers'' due to the authority to waive Medicaid requirements.

Since 1981, the section 1915(c) HCBS waiver program has afforded States considerable latitude in designing services to meet the needs of people who would otherwise require institutional care. In 2007, approximately 300 HCBS waivers under section 1915(c) of the Act serve over 1 million elderly and disabled individuals in their homes or alternative residential community settings. States have used HCBS waiver programs to provide numerous services designed to foster independence; assist eligible individuals in integrating into their communities; and promote self-direction, personal choice, and control over services and providers. The addition of section 1915(i) of the Act affords some of the same flexibility through the State plan.

Another important aspect to this background is the passage of the Americans with Disabilities Act of 1990 (ADA) and the *Olmstead* v. *L.C.*, 527 U.S. 581 (1999) U.S. Supreme Court decision. In particular, Title II of the ADA prohibits discrimination on the basis of disability by State and local governments and requires these entities to administer services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities. In applying the most integrated setting mandate, the U.S. Supreme Court ruled in *Olmstead* v. *L.C.* that unnecessary institutionalization of individuals with disabilities may constitute discrimination under the ADA. Under *Olmstead*, States may not deny a qualified individual with a disability a community placement when: (1) Treating professionals determine that community placement is appropriate; (2) the community placement is not opposed by the individual with a disability; and (3) the community placement can be reasonably accommodated.

In the following discussion and the proposed regulation, we refer to particular home and community-based service(s) offered under section 1915(i) of the Act as ''State plan HCBS'' or simply ''HCBS''.[1] We refer to the ''State plan home and community-based services benefit'' when describing the collective requirements of section 1915(i) of the Act that apply to States electing to provide one, or several, of the authorized HCBS. We choose to use the term ''benefit'' rather than ''program'' to describe section 1915(i) of the Act to avoid possible confusion with HCBS waiver programs. The State plan HCBS benefit shares many features with section 1915(c) waiver programs, and in other respects is similar to other State plan services, but differs from both in important respects.

The Secretary has delegated administration of the Medicaid program, including the State plan HCBS benefit furnished under Medicaid, to the Centers for Medicare & Medicaid Services (CMS). Effective January 2007, States that demonstrate they meet certain requirements may choose to furnish HCBS under the State plan. States may elect to provide HCBS through waiver programs, State plan services, or both. The availability of the State plan HCBS benefit does not foreclose, or otherwise restrict, a State's ability to operate its HCBS waiver programs, nor does the availability of HCBS waiver services within a State affect its ability to add the HCBS benefit to its State plan.

[1] Note that the abbreviation HCBS does not distinguish between singular and plural. Where this could be confusing, we spell out home and community-based service(s).

A. Overview of the State Plan HCBS Benefit

The following overview describes the provisions of the DRA in the order they are presented in section 1915(i) of the Act. The proposed regulation and the explanation of each proposed requirement in section II. are arranged so that related requirements are grouped for clarity.

1. General Provisions of the State Plan Amendment Option To Provide Home and Community-Based Services for Elderly and Disabled Individuals

Section 1915(i)(1) of the Act grants States the option to provide, under the State plan, the services and supports listed in section 1915(c)(4)(B) of the Act governing HCBS waivers, not including the ''other services'' described therein. The services specifically listed in section 1915(c)(4)(B) of the Act are as follows: Case management, homemaker/home health aide, personal care, adult day health, habilitation, respite care, and for individuals with chronic mental illness: Day treatment, other partial hospitalization services, psychosocial rehabilitation services, and clinic services (whether or not furnished in a facility). The HCBS may not include payment for room and board (see additional discussion in section I.D.3.).

We interpret the statute as authorizing the services as titled in section 1915(c)(4)(B) of the Act. Therefore, we would expect States to define State plan HCBS with sufficient specificity that the nature and scope of the service clearly relates to those listed in section 1915(c)(4)(B) of the Act.

Section 1915(i) of the Act explicitly provides that State plan HCBS may be provided without determining that, but for the provision of such services, individuals would require the level of care provided in a hospital, a nursing facility (NF), or an intermediate care facility for the mentally retarded (ICF/MR) as is required in section 1915(c) HCBS waivers. While HCBS waivers must be ''cost-neutral'' to Medicaid, no cost neutrality requirement applies to the section 1915(i) State plan HCBS benefit. States are not required to produce comparative cost estimates of institutional care and the State plan HCBS benefit. This significant distinction allows States to offer HCBS to individuals whose needs are substantial, but not severe enough to qualify them for institutional or waiver services, and to individuals for whom

there is not an offset cost savings in NFs, ICFs/MR, or hospitals.

While eligibility for State plan HCBS does not require that the individual would otherwise need an institutional level of care, the services are intended to prevent progression to institutionalization and to enable individuals to receive needed services in their own homes, or in alternative living arrangements in what is collectively termed the ''community'' in this context. (See additional discussion in section I.D.2. regarding institutions not considered to be in the community, and in which State plan HCBS will not be available.)

Section 1915(i)(1) of the Act requires that in order to receive State plan HCBS, individuals must be eligible for Medicaid under an eligibility group covered by the State plan. This section does not create a new eligibility group. Individuals who have not been found eligible for Medicaid cannot be enrolled in the State plan HCBS benefit, even if they otherwise meet the requirements for the benefit. In addition, individuals may not be enrolled in the State plan benefit if their income exceeds 150 percent of the FPL.[2] In determining whether the 150 percent of the FPL requirement is met, the regular rules for determining income eligibility for the individual's eligibility group apply, including any more liberal income disregards used by the State for that group under section 1902(r)(2) of the Act.

2. Needs-Based Criteria

In contrast to the institutional level of care requirement for eligibility in HCBS waivers, section 1915(i)(1)(A) of the Act requires States to impose needs-based criteria for eligibility for the State plan HCBS benefit. Additionally, the State may establish needs-based criteria for each specific State plan home and community-based service that an individual would receive.

Section 1915(i) of the Act does not authorize States to waive the requirement of section 1902(a)(10)(B) of the Act relating to comparability, as does section 1915(c) of the Act. Waiver of comparability is a key feature of HCBS waivers, permitting the State to target the HCBS benefit to certain populations by defining which groups will be eligible for waiver services, and by having separate waivers for different groups. Through use of eligibility criteria, States can provide services for certain high need target groups that are not comparable to the services received by other Medicaid beneficiaries in the State. Under section 1915(i) of the Act, States are not authorized to establish eligibility criteria in order to target services to certain populations. Since comparability may not be waived, States must determine eligibility for State plan HCBS on the basis of the following criteria only:

- The individual is eligible for medical assistance under the State plan.
- The individual's income does not exceed 150 percent of the FPL.
- The individual resides in the home or community.
- The individual meets the needs-based criteria established by the State.

Needs-based criteria for an individual service are subject to the same requirements as needs-based eligibility criteria, and may not limit or target any service based on age, nature or type of disability, disease, or condition.

The heading of section 1915(i) of the Act describes the State plan HCBS benefit as ''for Elderly and Disabled Individuals.'' However, section 1915(i) of the Act does not include definitions of the terms ''elderly'' or ''disabled'' in setting forth eligibility criteria, and instead requires eligibility to be based on need and on eligibility for medical assistance under a State plan group. Thus, we believe that the use of these terms in the statute is descriptive. Individuals who are eligible for medical assistance under a group covered in the State's plan and who meet the needs-based eligibility criteria for State plan HCBS will have needs stemming either from a disability or from being elderly. We note that section 1902(b)(1) of the Act prohibits the Secretary from approving any plan for medical assistance that imposes an age requirement of more than 65 years as a condition of eligibility.

The statute does not define ''needs-based.'' We are proposing to define the nature of needs-based criteria to distinguish them from targeting criteria, which are not permitted under the statute. However, we would propose to provide States with the flexibility to define the specific needs-based criteria they will establish. (See discussion below of section 1915(i)(1)(D) of the Act.)

Section 1915(i)(1)(B) of the Act additionally requires that the needs-based criteria for determining whether an individual requires the level of care provided in a hospital, NF, or ICF/MR or under a waiver of the State plan be more stringent than the needs-based eligibility criteria for the State plan HCBS benefit. ''Stringency'' is not defined in the statute. States establish stringency in defining particular needs-based criteria. There is no expectation that States will modify institutional levels of care to make them more stringent, in order to satisfy this requirement. If the State's existing criteria for receipt of institutional and HCBS waiver care are needs-based, and more stringent than the criteria it will use for the State plan HCBS benefit, the State need not modify its institutional criteria. We anticipate that States will adopt the much simpler strategy of defining the new State plan HCBS needs-based eligibility criteria at a less stringent level than existing institutional criteria. In order to implement the State plan HCBS benefit, States may need to add needs-based criteria to their institutional level of care requirements, if none presently exist. Section 1915(i) of the Act does not require that such added needs-based institutional level of care criteria necessarily result in excluding individuals who would be served without the added criteria. In fact, the purpose of section 1915(i) of the Act appears to be to expand access to HCBS to individuals who are not at an institutional level of care, rather than to reduce access to institutional and waiver services.

We note that section 1915(i) of the Act does not modify the statutory coverage provisions of institutional benefits. States must be cautious not to establish more stringent needs-based criteria for hospitals, NFs or ICFs/MR that would reduce access to services mandated elsewhere in title XIX, since those other provisions of the statute were not amended. For example, the NF benefit is defined in section 1919(a)(1) of the Act as an institution that is primarily engaged in providing to residents skilled nursing care, rehabilitation services, and ''[o]n a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities.'' To the extent that needed health-related care and services above the level of room and board are not available in the community, the NF institutional benefit must remain available to all Medicaid eligible individuals described in section 1919(a)(1)(C) of the Act.

We interpret the reference to hospitals in section 1915(i)(1)(B) of the Act to

[2] The statute refers to ''the poverty line as defined in section 2110(c)(5)''. The poverty guidelines are formally referenced as ''the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2).'' Commonly referred to as the ''Federal Poverty Level'' or ''Federal Poverty Line'' (FPL), we will adopt the term FPL in this regulation.

mean facilities certified by Medicaid as hospitals that are providing long-term care services or services related to the HCBS to be provided under the State plan HCBS benefit. General acute care Medicaid hospital services are not subject to level of care determinations by the State.

We interpret the reference in section 1915(i)(1)(B) of the Act ''under any waiver of such plan'' to apply to section 1915(c) waivers, as well as those section 1115 waivers that include HCBS. Section 1915(c) waivers by definition will have more stringent criteria than the State plan HCBS benefit, as the waivers are required to use level of care assessments equivalent to one or more of the institutional levels of care.

In summary, the needs-based eligibility criteria for the State plan HCBS benefit must have the effect of potentially admitting to the benefit some individuals who do not meet the needs-based criteria for institutionalized care, and may admit to the benefit individuals who do meet the institutional needs-based eligibility criteria. We note that individuals who meet eligibility requirements for both an institutional benefit and the State plan HCBS benefit must be offered a choice of either benefit.

3. Number Served

Section 1915(i)(1)(C) of the Act contains two provisions regarding the number of individuals served. The first provision requires a State to provide to the Secretary a projection of the number of individuals expected to receive services. If this projection is exceeded, section 1915(i)(1)(D)(ii) permits the State to constrict its needs-based eligibility thresholds for State plan HCBS. The second provision allows the State to impose a maximum limit to the number of individuals to be served through the State plan HCBS benefit. The latter provision carries with it authority for the State to establish waiting lists for the State plan HCBS benefit.

Section 1915(i)(1)(C)(i) of the Act requires that the State submit projections of the number of individuals to be provided HCBS, in the form and manner, and upon the frequency as the Secretary specifies. We would propose to follow the practice used in HCBS waivers to calculate the number served as unduplicated persons receiving services during a 12-month period. We would specify that States annually submit both the projected number of individuals to be served and the actual number of individuals served in the previous year. We refer to individuals served under the benefit and included in the annual number served as having been enrolled in the benefit. The statute refers to ''enrollment'' in section 1915(i)(1)(D)(ii) of the Act concerning Adjustment Authority. Because there are a number of steps involved in an individual initiating service under the State plan HCBS benefit, ''enrollment'' is a useful term to indicate individuals for whom those steps have been completed, services have been authorized or provided, and who will be accounted for in the annual number served under the benefit.

If the State exceeds its enrollment estimate, the State would report the number of individuals actually served in the required annual report to the Secretary, and revise the estimate for succeeding years.

Section 1915(i)(1)(C)(ii) of the Act provides an option for the State to limit the number of eligible individuals to whom it will provide the State plan HCBS benefit. The limit does not need to be the same as the projected number of individuals to be served. As with the projected number, we would specify that the limit be expressed in terms of the number of unduplicated recipients eligible to receive the State plan HCBS benefit, for a period of 12 months. We would propose that States may establish limits for individuals to be served annually. States may establish a phase-in and phase-out schedule for limits. The State may also elect to place a limit on the number of individuals to be served at any given time in the year (''slot'' methodology), so long as the State also provides the annual report of actual unduplicated recipients.

We would specify that the State submit a State plan amendment to initiate or adjust the limit on the number of individuals to be served. Consistent with 42 CFR 430.20, we would permit a service expansion to become effective on the first date of the calendar quarter in which an approvable amendment is received in CMS.

A State electing to use a waiting list must develop policies for establishing and maintaining the list, if it elects to establish a limit to the number of individuals served. We do not believe it would be appropriate for us to describe waiting list policies that must operate in each State. Rather, we would require the State to assure that its policies are published with opportunity for comment, equitable, and meet all applicable State and Federal requirements. Those requirements include but are not limited to Medicaid provisions such as timely evaluation and right to fair hearing; civil rights protections such as the State's compliance with the Americans with Disabilities Act (ADA) and the decision of the United States Supreme Court in *Olmstead* v. *L.C.* and, in some cases, other judicial decisions or procedures for court monitoring. Waiting list policies will also be affected by the option in section 1915(i)(3) of the Act for the State to elect not to comply with the requirement for statewideness (see discussion in section I.14. of this proposed rule).

4. Independent Evaluation

Section 1915(i)(1)(D) of the Act sets forth a requirement for an individual evaluation of need for each person applying for the State plan HCBS benefit. The statute here uses the term ''assessment,'' while sections 1915(i)(1)(E) and (H) of the Act refer to the initial eligibility determination as the ''independent evaluation.'' We would use the latter term for consistency. ''Independent evaluation,'' as understood in light of section 1915(i)(1)(H) of the Act, means free from conflict of interest on the part of the evaluator.

The independent evaluation applies the needs-based HCBS eligibility criteria (established by the State according to section 1915(i)(1)(A) of the Act), to an applicant for the State plan HCBS benefit. Section 1915(i)(1)(D) of the Act establishes that determining whether an individual meets the needs-based eligibility criteria specified in sections 1915(i)(1)(A) and (B) of the Act requires an individualized and independent evaluation of each person's support needs and capabilities. We interpret ''needs and capabilities'' to mean a balanced approach that considers both needs and strengths. However, the words ''capability'' and ''ability'' are historically connected with a deficit-oriented approach to assessment, which is the opposite of the statute's person-centered approach. Therefore, we would refer to needs and strengths in this discussion and in the regulation.

We believe that the statute distinguishes needs-based criteria from other possible descriptors of an individual's medical condition or demographic situation, for example a diagnosis. We interpret needs-based criteria as describing the individual's particular need for support, regardless of the conditions and diagnoses that may cause the need. Therefore, we would propose that a useful test of whether a criterion is needs-based will be the type of data that would be needed to complete that item in an evaluation. A needs-based criterion requires the evaluator to determine the unique requirements of the applicant, through interview if necessary.

Institutional/waiver level of care (LOC) criteria in some States do not include needs-based criteria. We believe that States must include a needs-based evaluation component of the institutional/waiver LOC determination process so that stringency of those criteria can be compared to stringency of eligibility criteria for the State plan HCBS benefit.

Section 1915(i)(1)(D) of the Act indicates that the independent evaluation may ''take into account'' the inability of the individual to perform two or more activities of daily living (ADLs), (which the statute defines by reference to section 7702B(c)(2)(B) of the Internal Revenue Code of 1986), or the need for significant assistance to perform these activities. The State may also assess other risk factors it determines to be appropriate in determining eligibility for, and receipt of, HCBS. The statute does not limit the factors a State may take into account in the evaluation. For example, instrumental activities of daily living (IADLs) could be considered.

5. Adjustment Authority

Section 1915(i)(1)(D)(ii) of the Act permits the State to adjust the needs-based criteria described in section 1915(i)(1)(B) of the Act in the event that enrollment exceeds the annual maximum number of individuals that the State has projected it would serve. The purpose of such an adjustment would be to revise its needs-based criteria in order to reduce the number of individuals in the State who would be eligible for the HCBS benefit. To preserve the requirement of 1915(i)(1)(B) that more stringent needs-based criteria be in place for institutionalized care, the adjusted eligibility criteria must still be less stringent than those applicable to institutional levels of care. If the State chooses to make this adjustment, it must provide at least 60 days written notice to the Secretary and the public, stating the revisions it proposes.

While the adjustment authority is granted to States without having to obtain prior approval from the Secretary, we believe that the statute requires the State to amend the State plan to reflect the adjusted criteria. We believe that the State's adjustment authority does not prevent the Secretary from disapproving a State plan amendment that fails to comply with the statute and regulations. Therefore, the Secretary would evaluate the State's adjusted criteria for compliance with the provisions of this subparagraph and all requirements of subpart K. A State may implement the adjusted criteria as early as 60 days after notifying all required parties. Section 430.16 provides the Secretary 90 days to approve or disapprove a State plan amendment, or request additional information. If the State implements the modified criteria prior to the Secretary's final determination with respect to the State plan amendment, the State would be at risk for any actions it takes that are later disapproved.

After needs-based criteria are adjusted under this authority, the statute provides for a period during which individuals previously served under the State plan HCBS benefit would continue to receive HCBS. Section 1915(i)(1)(D)(ii)(II) of the Act provides that an individual who is receiving HCBS before the effective date for modified needs-based criteria, (based on the most recent version of the criteria in effect before the modification), must be deemed by the State to continue to be eligible for State plan HCBS for a period of at least 12 months, beginning on the date on which the individual first received a covered State plan HCBS. In order to ensure that an individual who has been receiving HCBS for a year or more would not be subject to immediate discontinuation of service, we are proposing to apply the phrase ''at least'' in this context to require that regardless of the length of time HCBS has been provided, the State must continue to deem the individual eligible for services for no less than 60 days after official notification of all required parties.

The statute does not provide any new remedy for individuals who will lose services due to the adjustment in eligibility criteria for the HCBS benefit. However, the requirements of 42 CFR subpart E would apply. Loss of eligibility for the HCBS benefit does not affect eligibility for other services for which the individual would be eligible under the State plan.

We interpret section 1915(i)(1)(D)(III) of the Act to require that if the State chooses to modify the needs-based criteria under the adjustment authority of section 1915(d)(1)(D)(ii) of the Act, the eligibility criteria for institutional levels of care (hospital, NF, ICF/MR, and HCBS waiver services) applied by the State may be no less stringent than those that were in effect before the inception of the State plan HCBS benefit. Criteria for determining whether an individual requires an institutional level of care must also be more stringent than the adjusted needs-based eligibility criteria for the State plan HCBS benefit.

Finally, we conclude that the State may choose to modify its needs-based criteria at any time through the usual process of a State plan amendment, whether or not the projected enrollment is exceeded.

6. Independent Assessment

Section 1915(i)(1)(E) of the Act describes the relationship of several required functions. Section 1915(i)(1)(E)(i) of the Act refers to the independent evaluation of eligibility in section 1915(i)(1)(A) and (B), emphasizing the independence requirement. Section 1915(i)(1)(E)(ii) of the Act introduces the requirement of an independent assessment following the independent evaluation. Thus, there are two steps to the process: the eligibility determination, which requires the application of the needs-based criteria, and the assessment for individuals who were determined to be eligible under the first step, to determine specific needed services and supports. The assessment also applies the needs-based criteria for each service (if any). Like the eligibility evaluation, the independent assessment is based on the individual's needs and strengths. More specifically, both physical and mental needs and strengths are assessed. These requirements describe a person-centered assessment including mental health, which will take into account the individual's total support needs as well as need for the HCBS to be offered. The State must use the assessment to: determine the necessary level of services and supports to be provided; prevent the provision of unnecessary or inappropriate care; and establish a written individualized plan of care.

In order to achieve the three purposes of the assessment listed above, the assessor must be independent; that is, free from conflict of interest with providers, with the individual and related parties, and with concern for budget. HCBS provided under the State plan may be limited only by the needs-based criteria and medical necessity, not budget controls. Therefore, we would propose specific requirements for independence of the assessor in accord with section 1915(i)(1)(H)(ii) of the Act, and we would apply these also to the evaluator and the person involved with developing the plan of care, where the effects of conflict of interest would be equally deleterious. These considerations of independence inform the discussion below under section 1915(i)(1)(H)(ii) of the Act regarding conflict of interest standards.

Section 1915(i)(1)(F) of the Act provides detailed requirements for the independent assessment:

- An objective evaluation of the individual's inability to perform two or more ADLs, or the need for significant assistance to perform such activities is

required. We do not interpret ''objective'' to refer to the independence required of the assessor as discussed above, but to refer to an additional requirement for reliance on some level of valid measurement appropriate to the ADLs. For example, an occupational therapy (OT) or physical therapy (PT) evaluation could be required, the results of which would be utilized by the assessor. We note that the trained assessor is not necessarily responsible for performing the objective evaluation, but should make sure that the objective evaluation is performed by qualified individuals. We do not propose methods to achieve this requirement, as the nature of the HCBS to be provided and the needs-based criteria for the State plan HCBS benefit will determine the appropriate means of evaluating ADLs.

Section 1915(i)(1)(F) of the Act defines ADLs in terms of section 7702B(c)(2)(B) of the Internal Revenue Code of 1986, which includes the following: Bathing, dressing, toileting, transferring, eating, and continence. This section of the Internal Revenue Code does not define the terms ''inability'' or ''significant assistance.'' While States have some flexibility to define these factors, we interpret ''inability'' to mean need for total support to perform an ADL, and ''significant assistance'' to mean assistance from another individual or from assistive technology necessary for the successful performance of the task.

An objective evaluation of ability to perform two or more ADLs is a required element of the assessment but only a suggested element of the eligibility evaluation. We conclude that partial or complete inability to perform two or more ADLs is not a statutory prerequisite to receive State plan HCBS, but is a required element of the assessment.

- A face-to-face evaluation of the individual by an assessor trained in the assessment and evaluation of persons whose physical or mental conditions trigger a potential need for HCBS. To fulfill this statutory requirement, we would propose that the State shall develop standards and determine the qualifications necessary for agencies and individuals who will perform independent assessments and be involved with developing the plans of care.
- Consultation with any responsible persons appropriate to the individual and the needed supports, including family, spouse, guardian, or healthcare and support providers. We do not believe the examples listed in the statute to be prescriptive or limiting. The assessor must give the individual and, if applicable, the individual's authorized representative, the opportunity to identify appropriate persons who should be consulted during this process. The role of the assessor is to facilitate free communication from persons relevant to the support needs of the individual, while protecting privacy, and promoting the wishes and best interests of the individual. In necessary circumstances, such as telephone communication with parties not available for the meeting, consultations are not required to be performed in person or at the same time and place as the face-to-face evaluation, so long as any ancillary contacts are with persons the individual has identified, are divulged and discussed with the individual/representative, and documented.
- An examination of the individual's relevant history, medical records, and care and support needs.
- Knowledge of best practices, and research on effective strategies that result in improved health and quality of life outcomes. The statute requires that the examination of the individual's history, medical records, and care and support needs be guided by this knowledge, and we would propose that this evidence-based approach should apply to the entire process for assessment and plan of care development.
- If the State offers the option of self-direction and the individual so elects, the assessment should include gathering the information required to establish self-direction of services. We do not propose to require States to conduct a separate or additional assessment process for self-direction.

As long as States comply with all provisions related to conducting the eligibility evaluation, independent assessment, and developing the plan of care, States have flexibility in determining whether they will require that the functions be performed as one activity by a single agency or individual, or whether they wish to separate those functions and have different entities involved.

7. Plan of Care

Section 1915(i)(1)(G) of the Act requires that the State plan HCBS benefit be furnished under an individualized plan of care based on the assessment. The statute describes a person-centered planning process, which can only be achieved when States affirmatively and creatively support individuals in the planning process. We would propose certain requirements for developing the plan of care, but note that the degree to which the process achieves the goal of person-centeredness can only be known with appropriate quality monitoring by the State.

Unless the State has elected to impose a limit on the number of individuals it would serve through its State plan HCBS benefit, the State must make the services available to all eligible individuals as they are assessed to need them. We conclude that the statute permits determining the level of services required by an individual only according to assessment of the individual's need, not according to available funds. Individuals who qualify for HCBS may not be compelled to receive them. Individuals may exercise their freedom to choose among qualified providers in the planning process.

The State Medicaid agency may delegate other agents to develop the plan of care, but remains responsible for ensuring compliance with all requirements and must approve each plan of care developed.

Section 1915(i)(1)(G)(ii)(I)(aa) of the Act requires that the plan of care is developed in consultation with the individual. The requirements for who is consulted in developing the plan of care parallel those describing who may be consulted during the assessment process.

Section 1915(i)(1)(G)(ii)(I)(bb) of the Act requires that the development of the plan of care take into account the extent of, and need for family or other supports for the individual, and section 1915(i)(1)(G)(ii)(II) of the Act requires that the individualized plan of care identify needed services. We interpret these provisions to indicate that natural supports are explicitly included in the plan of care. This means that individuals with equivalent need for support but differing levels of family or other natural supports may be authorized for different levels of HCBS. In the context of person-centered planning and consultation with natural supports, we conclude that the statute requires that the plan of care should neither duplicate, nor compel, natural supports.

Section 1915(i)(1)(G)(ii)(III) of the Act provides that plans of care will be reviewed at least annually and upon significant change in the individual's circumstances. We interpret this provision to indicate that diagnostic or functional changes are not required in order to adjust a plan of care. Changes in external factors such as gain or loss of other supports may trigger a review. We would require revision of the plan of care if the review indicates that revision is appropriate. By ''annually,'' we mean not less often than every 12

months. Finally, we would relate this requirement to the independent assessment, since developing or revising the plan of care is based on the assessment. We therefore would propose that the independent assessment (number 6. above) is required at least annually, and when needed upon change in circumstances, in order to comply with the requirement to review plans of care with that frequency.

8. Self-Direction

Section 1915(i)(1)(G)(iii)(I) and (II) provides that States may offer enrolled individuals the option to self-direct some or all of the State Plan HCBS that they require. Many States have incorporated elements of self-direction into section 1915(c) waiver programs as well as section 1115 demonstration programs. Self-directed State plan HCBS allow States another avenue by which they may afford individuals maximum choice and control over the delivery of services, while comporting with all other applicable provisions of Medicaid law. We have urged all States to afford waiver participants the opportunity to direct some or all of their waiver services. With the release of an updated, revised section 1915(c) waiver application in 2005, we refined the criteria and guidance to States surrounding self-direction (also referred to as participant-direction), and established a process by which States are encouraged, to whatever degree feasible, to include self-direction as a component of their overall HCBS waiver programs. While section 1915(i) of the Act does not require that States follow the guidelines for section 1915(c) waivers in implementing self-direction in the HCBS State plan benefit, we anticipate that States will make use of their experience with 1915(c) waivers to offer a similar pattern of self-directed opportunities with meaningful supports and effective protections. Individuals who choose to self-direct will be subject to the same requirements as other enrollees in the State plan HCBS benefit.

Section 1915(i)(1)(G)(iii)(II) of the Act defines self-direction, and requires that there be an assessment and plan of care. We do not interpret these requirements to indicate assessments and plans in addition to those required in sections 1915(i)(1)(F) and (G) of the Act. Accordingly, we would propose that the requirements for a self-directed plan of care at section 1915(i)(1)(G)(iii)(III) of the Act be components of the assessment and plan of care required for all enrollees in the State plan HCBS benefit.

Section 1915(i)(1)(G)(iii)(III) of the Act contains specific requirements for the self-directed plan of care, for which we describe proposed regulations in Section II. of this proposed rule. The proposed regulations are consistent with our requirements for self-direction under section 1915(c) HCBS waivers. Section 1915(i)(1)(G)(iii)(III)(dd) of the Act requires that the plan of care be developed with a person-centered process, which we would propose to require of all plans of care for the State plan HCBS benefit.

Section 1915(i)(1)(G)(iii)(IV) of the Act describes certain aspects of a self-directed budget, which we have termed budget authority. Section 1915(i)(1)(G)(iii)(III)(bb) of the Act provides for self-directed selecting, managing, or dismissing of providers of the State plan HCBS, which we term employer authority. The proposed rule explains both budget authority and employer authority in a manner consistent with Section 1915(c) HCBS waiver policy.

Individuals require information and assistance to support them in successfully directing their services. Therefore, we would require States to design and provide functions in support of self-direction that are individualized according to the support needs of each enrollee. These functions should include information and assistance consistent with sound principles and practice of self-direction, and financial management supports.

Section 6087 of the DRA also amended the Act to add a new section 1915(j), that permits States to provide medical assistance for the ''Optional Choice of Self-Directed Personal Assistance Services (Cash and Counseling).'' Section 6087 of the DRA is similar, but more expansive than, the self-direction provisions in section 6086 of the DRA. States should carefully examine the opportunities for providing self-directed HCBS under either or both sections 1915(i) or 1915(j) of the Act, depending on the goals and objectives of their Medicaid programs.

9. Quality Assurance

Section 1915(i)(1)(H)(i) of the Act requires the State to ensure that the State plan HCBS benefit meets Federal and State guidelines for quality assurance, which we interpret as assurances of quality improvement. Consistent with current trends in health care, the language of quality assurance has evolved to mean quality improvement, a systems approach designed to continuously improve care and prevent or minimize problems prior to occurrences. This approach to quality is consistent with guidelines developed by CMS in the *CMS Quality Improvement Roadmap* and *The Medicaid/SCHIP Quality Strategy*. Guidelines for quality improvement have also been made available through CMS policies governing section 1915(c) HCBS waivers.

Additionally, section 6086(b) of the DRA requires the Secretary to act through the Agency for Healthcare Research and Quality to develop program performance and quality of care measures for Medicaid HCBS. The Secretary is to use the indicators and measures to assess and compare State plan HCBS, particularly with respect to the health and welfare of the recipients of the services.

We would require States to have a quality improvement strategy, and to measure and maintain evidence of quality improvement, including system performance and individual quality of care indicators approved or prescribed by the Secretary. We would require States to make this information available to CMS upon request.

10. Conflict of Interest

Section 1915(i)(1)(H)(ii) of the Act provides that the State will establish conflict of interest standards for the independent evaluation and independent assessment. For reasons described above under independent assessment, we believe that the same independence is necessary for those involved with developing the plan of care. In this discussion, we will refer to persons or entities responsible for the independent evaluation, independent assessment, and the plan of care as ''agents'' to distinguish them from ''providers'' of home and community-based services.

The design of services, rates and payment, and method of administration by the State Medicaid agency all may contribute to potential conflicts of interest. These contributing factors can include obvious conflicts such as incentives for either over-or under-utilization of services, subtle problems such as interest in retaining the individual as a client rather than promoting independence, or practices that focus on the convenience of the agent or service provider rather than being person-centered.

The independent agent must not be influenced by variations in available funding, either locally or from the State. Within the services the State decides to offer, the plan of care must offer to each enrollee the home and community-based services for which they demonstrate need. The plan of care must be based on medical necessity only, not funding levels. When local

entities directly expend funds or direct allocated resources for services, in accordance with § 433.53(c)(2), the State must have a mechanism to ensure that availability of local funds does not affect access to services, for example, using State resources to compensate for variability in local funding. However, States may elect not to apply statewideness requirements, making the benefit available only in selected localities, possibly those that can provide greater resources.

We would require States to define conflict of interest standards, to include criteria that reflect our experience with the issue in administering HCBS waivers, and that reflect the principles of section 1877 of the Act.

We are aware that in certain areas there may be only one provider available to serve as both the agent performing independent assessments and developing plans of care, and the provider of one or more of the home and community-based services. To address this potential problem we would propose to permit providers in some cases to serve as both agent and provider of services, but with guarantees of independence of function within the provider entity. In certain circumstances, we may require that States develop ''firewall'' policies, for example, separating staff that perform assessments and develop plans of care, from those that provide any of the services in the plan; and meaningful and accessible procedures for individuals and representatives to appeal to the State. We would not permit States to circumvent these requirements by adopting State or local policies that suppress enrollment of any qualified and willing provider. We do not believe that under any circumstances determination of eligibility for the State plan HCBS benefit should be performed by parties with an interest in providers of HCBS. We invite comment on practical solutions to this important balance of independence and access.

11. Eligibility Redeterminations; Appeals

Section 1915(i)(1)(I) of the Act requires the State to conduct redeterminations of eligibility at least annually. We interpret ''annually'' to mean not less than every 12 months. The State must conduct redeterminations and appeals in the same manner as required under the State plan. States must grant fair hearings consistent with the requirements of part 431, subpart E.

12. Option for Presumptive Eligibility for Assessment

Section 1915(i)(1)(J) of the Act gives States the option of providing for a period of presumptive eligibility, not to exceed 60 days, for individuals the State has reason to believe may be eligible for the State plan HCBS benefit.

We interpret this provision as follows:

- ''Presumptive'' we interpret to indicate that medical assistance will be available for evaluation even when an individual is subsequently found not to be eligible for the State plan HCBS benefit.
- ''Eligibility'' does not connote eligibility for Medicaid generally, as this provision ''shall be limited to medical assistance for carrying out the independent evaluation and assessment'' under section 1915(i)(1)(E) of the Act. For clarity, we would refer to this limited option as ''presumptive payment''. Individuals not eligible for Medicaid may not receive State plan HCBS.
- ''Evaluation and assessment'' under section 1915(i)(1)(E) of the Act, is described as evaluation for eligibility for the benefit and assessment to determine necessary services. We believe the statutory phrase ''and if the individual is so eligible, the specific home and community-based services that the individual will receive'' is further describing the assessment under section 1915(i)(1)(E) of the Act for which presumptive payment is available, and that this phrase is not offering presumptive payment for the actual services.
- ''Medical assistance'' we interpret to mean FFP for administration of the approved State plan, as we believe that determination of eligibility for the State plan HCBS benefit and assessment of need for specific HCBS are administrative activities of the Medicaid or single State agency rather than a medical service to individuals. Even if the evaluation and assessment could be considered a medical service, none of the services permitted under section 1915(i) of the Act could be construed to include these activities. ''Medical assistance'' in this provision would not refer to other Medicaid State plan services because individuals being considered for eligibility for the State plan HCBS benefit must be Medicaid eligible and so already have access to those services. Therefore, we interpret section 1915(i)(1)(J) of the Act to offer the State an option for a period of presumptive payment, not to exceed 60 days, for Medicaid eligible individuals the State has reason to believe may be eligible for the State plan HCBS benefit. FFP would be available as administration of the approved State plan for evaluation of eligibility for the State plan HCBS benefit and assessment of need for specific HCBS. During the period of presumptive payment, the individual would not receive State plan HCBS, and would not be considered to be enrolled in the State plan HCBS benefit for purposes of computing the number of individuals being served under the benefit. We invite comments that offer other interpretations of this presumptive payment option and comport with existing Federal requirements.

13. Individual's Representative

When an individual is not capable of giving consent, or requires assistance in making decisions regarding his or her care, the individual may be assisted or represented by another person. Section 1915(i)(2) of the Act defines the term ''individual's representative'' by listing certain examples, but also provides that ''* * * any other individual who is authorized to represent the individual'' [m]ay be included. We believe that ''authorized'' refers to State rules concerning guardians, legal representatives, power of attorney, or persons of other status recognized under State law or under the policies of the State Medicaid program. States should ensure that such representatives conform to good practice concerning free choice of the individual, and assess for abuse or excessive control.

14. Nonapplication

Section 1915(i)(3) of the Act allows States to be exempted from the requirements of two sections of the Medicaid statute: section 1902(a)(1) of the Act, regarding statewideness; and section 1902(a)(10)(C)(i)(III) of the Act, regarding income and resource rules for the medically needy in the community. The statute uses the terms ''nonapplication'' and ''may chose not to comply with'' rather than ''waive''. We would use this terminology to maintain clarity between HCBS waiver programs under section 1915(c) of the Act, and State plan HCBS under section 1915(i) of the Act. However, these non-applications apply only with regard to the provision of State plan HCBS. The State is not exempted from these requirements as they apply to the provision of any other medical assistance under the plan, or with regard to the provision of institutional services.

Non-application of the requirement of statewideness allows States to furnish the State plan HCBS benefit in particular areas of the State, for

example, where the need is greatest, or where certain types of providers are available. States may choose to be exempted from the requirements of statewideness in order to begin services on a limited basis, perhaps with a view towards later expansion. If a State intends to offer the HCBS State plan benefit throughout the State, but anticipates that services would be phased in as providers and enrollees are identified, it is not necessary to elect non-application of statewideness requirements.

Being exempt from the requirements of section 1902(a)(10)(C)(i)(III) of the Act enables States to provide medical assistance to medically needy individuals in the community by electing to treat such individuals as if they are living in an institution for purposes of determining income and resources. This would result in the State not deeming income and resources from an ineligible spouse to an applicant or from a parent to a child with a disability.

Section 1915(i)(4) of the Act emphasizes that State election to provide the State plan HCBS benefit does not in any way affect the State's ability to offer programs through a section 1915(b) or (c) waiver, or under section 1115 of the Act.

However, we note that section 1915(c) HCBS waivers may be affected when a State implements a State plan HCBS benefit if institutional levels of care are modified to make them more stringent than needs-based eligibility criteria for the State plan HCBS benefit.

15. Federal Financial Participation for Institutional Level of Care Shall Continue for Individuals Receiving Services as of the HCBS State Plan Amendment's Effective Date

If the State modifies institutional level of care requirements so that they will be more stringent than the needs-based criteria for the State plan HCBS benefit, Section 1915(i)(5) of the Act provides protection for individuals who are receiving services in NFs, ICFs/MR, applicable hospitals or under section 1915(c) or section 1115 HCBS demonstration projects before the modification. These individuals need not satisfy the more stringent institutional eligibility criteria. FFP under the unmodified criteria continues until such time as the individual is discharged from the institution, waiver program, or demonstration, or no longer requires this level of care. States may avoid this requirement and the complications of implementing a dual institutional level of care process by preserving existing level of care requirements, and defining the State plan HCBS benefit needs-based criteria as less stringent than the existing institutional criteria.

B. Effective Date

The effective date on which States may provide HCBS through the State plan, as set forth by the DRA of 2005 is January 1, 2007.

C. The State Plan HCBS Benefit in the Context of the Medicaid Program as a Whole

The section 1915(i) State plan HCBS benefit is subject to provisions of the Medicaid program as a whole. Therefore, it is useful to note certain requirements of the Medicaid program that have an impact on the administration of the State plan HCBS benefit.

To be eligible for the State plan HCBS benefit, an individual must be included in an eligibility group that is contained in the State plan. Each individual must meet all financial and non-financial criteria set forth in the plan for the applicable eligibility group.

Section 1902(a)(8) of the Act requires States to furnish Medicaid services with reasonable promptness to individuals found eligible. However, under section 1915(i) of the Act, States may place limits on the number of persons that they would serve via the State plan HCBS benefit. If a State chooses to set a capacity limit for the State plan HCBS benefit as permitted in section 1915(i)(1)(C)(ii) of the Act, when the HCBS benefit reaches capacity, the requirements of reasonable promptness do not apply, since the option to choose these services is no longer available to additional individuals. When individuals apply for the State plan HCBS benefit after the State has reached capacity, the State would not be required to provide the State plan HCBS to the individuals, even when they meet otherwise applicable eligibility criteria.

Children included in eligibility groups under the State plan may meet the needs-based criteria and qualify for benefits under the State plan HCBS benefit. HCBS benefits that are not otherwise available under Medicaid's Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefit may be furnished to Medicaid eligible children who meet the State plan HCBS needs-based eligibility criteria, and who meet the State's medical necessity criteria for the receipt of services. State plan HCBS and EPSDT services may be provided concurrently. A mandate for EPSDT services applies only to services authorized by section 1905(a) of the Act. Therefore, HCBS under section 1915(i) of the Act are not included in the EPSDT program. Children who are eligible for the State plan HCBS benefit are eligible to receive medically necessary State plan HCBS, but the State is not required to provide HCBS as part of its EPSDT program. States may not reserve or protect ''slots'' for either adults or children, but must allow all individuals who meet eligibility and medical necessity criteria equal access to the State plan HCBS benefit.

Clinic services (whether or not furnished in a facility) for individuals with chronic mental illness are listed in section 1915(c)(4)(B) of the Act and therefore may be covered in the State plan HCBS benefit. If a State chooses to offer these services, they will be subject to the clinic upper payment limit (UPL) at 42 CFR 447.321. We also note that these services are defined differently than other clinic services offered under the State Plan in that they include services whether or not they are offered in a facility.

D. Other Background

1. Comparability and State Control of Costs

Section 1915(i) of the Act contains no provisions for waiving Medicaid amount, duration, and scope (''comparability'') requirements described under section 1902(a)(10)(B) of the Act. This provision has two important implications. First, States may not ''target'' the State plan HCBS benefit as is permitted with HCBS provided under section 1915(c) of the Act, which does provide the Secretary authority to waive comparability. Second, without targeting, States may not offer multiple versions of the State Plan HCBS benefit, each designed to serve different groups, as is permitted with HCBS waivers. States may design one State plan HCBS benefit, in which one or any combination of the permitted services is offered, and which includes needs-based eligibility and (optionally) service criteria. However, all individuals who meet the needs-based and other eligibility criteria for the State plan HCBS benefit must be served in the benefit (up to any limit the State optionally sets to the number of individuals the benefit will serve) regardless of how individuals may relate to target groups or other classifications.

States may assure appropriate utilization of the State plan HCBS benefit through application of the following provisions of 1915(i).

- The requirement to set eligibility standards built on needs-based criteria. States choose the needs-based criteria used to establish the thresholds of

program eligibility. States must set a lower threshold of need, but may also optionally define an upper threshold of need beyond which individuals may not be served on the benefit.

• Optionally, establishing needs-based criteria to determine eligibility for each State plan HCBS. These additional criteria may vary from service to service, and should assist States in identifying the individuals who could benefit from receipt of a particular State plan HCBS.

• The scope of services that the State chooses to offer may include any, but need not include all, of the services permitted under Section 1915(c)(4)(B). States can elect to offer a limited number of services under the State plan HCBS benefit.

• Limits on the amount or duration of each service.

• Since all State plan HCBS must be provided under a written plan of care, States have the opportunity to review an individual's plan of care to ensure that HCBS continue to be responsive to the needs of the individual, without being excessive.

General Medicaid requirements apply to the State plan HCBS benefit. All Medicaid services are to be provided only to those who need them according to medical necessity as defined by the State. Prior authorization or other utilization controls methods are available to the State.

2. HCBS Provided in the Community, Not in Institutions

Home and community-based services are not available in Medicaid-certified NFs, ICFs/MR, and hospitals, as these institutions are defined in statute and regulation. HCBS are available in private homes, apartments, or other non-institutional residential settings. While a simple definition of ''home and community-based'' would be any residence other than the three Medicaid certified institutions referenced above, this definition is insufficient to ensure that enrollees in this State plan benefit receive services in the type of setting intended. There are other public and private, large and small, residences whose character is equally institutional in the experience of residents. Therefore, we would propose that at the outset of this new Medicaid benefit, States should distinguish between institutional and community living arrangements for individuals being evaluated for enrollment in the State plan HCBS benefit.

Opportunities for independence and community integration in a variety of alternative living arrangements have been demonstrated for those receiving HCBS provided under section 1915(c) waivers and section 1115 demonstrations. The new Medicaid State plan HCBS benefit should be implemented based on those practices, and in the context discussed previously of the ADA and the *Olmstead* decision. We recognize that defining home and community is complex, and invite comments on this aspect of the proposed rule. We also believe that enough is known about methods to provide elderly and disabled individuals with housing that encourages independence and community participation to justify the need to establish standards around this important issue at the inception of a new benefit offering HCBS.

We interpret the distinction between ''institutional services'' and ''home or community-based services'' in terms of opportunities for independence and community integration as well as the size of a residence. Applicable factors include the resident's ability to control access to private personal quarters, and the option to furnish and decorate that area; if the personal quarters are not a private room, then unscheduled access to private areas for telephone and visitors, and the option to choose with whom they share their personal living space; unscheduled access to food and food preparation facilities; assistance coordinating and arranging for the resident's choice of community pursuits outside the residence; and the right to assume risk. Services provided in settings lacking these characteristics, with scheduled daily routines that reduce personal choice and initiative, or without personal living spaces, cannot be considered services provided in the home or community.

We would propose two mechanisms for the State to determine that residents are residing in the community rather than in an institution. First, we would require minimum standards, as prescribed by the Secretary, for community living facilities that take into account the factors discussed above.

Individuals vary widely in both support needs and preferences, so that a residence that meets the minimum standards for community living facilities may be homelike and community-integrated for one individual but may not be for another individual. While we do not find there to be any objective criteria, such as numbers of residents, to reliably distinguish facilities with institutional character from those with community character, we do believe that it is reasonable to use number of residents to trigger an assessment of the nature of the residence for a specific individual. We would therefore additionally propose that for individuals in larger residential settings there be an individualized determination that the residence is a community setting appropriate to the individual's need for independence, choice, and community integration. We believe that the person-centered assessment and plan of care required by section 1915(i) of the Act offers an efficient opportunity for such an individualized assessment of community residence. Therefore, we would propose to require that for individuals in residential settings meeting the standards for community living facilities, that house four or more persons unrelated to the proprietor and provide one or more services or treatments to the residents, the person-centered assessment and plan of care must include a determination that the residence is a community setting appropriate to the individual's need for independence, choice, and community integration.

We believe that these two mechanisms will provide States the flexibility to approve a variety of settings appropriate to the needs of the individuals served while also maximizing independence and opportunities for community integration.

For example, we anticipate that States could devise standards indicating that a residence with multiple independent living units (apartments) would not be considered to be housing four or more people together, and would therefore not trigger the requirement for the assessment to include documentation of community character.

The State plan HCBS benefit may be defined by States to serve individuals with widely varying degrees of independence. The person-centered assessment and plan of care will provide flexibility to approve different types of living arrangements according to need. For example, if physical or cognitive impairment makes unsupervised access to some food preparation facilities unsafe, and the person-centered plan reflects that there must be safeguards against this risk, then those portions of the kitchen would be made inaccessible when staff is not present. In this example, barring residents from the home's kitchen altogether would be an institutional, rather an integrated solution in all but the rarest of circumstances. A residence in which only the high risk equipment would be inaccessible when staff are not present, and the resident would have access to the kitchen, food, and equipment that does not pose a danger,

could be approved as a community living arrangement.

While HCBS are not available while an individual resides in an institution, HCBS should be available to individuals once they leave an institution. Recognizing that individuals leaving institutions require assistance to establish themselves in the community, we would allow for transition services to be claimed after the date of discharge from the institution. We propose that of the HCBS permitted under section 1915(i) of the Act, case management is the only service that could be commenced prior to discharge and could be used to assist individuals during the transition period of institutional residence.

3. HCBS Do Not Provide Room and Board

Payments for room and board are prohibited by section 1915(i)(1) of the Act. Except for respite care furnished in a facility approved by the State that is not a private residence, no service or combination of services may be used to furnish a full nutritional regimen (3 meals a day) through the State plan HCBS benefit. FFP for State plan HCBS is not available in the cost of meals that are furnished in alternative residential facilities in the community, regardless of whether services (other than respite care) are provided by or through the setting in which the individual resides.

When an individual must be absent from his or her residence in order to receive a service authorized by the individualized plan of care, it may be impractical to obtain a meal outside the venue in which the service is provided. This may occur during the receipt of facility-based respite care, adult day care, or site-based habilitation. In these instances, the individual may be unable to leave the site to obtain food at mealtime. Therefore, the State plan HCBS provider may elect to furnish the meal. When meals are furnished as an integral component of the service, the State may consider the cost of food in setting the rate it would pay for the State plan HCBS as the cost is then considered part of the service itself. We would not consider the meal to be an integral part of the State plan HCBS when two rates are charged to the public, one that includes a meal and one that does not include a meal.

II. Provisions of the Proposed Rule

[If you choose to comment on issues in this section, please indicate the caption ''Provisions of the Proposed Rule'' at the beginning of your comments.]

To incorporate the policies and implement the statutory provisions described above, we are proposing the following revisions:

Part 431 (State Organization and General Administration)

- In § 431.40, we are proposing to amend paragraph (a)(7), by adding reference to section 1915(i) of the Act to the scope of subpart B, as an exception to statewide operation, and correcting the paragraph to include reference to sections 1915(d) and (e) of the Act.
- In § 431.50, we are proposing to amend paragraph (c) to include HCBS (under waivers and the State plan) as an exception to statewide operation.

Part 440 (Services: General Provisions)

- In § 440.1, we are proposing to add a reference to a new statutory basis to read ''1915(i) Home and community-based services furnished under a State plan to elderly and disabled individuals under the provisions of part 441, subpart K.''
- In § 440.180, we are proposing to revise the heading ''Home or community-based services'' to read ''Home and community-based waiver services'' to standardize the term ''home and community-based services'' and clarify that this section concerns only HCBS provided through 1915(c) waivers.
- In part 440 subpart A, we are proposing to add § 440.182, ''State plan home and community-based services'', which would define a new optional Medicaid service for which FFP is available to States, as specified in part 441, subpart K.

Section 440.182 (State Plan Home and Community-Based Services Benefit)

In § 440.182(a), we propose that the services authorized in section 1915(i) of the Act, and meeting the requirements outlined in proposed subpart K, be known as ''State plan home and community-based services.'' When referring to the specific service(s) offered under the State plan HCBS benefit listed in § 440.180(b), we use the term ''State plan HCBS.'' When referring to overall State activities under section 1915(i) of the Act as described in subpart K, we use the term ''benefit'', or ''State plan HCBS benefit''.

In § 440.182(b) and § 440.182(c)(1), we propose that the optional State plan HCBS benefit may consist of any or all of the HCBS listed in section 1915(c)(4) for waiver programs, as specified in regulation at § 440.180, except for the ''other'' services which the Secretary has the authority to approve for an HCBS waiver. Because section 1915(i) of the Act defines services by reference to section 1915(c) of the Act, we believe that the regulatory requirements should be parallel. Therefore, we list the permitted services for the State plan HCBS benefit in § 440.182 identically to the services specified in § 440.180 for HCBS waivers. We further specify that the conditions set forth in § 440.180(b) for services to individuals with chronic mental illness, and in § 440.180(c) for expanded habilitation services, apply to State plan HCBS services. In particular, due to concern over duplication of habilitation services, we propose to require at § 441.562(a)(2)(vix) an explanation of the manner in which nonduplication of services will be documented in the assessment of each individual receiving habilitation services. Section 1915(i) of the Act prohibits reimbursement for room and board. At § 440.182(c)(2) we define the term ''room'' to mean shelter type expenses, including all property-related costs such as rental or purchase of real estate and furnishings, maintenance, utilities, and related administrative services. The term ''board'' means three meals a day or any other full nutritional regimen. We propose in § 440.182(c)(2) to require an assurance that the State has a methodology to prevent claims and ensure that no payment is made for room and board in State plan HCBS. We propose to specify three types of service costs involving food and housing that are not considered room and board. We adopt the existing requirement for HCBS waivers in § 441.310(a)(2), to permit the cost of food and residence to be claimed for respite services furnished in State-approved settings that are not private residences. We clarify that a State may claim FFP for the costs of meals that are furnished as part of a program of adult day health or a similar activity conducted outside the participant's living arrangement on a partial day basis. Finally, we propose that a State may claim FFP for a portion of the housing expense and food that may be reasonably attributed as a service cost to compensate an unrelated caregiver providing State plan HCBS, who is residing in the same household with the recipient. We propose, as is the policy in HCBS waivers that FFP is available only for the reasonable additional costs of the caregiver residing in the recipient's home, not to support the cost of a caregiver's household in which the recipient resides. We would therefore provide that FFP not be available for caregiver living costs when the residence is owned or leased by the caregiver.

Part 441 (Services: Requirements and Limits Applicable to Specific Services)

In part 441, ''Requirements and Limits Applicable to Specific Services,'' we are proposing to add a new subpart K titled ''State Plan Home and Community-Based Services for Elderly and Disabled Individuals,'' consisting of § 441.550 through § 441.577, which describes requirements for providing the State plan HCBS benefit. This construction parallels that for HCBS waivers, which are the subject of subpart G of part 441.

In this new subpart, it is necessary in several paragraphs to indicate that certain provisions apply to an individual or an individual's representative. To reduce redundancy, we indicate in those paragraphs that ''individual'' means the eligible individual and, if applicable, the individual's representative, to the extent of the representative's authority recognized by the State. ''Individual and representative'' more accurately convey the person-centered process than ''individual or representative''. This provision clarifies that there is no implication that individuals will or will not have representatives.

Section 441.550 (Basis and Purpose)

We set forth in § 441.550 language to implement the provisions of section 1915(i) of the Act permitting States to offer HCBS to qualified elderly and disabled individuals under the State plan. Those services are listed in § 440.182, and are described by the State, including any limitations of the services. This optional benefit is known as the State plan HCBS benefit. This subpart describes what a State Medicaid plan must provide, and defines State responsibilities.

Section 441.553 (State Plan Requirements)

In § 441.553, we propose that a State plan that includes home and community-based services for elderly and disabled individuals must meet the requirements of this subpart. We would require that the State plan amendment in which the State establishes the State plan HCBS benefit satisfy the requirements set forth in this proposed regulation.

Section 441.556 (Eligibility for Home and Community-Based Services Under Section 1915(i)(1) of the Act)

We propose in § 441.556(a)(1) to require that the individual be eligible for Medicaid under an eligibility group covered under the State's Medicaid plan. Enrollment in the State plan HCBS does not confer Medicaid eligibility. In addition to meeting State Medicaid eligibility requirements, the statute requires that applicants for State plan HCBS must have income that does not exceed 150 percent of the Federal Poverty Level (FPL). (The poverty guidelines are updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2).) We propose in § 441.556(a)(2) that determinations that the individual's income does not exceed 150 percent of FPL must be made using the applicable rules for income eligibility for the individual's eligibility group, including any more liberal income disregards used by the State for that group under section 1902(r)(2) of the Act. We see no authority in the statute for States to choose income limits other than 150 percent of FPL.

To implement the intent of the Congress that the benefit be ''home and community-based,'' we would require in § 441.556(a)(3) that the individual reside in the home or community, not in an institution, according to standards for community living facilities prescribed by the Secretary. As discussed in section I.D.2., there are a variety of living arrangements other than a private home or apartment that promote independence and community integration, as well as arrangements that do not. We propose that the person-centered assessment and plan of care required under the State plan HCBS benefit provides an opportunity to make individualized determinations of community residence. Therefore, we propose to require that if the individual resides in a setting with four or more persons unrelated to the proprietor, and which furnishes one or more services or treatments, the independent assessment must include documentation that the individual is living in a community setting, and not in an institution.

We would require in § 441.556(a)(4) that the individual must meet the needs-based eligibility criteria as set forth in § 441.559. We propose in § 441.556(a)(5) that individuals are not eligible for the State plan HCBS benefit until they have met all eligibility requirements, including the need for at least one service provided under the State plan as part of the HCBS benefit.

We propose in § 441.556(b) that States may elect to follow institutional income and resource eligibility rules for the medically needy living in the community. Waiving the requirements of section 1902(a)(10)(C)(i)(III) of the Act allows States to treat medically needy individuals as if they are living in an institution by not deeming income and resources from an ineligible family member. We use the term ''non-application'' instead of ''waive'' as does the statute. We further propose that States may elect non-application of section 1902(a)(1) of the Act, concerning statewide application of Medicaid, which permits the State plan HCBS benefit to be offered only in certain defined geographic areas of the State.

Section 441.559 (Needs-Based Criteria and Evaluation)

The statute uses a number of terms at times interchangeably. We adopt the wording used most frequently in the law, and specify a term for each requirement. For example, regarding the terms ''assessment'' and ''evaluation,'' we would adopt the language in section 1915(i)(1)(H)(ii) of the Act, which refers to the ''independent evaluation'' and the ''independent assessment.''

• Needs-based eligibility criteria.

In § 441.559(a), we propose that States establish needs-based criteria for determining an individual's eligibility under the State plan for HCBS, and may establish needs-based criteria for each specific service. We do not define support needs, as we believe that States should have the flexibility to match eligibility criteria to the nature of the services they would provide under the HCBS benefit. By statute, the needs-based criteria would consist of needs for specified types of support, such as assistance with ADLs, or risk factors defined by the State. We propose to require that State-defined risk factors affecting eligibility must be included as needs-based eligibility criteria in the State plan amendment. While we do not propose requirements for State-defined risk factors, we believe that as needs-based criteria, risk factors should be related to support needs, such as availability of family members or other unpaid caregivers and their willingness and ability to provide necessary care.

We distinguish support needs from other types of characteristics. We propose that a distinguishing characteristic of needs-based criteria is that they can only be ascertained for a given person through an individual evaluation. This differentiates a targeting criterion such as a diagnosis, which many individuals may identically share, from a support need, which will vary widely among those individuals with the same diagnosis. Also set forth in § 441.559(a) are the examples of needs-based eligibility criteria and factors to consider that are supplied in the statute. Section 1915(i) of the Act defines ADLs by reference to section 7702B(c)(2)(B) of the Internal Revenue Code of 1986. This section of the Internal Revenue Code lists eating, toileting, transferring, bathing, dressing,

and continence. This mobility-oriented definition of ADLs is one that States may consider, meaning that States are free to define criteria in other domains such as cognitive or behavioral needs for support.

We note that the regulation requires only that the needs-based criteria for the State plan HCBS benefit establish the lowest threshold of need to enroll in the benefit. There is an upper limit of need to be eligible for the HCBS benefit only if the State so specifies in the needs-based eligibility criteria. The more stringent institutional criteria required in § 441.559(b) of this section do not constitute an upper limit of need to be eligible for the State plan HCBS benefit. The institutional criteria are only a lowest threshold of need to receive institutional services. We also note that section 1915(i)(1) of the Act clarifies that State plan HCBS are not required to be direct alternatives to institutional care. The statute specifically provides that the State plan HCBS benefit does not need to meet the section 1915(c) requirement that, but for the services provided under the HCBS waiver, the individual would require institutional care.

• More stringent institutional and waiver needs-based criteria

In § 441.559(b), we propose that the State plan HCBS benefit is available to a State only if individuals may demonstrate a lower level of need to obtain State plan HCBS than is required to obtain institutional or waiver services. States that have functional level of care criteria for institutions (that meet the requirements in § 441.559(a)(1)), may have no need to modify their existing institutional criteria so long as the needs-based eligibility criteria established for State plan HCBS are less stringent. States without need-based institutional level of care criteria must add need-based requirements to their level of care assessments in order to establish the State plan HCBS benefit.

We propose in § 441.559(b) to define by reference to statute and regulation the institutions for which section 1915(i) of the Act requires more stringent eligibility criteria. Nursing facility and intermediate care facilities for the mentally retarded are so cited. We interpret reference in section 1915(i)(1)(B) of the Act to hospitals to mean facilities certified by Medicaid as hospitals that are providing long-term care services or services related to the HCBS to be provided under the benefit. The proposed regulation requires that States have or establish for such hospitals (if any), needs based criteria for admission that are more stringent than those for eligibility in the State plan HCBS benefit. We further propose, when the State covers more than one service in the State plan HCBS benefit, to require that any needs-based criteria for individual HCBS, combined with the needs-based eligibility criteria for the benefit, must be less stringent than needs-based eligibility criteria for any related institutional services. Without this provision, it would be possible for States to define needs-based eligibility criteria that are less stringent than those for institutions, but then set each needs-based service criteria at a more stringent level, effectively requiring all persons served by the benefit to be at a higher level of need than the statute intends.

In § 441.559(b), we further propose to require that the more stringent needs-based criteria for institutions and waivers be part of the State's level of care processes, to ensure that the criteria are uniformly utilized. We would require that these more-stringent needs-based criteria be submitted for comparison with the State plan amendment that establishes the State plan HCBS benefit. We note that needs-based criteria, as defined in § 441.559(a) require an evaluation to determine the individual's support needs. Therefore, the assessment process for institutional levels of care that include needs-based criteria must include an individual evaluation of support needs. We also propose to require that the State's more stringent institutional and waiver needs-based criteria be in effect on or before the effective date of the State plan HCBS benefit.

Finally, in § 441.559(b)(2), we propose that if States modify their institutional levels of care in order to satisfy the requirement that the levels of care be more stringent than the needs-based eligibility criteria for the State plan HCBS benefit, individuals receiving institutional and waiver services as of the date that more stringent eligibility criteria for those services become effective, would not be subject to the more stringent criteria. Exemption from the more stringent criteria is indefinite, but ends when the individual is discharged from the facility or waiver, or the individual no longer meets the criteria for the applicable level of care. We note that in long-term care facilities a transfer is not a discharge and would not cause the individual to lose this exemption. States would determine the effect of any subsequent changes to general level of care requirements (unrelated to the more stringent criteria) upon individuals with this exemption.

• Adjustment authority

In § 441.559(c), we propose to permit States under certain conditions to adjust, without prior approval from the Secretary, the needs-based eligibility criteria and service criteria (if any) established under § 441.559(a), in the event that the State experiences enrollment in excess of the number projected to be served by the HCBS benefit. We propose a retroactive effective date, as approved by the Secretary, for the State plan amendment modifying the needs-based criteria under § 441.559(c)(1). We set forth the following conditions required by the statute.

The State must provide for at least 60 days notice to the Secretary, the public, and we would add, each enrollee. Since the effect of adjusted criteria would be to reduce the scope of services, eligibility for services, or eligibility for the entire State plan HCBS benefit, the adjusted criteria would not apply to individuals already enrolled in the State plan HCBS benefit for at least 12 months from inception of such services, and we would add, for the additional length of the required minimum 60 day notification period. If the State also adjusts institutional levels of care, the adjusted institutional levels of care may not be less stringent than the institutional level of care prior to the effective date of the State plan HCBS benefit.

In § 441.559(c), we further propose to require explicitly that the adjusted needs-based eligibility criteria for the State plan HCBS benefit must be less stringent than all needs-based institutional level of care criteria in effect at the time of the adjustment.

We propose that the notice to the Secretary be submitted as a State plan amendment. In order to implement the adjustment authority without prior approval of the Secretary, the Secretary would approve a State plan amendment adjusting the needs-based HCBS benefit eligibility criteria with a retroactive effective date, as early as 60 days after the State notified each enrollee, the Secretary, and the public, (or whichever is later). Under the provision of section 1915(i)(1)(D)(ii) of the Act, the Secretary will evaluate the State's adjusted criteria for compliance with the provisions of this paragraph and subpart K. We also note that while the State may under this provision implement the adjusted criteria as early as 60 days after notification and before the State plan amendment is retroactively approved, the State is at risk for any actions it takes that are later disapproved.

Finally, we would require that the State notify affected individuals of their right to a fair hearing according to 42 CFR part 431, subpart E.

• Independent evaluation and determination of eligibility

In § 441.559(d), we propose that eligibility for the State plan HCBS benefit be determined by an independent evaluation of each individual, applying the general eligibility requirements in § 441.556 of this subpart, and the needs-based criteria that the State has established under § 441.559(a). Independence of the review requires meeting the conflict of interest standards set forth in § 441.568, where provider qualifications for evaluators are specified.

The evaluation must assess an individual's support needs and strengths. We interpret this provision of the statute to indicate that the evaluation process draws conclusions about supports that the individual requires because of age or disability, and supports that the individual does not require because of abilities to perform those functions independently. The evaluation compares those conclusions with the needs-based eligibility criteria for the State plan HCBS benefit to determine eligibility for the benefit. Section 1915(i)(1)(D)(i) of the Act provides that the State may take into account the need for significant assistance to perform ADLs, indicating that the statute does not require that eligibility be dependent upon lack of natural supports.

We note that appraisal of whether an individual has medical necessity for, and meets additional needs-based criteria (if any) for specific HCBS offered under the benefit, is part of the independent assessment and plan of care development process. However, this assessment affects eligibility for the benefit in that we propose at § 441.562 that individuals are considered enrolled in the State plan HCBS benefit only if they are assessed to require at least one home and community-based service offered under the State plan benefit in addition to meeting the eligibility and needs-based criteria for the benefit.

The evaluation process designed by the State would reflect the nature of the State plan HCBS benefit designed by the State. However, in order to meet the forgoing requirements, all independent evaluations require specific information about each individual's support needs, sufficient to draw the appropriate conclusions. In some cases this information may be well documented and current in the individual's existing records. In other cases, we would require that the evaluator obtain this information by whatever means are appropriate to secure a valid appraisal of the individual's current needs. This requirement could include professional assessment of certain functional abilities. State evaluation procedures that rely solely on review of medical records would not meet these requirements.

• Periodic redetermination

In § 441.559(e), we propose that individuals receiving the State plan HCBS benefit must be reevaluated at a frequency defined by the State, but not less than every 12 months, to determine whether the individuals continue to meet eligibility requirements. The independent reevaluations must meet the requirements for initial independent evaluations specified in § 441.559(d).

Section 441.562 (Independent Assessment)

In § 441.562, we propose requirements for independent assessment of need of each individual who has been determined by the independent evaluation to be eligible for the State plan HCBS benefit. The purpose of the assessment is to obtain, in combination with the findings of the independent eligibility evaluation, all the information necessary to establish a plan of care. The assessment is based on the needs of the individual, which we believe precludes assessment protocols that primarily determine diagnoses, or only assess function. Assessment protocols must not assign supports automatically by functional limitation. The independent assessment must determine the specific supports needed to address the individual's unique circumstances and needs.

The assessment also applies the State's needs-based criteria for each service (if any). We propose that an individual be considered enrolled in the State plan HCBS benefit only if the assessment finds that the individual needs and meets the needs-based criteria (if any) for, at least one State plan HCBS. This proposed requirement is to provide States with a mechanism to prevent the situation of an individual being eligible for the State plan HCBS benefit but not able to receive any of the services it offers. Such a circumstance would, among other problems, be of no utility to the individual, may make it difficult for the State to meet an assessed need, and would count towards the maximum number of individuals the State could serve, using up a ''slot'' for no purpose.

We make clear that the assessment must include an objective evaluation of the individual's inability to perform two or more activities of daily living (ADL) as defined in the Internal Revenue Code of 1986, or need for significant assistance to perform ADLs. We interpret the statutory term ''objective'' to require an accepted method of measuring functioning appropriate to the ADL.

We propose to require in § 441.562(a)(2) that the assessment include a face-to-face meeting with the individual (''individual'' meaning in this context, if applicable, the individual and the individual's authorized representative). In § 441.562(a)(2)(i), we propose to require that the assessment is performed by an agent that is independent and qualified as defined in § 441.568. The assessment is to be guided by best practice and research on effective strategies that result in improved health and quality of life outcomes. We further propose that the assessment includes consultation, as appropriate, with other responsible parties. The assessment must include an examination of the individual's relevant history, medical records, and care and support needs, including the findings from the independent eligibility evaluation.

If self-direction of services is offered by the State and elected by the individual, the independent assessment must include a self-direction appraisal as described in § 441.574.

We propose documentation requirements in the assessment to address two specific circumstances. For individuals living in a residence with four or more persons unrelated to the proprietor, that furnishes one or more treatments or services and meets the criteria listed in paragraph (a)(3) of § 441.556, we propose that the assessment must include documentation that the individual is living in a community setting, and not in an institution.

For individuals receiving habilitation services, we propose to require documentation that no services are provided under Medicaid that would otherwise be available to the individual, specifically including but not limited to services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973, or the Individuals with Disabilities Improvement Act of 2004. We believe that these documentation requirements would provide a clear method for States to comply with Federal requirements, focus only on the individuals for whom these circumstances could apply, and would not add significantly to the burden of the assessment.

Finally, in § 441.562(b), we propose to require that the independent assessment of need is conducted at least every 12 months and as needed when the individual's needs and circumstances change significantly, in order to revise the plan of care.

Section 441.565 (Plan of Care)

In § 441.565 we propose to require that based on the independent assessment specified in § 441.562, the State develops (or approves, if the plan is developed by others) a plan of care through a person-centered planning process. Section 1915(i)(1)(G)(iii)(III)(dd) of the Act requires a person-centered approach to establishing a plan of care for an individual (''individual'' meaning in this context, if applicable, the individual and the individual's authorized representative) electing to direct his or her own services. We propose to require that person-centered principles guide all plans of care for the State plan HCBS benefit.

We propose that the plan of care must be developed jointly with the individual. While we propose several specific requirements for the process of developing a plan of care, we note that the intent of these requirements is to ensure a process with shared authority between the individual and the agency or agent. To achieve this intent, States must affirmatively and creatively work to establish such shared authority.

The assessment must include consultation with appropriate persons. Definition of appropriate persons would be determined in each case, and while we include examples, we do not propose any required or excluded category of persons to consult. When the plan of care is finalized between the parties, a written copy is provided to the individual.

Also, in § 441.565(a), we propose certain content to be required in the plan of care. The plan of care must identify the specific State plan HCBS to be provided to the individual, that take into account the individual's strengths, preferences, and desired outcomes, as well as support needs arising from the individual's disability. In the planning process, the degree of assistance with ADLS available to the individual outside of the State plan HCBS benefit may be taken into account in planning the scope and frequency of HCBS to be provided. Thus, the plan of care provides for all needed services to the individual while preventing provision of unnecessary services.

We propose a single plan of care for both self-directed and non self-directed services. When an individual self-directs some or all of their HCBS, the plan of care includes the information required in § 441.574.

We further propose to require that the plan of care be reviewed and revised at least every 12 months, and as needed when the individual's circumstances or needs change significantly.

Section 441.568 (Provider Qualifications)

In § 441.568, we propose to require that the State provide assurance that necessary safeguards have been taken to protect the health and welfare of the enrollees in State plan HCBS by provision of adequate standards for all types of providers of HCBS. States must define qualifications for providers of HCBS services, and for those persons who conduct independent evaluation of eligibility for State plan HCBS, independent assessment of need, and are involved with developing the plan of care.

We propose at § 441.568(b) and (c) to require minimum qualifications for individuals and agencies who conduct independent evaluation of eligibility for State plan HCBS, independent assessment of need, and are involved with developing the plan of care. We will refer to these individuals and entities involved with determining access to care as ''agents'' to distinguish this role from providers of services. We believe that these qualifications are important safeguards for individuals enrolled in the State plan HCBS benefit and propose that they be required whether activities of the agents are provided as an administrative activity or whether some of the activities are provided as a Medicaid service. At a minimum, these qualifications include conflict of interest standards, and for providers of assessment and plan of care development, these qualifications must include training in assessment of individuals whose physical or mental condition may trigger a need for home and community-based services and supports, and an ongoing knowledge of current best practices to improve health and quality of life outcomes.

The minimum conflict of interest standards we propose to require ensure that the provider is not a relative of the individual or responsible for the individual's finances or health-related decisions. Relatives and decision makers are required to be permitted in the assessment and planning process, as appropriate, but we do not see any necessity or value in family members being responsible for evaluation, assessment, or planning. Our experience with HCBS in waivers indicates that assessment and plan of care development should not be performed by providers of the services prescribed. However, we recognize, as discussed in Section I., that in some circumstances there are acceptable reasons for a single provider of service that performs all of those functions. In this case, the Secretary would require the State Plan to include provisions assuring separation of functions within the provider entity.

Section 441.571 (Definition of Individual's Representative)

In § 441.571, we propose to define the term ''individual's representative'' to encompass any party that is authorized to represent the individual for the purpose of making personal or health care decisions, either under State law or under the policies of the State Medicaid agency. We do not propose to regulate the relationship between an individual enrolled in the State plan HCBS benefit and his or her authorized representative, but note that States should have policies to assess for abuse or excessive control and ensure that representatives conform to applicable State requirements.

Section 441.574 (Self-Directed Services)

We propose in § 441.574 to permit States to offer an election for self-directing HCBS. In § 441.574(a), we would define ''self-direction.'' Provisions related to self-direction apply to an individual or an individual's representative. In § 441.574(b), we propose that when an individual chooses self-direction, the independent assessment and person-centered planning required under §§ 441.562 and 441.565 would include examination of the support needs of the individual to self-direct the purchase of, or control the receipt of, such services. The evaluation should not reject election to self-direct based solely on the individual's disability or a manifestation of his or her disability. We therefore propose to require that the evaluation for self-direction result in a determination of ability to self-direct both with and without specified supports.

We propose regulations containing the specific requirements for self-direction found in section 1915(i)(1)(G)(iii) of the Act. These regulations are consistent with our policy for self-direction under section 1915(c) HCBS waivers. We propose to require in § 441.574(b) that the plan of care indicate the HCBS to be self-directed and the methods by which the individual will plan, direct, or control the services; the role of family or others who will participate in the HCBS; and risk management techniques. Our experience with HCBS waivers indicates that contingency plans are an important protection for the individual, in the absence of an agency that would otherwise be responsible for absent workers or other common problems.

Contingency plans are most effective when designed for the unique circumstances of each self-directing individual. We propose that the plan of care describe the process for facilitating voluntary and involuntary transition from self-direction. When the plan of care is finalized between the parties, a written copy is provided to the individual, as required in § 441.565(a).

In § 441.574(c) and (d), we define self-direction of services in terms of employer authority and budget authority, as we have with self-directed HCBS in Medicaid section 1915(c) waivers. In § 441.574(c), employer authority is defined as the ability to select, manage, or dismiss providers of the State plan HCBS. We propose that the plan of care must specify the authority to be assumed by the individual and the individual's representative, any parties responsible for functions outside the assumed authority, and the financial management supports to be provided as required in § 441.574(e).

In § 441.574(d), we propose to define budget authority as an individualized budget which identifies the dollar value of the services and supports under the control and direction of the individual. We propose that the plan of care must specify the method for calculating the dollar values in the budget, a process for adjusting the budget to reflect changes in assessment and plan of care, a procedure to evaluate expenditures under the budget, and the financial management supports, as required in § 441.574(e), to be provided. We clarify here that while budget authority grants control of expenditures to the individual, it does not include performing the transactions or conveying cash to the individual or representative.

In § 441.574(e), we propose to define functions in support of self-direction that the State must offer, based on our experience with self-directed HCBS in section 1915(c) waivers and section 1115 demonstrations. These provisions are required in order to equip individuals for success in managing their services, and to comply with Federal, State, and local requirements, particularly the many tax, labor, and insurance issues that arise when the self-directing individual is the employer of record. Supports for self-direction should provide the technical expertise and business functions that will free individuals to exercise choice and control over their experience of the HCBS provided to them.

Section 441.577 (State Plan HCBS Administration: State Responsibilities and Quality Improvement)

- State responsibilities.

We would require in § 441.577(a)(1)(i) that the State annually provide CMS with the projected number of individuals to be enrolled in the benefit, and the actual number of unduplicated individuals enrolled in the State plan HCBS benefit in the previous year. States may choose to limit the number to be served at any point in time, as provided in § 441.577(a)(1)(ii). If the State so chooses, we propose that it would also provide annually to CMS the maximum number enrolled at one time.

In § 441.577(a)(1)(ii) we propose that a State may elect to set a limit on the number of individuals enrolled in the State plan HCBS benefit, either as an annual limit or as limit at any one point in time. The State must establish or adjust the limit by amending the State plan. The State may, but is not required to, establish a waiting list. States must consider many legal requirements and competing demands in establishing waiting list policy, including the Americans with Disabilities Act (ADA). We do not specify waiting list requirements, but propose to require that if a State elects to maintain a waiting list, it must do so with written and publicly published policies to ensure fairness and consistency. The public should have opportunity for notice and comment on this important limitation to access. We propose to require a formally established schedule and procedure for reevaluation and revision to waiting list policy. We also would require assurance that States will adhere to all applicable Federal and State requirements. For example, individuals who may be denied access to services would have all rights required under 42 CFR part 431, subpart E.

Because section 1915(i) of the Act does not authorize waiver of comparability requirements, we clarify in § 441.577(a)(1)(iii) that the State may not limit enrollee access to services in the benefit for any reason other than assessed need, including limits based on type of disability or other targeting, or limiting the number of persons receiving particular services. This is an important distinction between the limits States place on the services to be offered when they design the benefit, as opposed to limiting access to the services that are in the benefit for particular enrolled individuals. As discussed in Section I.D.1 above, States have a number of permitted methods to control utilization by placing limits on the overall benefit and particular services offered. We propose that once an individual is found eligible and enrolled in the benefit, access to offered services can only be limited by medical necessity. Medical necessity in the State plan HCBS benefit is determined by the independent assessment and person-centered plan of care. By not limiting access, we mean that an enrollee must receive any or all of the HCBS offered by the benefit, in scope and frequency up to any limits on those services defined in the State plan, to the degree the enrollee is determined to need them. Enrollees should receive no more, and no fewer, services than they are determined to require. We note that one function of the plan of care as proposed at § 441.565(a)(3) is to prevent the provision of unnecessary or inappropriate care.

- Administration.

We propose in § 441.577(a)(2)(i) an option for presumptive payment. The State may provide for a period of presumptive payment, not to exceed 60 days, for evaluation of eligibility for the State plan HCBS benefit and assessment of need for HCBS. This period of presumptive payment would be available for individuals who have been determined to be Medicaid eligible, and whom the State has reason to believe may be eligible for the State plan HCBS benefit. We propose that FFP would be available for evaluation and assessment as administration of the approved State plan prior to an individual's determination of eligibility for and receipt of other 1915(i) services. If the individual is found not eligible for the State plan HCBS benefit, the State may claim the evaluation and assessment as administration, even though the individual would not be considered to have participated in the benefit for purposes of determining the annual number of individuals served by the benefit. FFP would not be available during this presumptive period for receipt of State plan HCBS.

In § 441.577(a)(2)(ii), we propose that a State plan amendment submitted to establish the State plan HCBS benefit must include a reimbursement methodology for each covered service. In some States, reimbursement methods for self-directed services may differ from the same service provided without self-direction. In such cases, the reimbursement methodology for the self-directed services must also be described.

In § 441.577(a)(2)(iii), we propose that the State Medicaid agency describe the line of authority for operating the State plan HCBS benefit. The State plan HCBS benefit requires several functions

to be performed in addition to the service(s) provided, such as eligibility evaluation, assessment, and developing a plan of care. To the extent that the State Medicaid agency delegates these functions to other entities, we propose that the agency describe the methods by which it will retain oversight and responsibility for those activities, and for the operation and quality improvement of the benefit as a whole.

• Quality improvement strategy.

We propose in § 441.577(b) the guidelines for quality assurance required in the statute at section 1915(i)(1)(H)(i) of the Act. We propose to require a State to maintain a quality improvement strategy for its State plan HCBS benefit. The State's quality improvement strategy should reflect the nature and scope of the benefit the State will provide.

As discussed in section I of this preamble, section 6086(a) of the DRA established section 1915(i) of the Act, the optional State plan HCBS benefit. Section 6086(b), Quality of Care Measures, sets forth requirements for the Secretary to develop through the Agency for Healthcare Research and Quality (AHRQ) indicators and measures for program performance and quality of care to assess HCBS at the State and national level, and service outcomes, particularly regarding health and welfare of recipients. Likewise, we propose that measures in the State quality improvement strategy consist of indicators for program performance and quality of care as approved and prescribed by the Secretary, and applicable to the nature of the benefit.

In § 441.577(b)(2), we propose to require States to have program performance measures, appropriate to the scope of the benefit, designed to assess the State's overall system for providing HCBS.

In § 441.577(b)(3), we propose to require States to have quality of care measures as approved or prescribed by the Secretary that may be used to assess individual outcomes of participants in home and community-based services, such as client function indicators and measures of client satisfaction. Outcome measures may be reflective of the design and scope of the benefit and the specific HCBS provided.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we 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 by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 441.559 Needs-Based Criteria and Evaluation

Section 441.559(a) requires a State to establish needs-based criteria for determining an individual's eligibility under the State plan for the HCBS benefit, and may establish needs-based criteria for each specific service.

The burden associated with this requirement is the time and effort put forth by the State to establish such criteria. We estimate it would take 1 State 24 hours to meet this requirement. We estimate that on an annual basis, 3 States will submit a State plan amendment to offer the State plan HCBS benefit, and be affected by this requirement; therefore, the total annual burden hours for this requirement is 72 hours. This would be a one-time burden.

Section 441.559(c) reads that a State may modify the needs-based criteria established under paragraph (a) of this section, without prior approval from the Secretary, if the number of individuals enrolled in the State plan HCBS benefit exceeds the projected number submitted annually to CMS.

Section 441.559(c)(1) requires the State to provide at least 60 days' notice of the proposed modification to the Secretary, the public, and each individual enrolled in the State plan HCBS benefit. The State notice to the Secretary will be considered an amendment to the State plan.

Section 441.559(c)(2) reads that the State may under this provision implement the adjusted criteria as early as 60 days after submitting the State plan amendment and notifying all required parties.

The burden associated with the requirements found under 441.559(c) is the time and effort put forth by the State to modify the needs-based criteria and provide notification of the proposed modification to the Secretary. We estimate it would take 1 State 24 hours to make the modifications and provide notification. This would be a one-time burden. The total annual burden of these requirements would vary according to the number of States who choose to modify their needs-based criteria. We do not expect any States to make this modification in the next 3 years.

Section 441.559(d) states that eligibility for the State plan HCBS benefit is determined, for individuals who meet the requirements of 441.556(a)(1) through (3), through an independent evaluation of each individual that meets the specified requirements. Section 441.559(d)(5) requires the evaluator to obtain information from existing records, and when documentation is not current and accurate, obtain any additional information necessary to draw a valid conclusion about the individual's support needs. Section 441.559(e) requires at least annual reevaluations.

The burden associated with this requirement is the time and effort put forth by the evaluator to obtain information to support their conclusion. We estimate it would take one evaluator 2 hours per participant to obtain information as necessary. The total annual burden of this requirement would vary according to the number of participants in each State who may require and be eligible for home and community-based services under the State plan.

Section 441.562 requires the State to provide for an independent assessment of need in order to establish a plan of care. At a minimum, the plan must meet the requirements as discussed under 441.565.

Section 441.568 requires the State to define in writing adequate standards for providers of HCBS services and for providers conducting independent evaluation, independent assessment, and plan of care development.

While the burden associated with the requirements under §§ 441.562 and 441.568 is subject to the PRA, we

believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities.

Section 441.574 Self-Directed Services

Section 441.574 reads that a State may choose to offer an election for self-directing HCBS.

The burden associated with this requirement is the time and effort put forth by the State to elect for self-directing HCBS. We estimate it would take one State 5 hours to meet this requirement; therefore, if all of the States and territories estimated to apply for State plan HCBS on an annual basis (3) chose to offer an election for self-directing HCBS the total annual burden would be 15 hours. This would be a one-time burden.

Section 441.577 State Plan HCBS Administration: State Responsibilities and Quality Improvement

Section 441.577(a)(1)(i) reads that a State will annually provide CMS with the projected number of individuals to be enrolled in the benefit, and the actual number of unduplicated individuals enrolled in State plan HCBS in the previous year. If the State chooses to limit the number to be served at any point in time, as provided in § 441.577(a)(1)(ii), the State will annually provide to CMS the maximum number enrolled at one time.

The burden associated with this requirement is the time and effort put forth by the State to annually project the number of individuals who will enroll in State plan HCBS. We estimate it will take one State 2 hours to meet this requirement. The total annual burden of these requirements would vary according to the number of States offering the State plan HCBS benefit. The maximum total annual burden is 112 hours (56 States × 2 hours = 112 hours).

Section 441.577(a)(1)(ii)(B) reads that if a State elects to maintain a waiting list for State plan HCBS, the State establishes and adheres to policies and procedures for formation and maintenance of a waiting list that complies with all applicable Federal and State requirements.

While this burden associated with this requirement is subject to the PRA, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities.

Section 441.577(a)(2)(ii) reads that the State plan amendment to provide State plan HCBS must contain a description of the reimbursement methodology for each covered service.

The burden associated with this requirement is the time and effort put forth by the State to describe the reimbursement methodology for each State plan HCBS. We estimate that it will take one State an average of 2 hours to determine the reimbursement methodology for one covered HCBS. This would be a one-time burden. The total annual burden for this requirement would vary according to the number of services that the State chooses to include in the State plan HCBS benefit.

Section 441.577(a)(2)(iii) reads that the State plan amendment to provide State plan HCBS must contain a description of the State Medicaid agency line of authority for operating the State plan HCBS benefit, including distribution of functions to other entities.

The burden associated with this requirement is the time and effort put forth by the State to describe the State Medicaid agency line of authority. We estimate it will take one State 2 hours to meet this requirement. Since we have estimated that 3 States will annually request State plan HCBS, the total annual burden associated with this requirement is estimated to be 6 hours. This would be a one-time burden.

Section 441.577(b)(1) requires States to maintain a quality improvement strategy that includes methods for ongoing measurement of program performance and mechanisms of intervention to assure quality of care, proportionate to the scope of services in the State plan HCBS benefit, the needs-based criteria, and the number of individuals to be served.

The burden associated with this requirement is the time and effort put forth by the State to prepare and maintain a quality improvement strategy. We estimate it will take one State 45 hours for the preparation and maintenance of the strategy. The total annual burden of these requirements would vary according to the number of States offering the State plan HCBS benefit. The maximum total annual burden is estimated to be 2,520 hours (56 States × 45 hours = 2,520 hours).

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Mail copies to the address specified in the **ADDRESSES** section of this proposed rule and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, CMS–2249–P, *carolyn_lovett@omb.eop.gov*. Fax (202) 395–6974.

V. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please indicate the caption ''Regulatory Impact'' at the beginning of your comments.]

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866, as amended, directs agencies to identify the specific market failure or other problem that warrants agency action, assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that, adjusted for a phase-in period during which States gradually elect to offer the State plan HCBS benefit, in fiscal year 2009 the estimated cost would be $114 million. The estimated 5-year (FY 2007 through FY 2011) cost of this proposed rule would be $563 million. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million standard, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule would have a

significant impact on a substantial number of small businesses or small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. This rule imposes no requirements or costs on providers or suppliers for their existing activities. The rule implements a new optional State plan benefit established in section 1915(i) of the Act. Small entities that meet provider qualifications and choose to provide HCBS under the State plan would have a business opportunity under this proposed rule. The Secretary certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 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 Core-Based Statistical Area and has fewer than 100 beds. We have determined that this proposed rule would not have a significant effect on the operations of a substantial number of small rural hospitals because there would be no change in the administration of the provisions related to small rural hospitals. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $127 million. This proposed rule does not mandate any spending by State, local, or tribal governments or the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

B. Anticipated Effects

1. Effects on Medicaid Beneficiaries

The Medicaid beneficiaries who receive the State plan HCBS benefit will be substantial and beneficial. The State plan HCBS benefit will afford business opportunity for providers of the HCBS.

2. Effects on Other Providers

We do not anticipate any effects on other providers. Section 1915(i) of the Act delinks the HCBS from institutional level of care, and requires that eligibility criteria for the benefit include a threshold of need less than that for institutional level of care, so that it is unlikely that large numbers of participants in the State plan HCBS benefit will be discharged from the facilities of Medicaid institutional providers. There may be some redistribution of services among providers of existing non-institutional Medicaid services into State plan HCBS, but providers who meet qualifications for the State plan HCBS benefit have the option to enroll as providers of HCBS.

3. Effects on the Medicare and Medicaid Programs

This rule has no effect on the Medicare program. State Medicaid programs will make use of the optional flexibility afforded by the State plan HCBS benefit to provide needed long-term care home and community based services to eligible elderly or disabled individuals the State has not had means to serve previously, or to provide services to these individuals more efficiently and effectively. The State plan HCBS benefit will afford States a new means to comply with requirements of the Olmstead decision, to serve individuals in the least restrictive setting.

The cost of these services will be dependent upon the number of States electing to offer the benefit, the scope of the benefits States design, and the degree to which the benefits replace existing Medicaid services. States have more control over expenditures for this benefit than over other State plan services. For States that choose to offer these services, States may specify limits to the scope of HCBS, cap the number of recipients, and have the option to tighten eligibility requirements if costs escalate too rapidly.

Use of the State plan HCBS benefit is unlikely to result in increased access to other Medicaid services, because eligibility for the benefit is limited to individuals who are already eligible for Medicaid, and whose income is less than 150 percent of the FPL. Moreover, costs of the State plan HCBS benefit may be offset by lowered potential Federal and State costs of more expensive institutional care. Additionally, the requirement for a written individualized plan of care may discourage inappropriate utilization of costly services such as emergency room care for routine procedures.

After taking the above factors into account, the Federal and State cost estimates are shown in the table below.

MEDICAID COST ESTIMATE

[In millions]

	FY08	FY09	FY10	FY11	FY12	5-year total
Federal Cost	$68	$114	$169	$189	$210	$750
State Cost	51	86	127	142	159	565

C. Alternatives Considered

This proposed rule incorporates provisions of new section 1915(i) of the Act into Federal regulations, providing for Medicaid coverage of a new optional State plan benefit to furnish home and community-based State plan services. The statute provides States with an option under which to draw Federal matching funds; it does not impose any requirements or costs on existing State programs, on providers, or upon beneficiaries. States retain their existing authority to offer HCBS through the existing authority granted under section 1915(c) waivers and under section 1115 waivers. States can also continue to

offer, and individuals can choose to receive, some but not all components of HCBS allowable under section 1915(i) through existing State plan services such as personal care or targeted case management services. Therefore, this rule is entirely optional for States.

Alternatives to this rule as proposed include:

1. Not Publishing a Rule

Section 1915(i) of the Act is effective January 1, 2007. States may propose State plan amendments to establish the State plan HCBS benefit with or without this proposed rule. We considered whether this statute could be self-implementing and require no regulation. Section 1915(i) of the Act is complex; many States have contacted us for technical assistance in the absence of published guidance, and some have indicated they are waiting to submit an amendment until there is a rule. We further considered whether a State Medicaid Director letter would provide sufficient guidance regarding CMS review criteria for approval of a State plan amendment. We conclude that section 1915(i) of the Act establishes significant new features in the Medicaid program, and that States and the public should be afforded the published invitation for comment provided by this proposed rule. Finally, State legislation and judicial decisions are not alternatives to a Federal rule in this case since section 1915(i) of the Act provides Federal benefits.

2. Modification of Existing Rules

We considered modifying existing regulations at 42 CFR 440.180, part 441 subpart G, Home And Community-Based Services: Waiver Requirements, which implement the section 1915(c) HCBS waivers, to include the authority to offer the State plan HCBS benefit. This would have the advantage of not duplicating definitions of HCBS and certain requirements common to both types of HCBS. However, we believe that any such efficiency would be outweighed by the substantial discussion that would be required of the differences between the Secretary's discretion to approve waivers under section 1915(c) of the Act, and authority to offer HCBS under the State plan at section 1915(i) of the Act. While Congress clearly considered the experience to date with HCBS under waivers when constructing section 1915(i) of the Act, it did not choose to modify section 1915(c) of the Act, but chose instead to create a new authority at section 1915(i) of the Act. We, therefore, chose to propose a separate rule.

3. Alternative Methods for Delivering HCBS

CMS considered using existing operational methods for delivering State plan HCBS, but the unique and specific requirements in section 1915(i) of the Act are substantially different from currently-existing authorities, and ultimately required stand-alone implementation tailored to the particular characteristics of the State plan HCBS option as described in statute. CMS considered whether section 1915(i) of the Act permits States to: (1) Disregard comparability, (2) define HCBS other than the services specifically listed in statute, as allowable under section 1915(c), (3) offer HCBS to Medicaid beneficiaries without a 150 percent of FPL income test unique to this benefit, or (4) provide State plan HCBS in place of mandatory institutional benefits for some individuals. However, CMS determined that none of these options is allowable under section 1915(i) of the Act.

D. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. This table provides our best estimate of the proposed increase in Federal Medicaid outlays resulting from offering States the option to provide the State plan HCBS benefit established in section 1915(i) of the Act and implemented by CMS–2249–P (Medicaid program; Home and Community-Based State Plan Services).

TABLE: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2008 TO FY 2012

[In millions]

Category	Transfers	
Annualized Monetized Transfers	3% Units Discount Rate $147.9	7% Units Discount Rate $145.1
From Whom To Whom?	Federal Government to Providers	
Other Annualized Monetized Transfers	3% Units Discount Rate $111.4	7% Units Discount Rate $109.3
From Whom To Whom?	State Governments to Providers	

E. Conclusion

We anticipate that States will make widely varying use of the section 1915(i) State plan HCBS benefit to provide needed long-term care services for Medicaid beneficiaries. These services will be provided in the home or alternative living arrangements in the community, which is of benefit to the beneficiary and is less costly than institutional care. Requirements for independent evaluation and assessment, individualized care planning, and requirements for a quality improvement program will assure efficient and effective use of Medicaid expenditures for these services.

For the reasons stated above, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule will not have a significant

economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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

List of Subjects

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 441

Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Prescription drugs, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

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

Subpart B—General Administrative Requirements

2. Section 431.40 is amended by revising paragraph (a)(7) to read as follows:

§ 431.40 Basis and scope.

(a) * * *

(7) Exceptions to, and waiver of, State plan requirements—sections 1915(a) through (e), and (i) of the Act, and section 1916(a)(3) and (b)(3) of the Act.

* * * * *

3. Section 431.50 is amended by—

A. Redesignating paragraph (c)(2) as paragraph (c)(3).

B. Adding a new paragraph (c)(2).

The revisions read as follows:

§ 431.50 Statewide operation.

* * * * *

(c) * * *

(2) Home and community-based services for the elderly and disabled under sections 1915(c), (d), and (i) of the Act; and

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

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

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

5. Amend § 440.1 by adding the new statutory basis in numerical order.

The addition reads as follows:

§ 440.1 Basis and purpose.

* * * * *

1915(i) Home and community-based services furnished under a State plan to elderly and disabled individuals under the provisions of part 441, subpart K.

6. Section 440.180 is amended by revising the heading to read as follows:

§ 440.180 Home and community-based waiver services.

* * * * *

7. A new § 440.182 is added to read as follows:

§ 440.182 State plan home and community-based services.

(a) *Definition. State plan home and community-based services benefit* means the services listed in paragraph (b) of this section when provided under an amendment to the State's Medicaid plan under the provisions of part 441, subpart K of this chapter.

(b) *Services.* The State plan home and community-based services (HCBS) benefit provided by the State may consist of any or all of the following services as they are described by the State and included in the State's plan for medical assistance approved by the Secretary:

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Habilitation services, which include expanded habilitation services as specified in § 440.180(c).

(7) Respite care services.

(8) Subject to the conditions in § 440.180, for individuals with chronic mental illness:

(i) Day treatment or other partial hospitalization services;

(ii) Psychosocial rehabilitation services;

(iii) Clinic services (whether or not furnished in a facility.

(c) *Exclusions.* State plan HCBS do not include either of the following:

(1) Other services. The other services that the Secretary has the authority to approve under § 440.180 for a home and community-based services (HCBS) waiver;

(2) *Room and board.* For purposes of this provision, ''board'' means 3 meals a day or any other full nutritional regimen. ''Room'' means expenses for shelter, including all property-related costs, furnishings, maintenance, utilities, and related administrative services. FFP is not available for the cost of room and board in State plan HCBS. The following service costs are not considered room or board:

(i) The cost of food and housing in respite care services provided in a facility approved by the State that is not a private residence.

(ii) Meals provided as part of a program of adult day health services as long as the meals provided do not constitute a ''full'' nutritional regimen.

(iii) A portion of the housing expense and food that may be reasonably attributed to an unrelated caregiver providing State plan HCBS who is residing in the same household with the recipient, but not if the recipient is living in the home of the caregiver or in a residence that is owned or leased by the caregiver.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

8. The authority citation for part 441 continues to read as follows:

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

9. A new subpart K, consisting of § 441.550 through § 441.577, is added to part 441 to read as follows:

Subpart—K State Plan Home and Community-Based Services for Elderly and Disabled Individuals

Sec.

Subpart K—State Plan Home and Community-Based Services for Elderly and Disabled Individuals

§ 441.550 Basis and purpose.

Section 1915(i) of the Act permits States to offer one or more home and community-based services (HCBS) to qualified elderly and disabled individuals under their State Medicaid plans. Those services are listed in § 440.182 of this chapter, and are described by the State, including any limitations of the services. This optional benefit is known as the State plan HCBS

benefit. This subpart describes what a State Medicaid plan must provide, and defines State responsibilities.

§ 441.553 State plan requirements.

A State plan that includes home and community-based services for elderly and disabled individuals must meet the requirements of this subpart.

§ 441.556 Eligibility for home and community-based services under section 1915(i)(1) of the Act.

(a) *Eligibility.* To be eligible for State plan HCBS under section 1915(i) of the Act, an individual must meet the following requirements:

(1) Be eligible for Medicaid under an eligibility group covered under the State's Medicaid plan.

(2) Have income that does not exceed 150 percent of the Federal Poverty Level (FPL). In determining whether the 150 percent of FPL requirement is met, the rules for determining income eligibility for the individual's eligibility group under the State's Medicaid plan, including any more liberal income disregards used by the State for that group under section 1902(r)(2) of the Act, apply.

(3) Reside in the home or community, not in an institution, in accordance with the following:

(i) According to standards for community living facilities, as prescribed by the Secretary.

(ii) If the individual living in a residence with four or more persons unrelated to the proprietor, which furnishes one or more treatments or services, the independent assessment must include documentation that the individual is living in a community setting, and not in an institution.

(4) Meet needs-based criteria for eligibility for the State plan HCBS benefit, as required in § 441.554(d).

(5) Be assessed to require at least one home and community-based service, as required in § 441.562(a)(vi).

(b) *State options.* The State may elect in the State plan amendment approved under this subpart not to apply the following requirements:

(i) Section 1902(a)(10)(C)(i)(III) of the Act, pertaining to income and resource eligibility rules for the medically needy living in the community, but only for the purposes of providing State plan HCBS.

(ii) Section 1902(a)(1) of the Act, pertaining to statewide application of Medicaid, but only for the purposes of providing State plan HCBS.

§ 441.559 Needs-based criteria and evaluation.

(a) *Needs-based criteria.* The State must establish needs-based criteria for determining an individual's eligibility under the State plan for the HCBS benefit, and may establish needs-based criteria for each specific service.

(1) Needs-based criteria are factors used to determine an individual's requirements for support. The criteria are not characteristics that describe the individual or the individual's condition. A diagnosis is not a sufficient factor on which to base a determination of need. A criterion can be considered needs-based if it is a factor that can only be ascertained for a given person through an individualized evaluation of need.

(2) Needs-based criteria defined by the State may include:

(i) Need for total support to perform two or more activities of daily living (ADLs) (as defined in section 7702B(c)(2)(B) of the Internal Revenue Code of 1986).

(ii) Need for significant assistance to perform ADLs.

(iii) Other risk factors as the State determines to be appropriate and describes in the State Medicaid plan.

(b) *More stringent institutional and waiver needs-based criteria.* The State plan HCBS benefit is available only if the State has in effect needs-based criteria (as defined in paragraph (a)(1) of this section), for receipt of services in nursing facilities as defined in section 1919(a) of the Act, intermediate care facilities for the mentally retarded as defined in § 440.150 of this chapter, and hospitals as defined in § 440.10 of this chapter under the State plan and for which the State has established long-term level of care criteria, or waivers offering HCBS, and these needs-based criteria are more stringent than the needs-based criteria for the State plan HCBS benefit. If the State defines needs-based criteria for individual State plan home and community-based services, the needs-based institutional eligibility criteria must be more stringent than the combined effect of needs-based State plan HCBS benefit eligibility criteria and individual service criteria.

(1) These more stringent criteria must meet the following requirements:

(i) Be included in the level of care determination process for each institutional service and waiver.

(ii) Be submitted for inspection by CMS with the State plan amendment that establishes the State Plan HCBS benefit.

(iii) Be in effect on or before the effective date of the State plan HCBS benefit.

(2) In the event that the State modifies institutional level of care criteria to meet the requirements under paragraph (b) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, individuals receiving Medicaid in an institution or waiver HCBS, as of the effective date of the State plan amendment, will continue to be eligible for the institutional services or waiver HCBS under the level of care criteria previously in effect. Such individuals will not be subject to the more stringent modified institutional criteria, until such time as the individual is discharged from the institution or waiver, or no longer requires that level of care.

(c) *Adjustment authority.* The State may modify the needs-based criteria established under paragraph (a) of this section, without prior approval from the Secretary, if the number of individuals enrolled in the State plan HCBS benefit exceeds the projected number submitted annually to CMS. The Secretary will approve a retroactive effective date for the State plan amendment modifying the criteria, as early as the day following the notification period required under paragraph (c)(1) of this section, if all of the following conditions are met:

(1) The State provides at least 60 days notice of the proposed modification to the Secretary, the public, and each individual enrolled in the State plan HCBS benefit.

(2) The State notice to the Secretary is submitted as an amendment to the State plan.

(3) The adjusted needs-based eligibility criteria (in combination with service-specific needs-based criteria, if any) for the State plan HCBS benefit are less stringent than all needs-based institutional and waiver level of care criteria in effect after the adjustment.

(4) Individuals who were found eligible for the State plan HCBS benefit before modification of the needs-based criteria under this adjustment authority must remain eligible for the HCBS benefit and specific services on the basis of the unmodified criteria, for at least 12 months, beginning on the date the individual first received medical assistance for such services.

(5) Individuals continue to receive HCBS under the unmodified criteria during the not less than 60-day notification period, irrespective of the date the individual first received medical assistance for such services.

(6) Any changes in service due to the modification of needs-based criteria under this adjustment authority are treated as actions as defined in § 431.201 and are subject to the requirements of part 431 subpart E of this chapter.

(7) In the event that the State modifies institutional level of care criteria to meet the requirements under paragraph

(b) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, the State may adjust the modified institutional level of care criteria under this adjustment authority. The adjusted institutional level of care criteria must be at least as stringent as those in effect before they were modified to meet the requirements in paragraph (b) of this section.

(d) *Independent evaluation and determination of eligibility.* Eligibility for the State plan HCBS benefit must be determined through an independent evaluation of each individual according to the requirements of § 441.556(a)(1) through (4). The independent evaluation complies with the following requirements:

(1) Is performed by an agent that is independent and qualified as defined in § 441.568 of this section.

(2) Applies the needs-based eligibility criteria that the State has established under paragraph (a) of this section, and the general eligibility requirements under § 441.556(a)(1) through (3).

(3) If applicable, includes the individual's authorized representative.

(4) Assesses the individual's strengths as well as support needs.

(5) Uses only current and accurate information from existing records, and obtains any additional information necessary to draw valid conclusions about the individual's support needs.

(6) Evaluations finding that an individual is not eligible for the State plan HCBS benefit are treated as actions defined in § 431.201 and are subject to the requirements of part 431 subpart E of this chapter.

(e) *Periodic redetermination.* Independent reevaluations of each individual receiving the State plan HCBS benefit must be performed at least every 12 months, to determine whether the individual continues to meet eligibility requirements. Redeterminations must meet the requirements of paragraph (d) of this section.

§ 441.562 Independent assessment.

(a) For each individual determined to be eligible for the State plan HCBS benefit, the State must provide for an independent assessment of need in order to establish a plan of care. The independent assessment must include the following:

(1) An objective evaluation of the individual's inability to perform two or more activities of daily living (ADLs) (as defined in section 7702(c)(2)(B) of the Internal Revenue Code of 1986) or need for significant assistance to perform ADLs.

(2) A face-to-face assessment of the individual. The face-to-face assessment must meet the following requirements:

(i) The assessment must be performed by an agent that is independent and qualified as defined in § 441.568 of this section.

(ii) If applicable, the assessment must include the individual's authorized representative.

(iii) The assessment must be conducted in consultation with the individual, the individual's spouse, family, guardian, appropriate treating and consulting health and support professionals caring for the individual, support staff, and other responsible parties.

(iv) The assessment must include an examination of the individual's relevant history, medical records (including the independent evaluation of eligibility), physical and mental health care and support needs and all information needed to develop the plan of care as required in § 441.565.

(v) The assessment must be guided by best practice and research on effective strategies that result in improved health and quality of life outcomes.

(vi) The assessment must apply the State's needs-based criteria for each service (if any) that the individual may require. Individuals are considered enrolled in the State plan HCBS benefit only if they meet the eligibility and needs-based criteria for the benefit, and are also assessed to require at least one home and community-based service offered under the State plan for medical assistance.

(vii) If the State offers individuals (including, if applicable, the individual's authorized representative) the option to self-direct the purchase of, or control the receipt of, a home and community-based State plan service or services, the assessment must include an evaluation of the support needs of the individual and the ability of the individual (with and without supports) to self-direct the purchase of, or control the receipt of, these services if the individual so elects.

(viii) For individuals living in a residence with four or more persons unrelated to the proprietor, that furnishes one or more treatments or services, the assessment must include documentation of whether the individual resides in the community, according to § 441.556(a)(3).

(ix) For individuals receiving habilitation services, documentation that no Medicaid services are provided which would otherwise be available to the individual, specifically including but not limited to services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973, or the Individuals with Disabilities Improvement Act of 2004.

(b) The independent assessment of need must be conducted at least every 12 months and as needed when the individual's support needs or circumstances change significantly, in order to revise the plan of care.

§ 1.565 Plan of care.

(a) *Plan of care.* Based on the independent assessment required in § 441.562, the State must develop (or approve, if the plan is developed by others) a written plan of care jointly with the individual (including, for purposes of this paragraph, the individual and the individual's authorized representative if applicable). The person-centered planning process must identify the individual's physical and mental health support needs, strengths and preferences, and desired outcomes. The plan must be developed in consultation with the individual's health care or support professionals, or other appropriate persons, as determined by the State, and where appropriate, with the individual's family, spouse, caregiver, guardian, or representative. When the plan of care is finalized between the parties, a written copy is provided to the individual. At a minimum, the plan must determine HCBS to be provided that meet the following requirements:

(1) Take into account the extent of, and need for, any family or other supports for the individual.

(2) Be consistent with the individual's strengths and support needs arising from the individual's physical, sensory, or intellectual disability.

(3) Prevent the provision of unnecessary or inappropriate care, and provide the HCBS that the individual is assessed to require.

(4) Include those services, the purchase or control of which the individual elects to self-direct, meeting the requirements of § 441.574(b) through (d).

(b) *Reassessment.* The plan of care must be reviewed and revised upon independent reassessment, as required in § 441.562, at least every 12 months and when the individual's circumstances or needs change significantly.

(c) *Shared authority.* The plan of care must afford the individual the opportunity, with information and supports, for active participation and shared authority in developing the plan of care.

§ 441.568 Provider qualifications.

(a) The State must provide assurances that necessary safeguards have been taken to protect the health and welfare of enrollees in State plan HCBS, and must define in writing adequate standards for providers (both agencies and individuals) of HCBS services and for agents conducting independent evaluation, independent assessment, and plan of care development.

(b) The State must define conflict of interest standards that ensure the independence of individual and agency agents who conduct (whether as a service or an administrative activity) independent evaluation of eligibility for State plan HCBS, independent assessment of need, or are involved in developing the plan of care. The conflict of interest standards apply to all individuals and entities, public or private. At a minimum, these agents must not be any of the following:

(1) Related by blood or marriage to the individual, or to any paid caregiver of the individual.

(2) Financially responsible for the individual.

(3) Empowered to make financial or health-related decisions on behalf of the individual.

(4) Providers of State plan HCBS for the individual, or those who have an interest in or are employed by a provider of State plan HCBS for the individual, except when the only willing and qualified agent to perform independent assessments and develop plans of care in a geographic area also provides HCBS, and the State devises conflict of interest protections including separation of agent and provider functions within provider entities, which are described in the State plan for medical assistance and approved by the Secretary.

(c) Qualifications for agents performing independent assessments and plans of care must include training in assessment of individuals whose physical or mental conditions trigger a potential need for home and community-based services and supports, and current knowledge of best practices to improve health and quality of life outcomes.

§ 441.571 Definition of individual's representative.

In this subpart, the term *individual's representative* means, with respect to an individual being evaluated for, assessed regarding, or receiving State plan HCBS, the following:

(a) The individual's legal guardian or other person who is authorized under State law to represent the individual for the purpose of making decisions related to the person's care or well-being.

(b) Any other person who is authorized by policy of the State Medicaid Agency to represent the individual including but not limited to a parent, a family member, or an advocate for the individual. When the State authorizes representatives pursuant to this paragraph, the State must have policies describing the process for appointment; the extent of decision-making authorized; and safeguards to ensure that the representative functions in the best interests of the participant.

§ 441.574 Self-directed services.

(a) *State option.* The State may choose to offer an election for self-directing HCBS. The term ''self-directed'' means, with respect to State plan HCBS listed in § 440.182 of this chapter, services that are planned and purchased under the direction and control of the individual, including the amount, duration, scope, provider, and location of the HCBS. For purposes of this paragraph, *individual* means the individual and, if applicable, the individual's representative as defined in § 441.571.

(b) *Plan of care requirement.* Based on the independent assessment required in § 441.562, the State develops (or approves, if the plan is developed by others) a plan of care jointly with the individual as required in § 441.565. If the individual chooses to direct some or all HCBS, the plan of care must meet the following requirements:

(1) Be developed through a person-centered process that is directed by the individual, builds upon the individual's ability (with and without support) to engage in activities that promote community life, respects individual preferences, choices, strengths, and involves families, friends, and professionals as desired or required by the individual.

(2) Specify the State plan HCBS that the individual will be responsible for directing.

(3) Identify the methods by which the individual will plan, direct or control services, including whether the individual will exercise authority over the employment of service providers or authority over expenditures from the individualized budget.

(4) Specify the role of family members and others whose participation is sought by the individual with respect to the State plan HCBS.

(5) Include appropriate risk management techniques, including contingency plans, that recognize the roles and sharing of responsibilities in obtaining services in a self-directed manner and assure the appropriateness of this plan based upon the resources and support needs of the individual.

(6) Describe the process for facilitating transition from self-direction and any circumstances under which transition out of self-direction is involuntary.

(c) *Employer authority.* If the plan of care includes authority to select, manage, or dismiss providers of the State plan HCBS, the plan must meet the following requirements:

(1) Specify the authority to be assumed by the individual, any limits to the authority, and specify parties responsible for functions outside the authority to be assumed.

(2) Specify the financial management supports, as required in paragraph (e) of this section, to be provided.

(d) *Budget authority.* If the plan of care includes an individualized budget (which identifies the dollar value of the services and supports under the control and direction of the individual), the plan must meet the following requirements:

(1) Describe the method for calculating the dollar values in the budget, based on reliable costs and service utilization.

(2) Define a process for making adjustments in dollar values to reflect changes in an individual's assessment and plan of care.

(3) Provide a procedure to evaluate expenditures under the budget.

(4) Specify the financial management supports, as required in paragraph (e) of this section, to be provided.

(5) Not result in payment for medical assistance to the individual.

(e) *Functions in support of self-direction.* When the State elects to offer self-directed State plan HCBS, it must also offer the following supports to individuals receiving the services and their representatives:

(1) Information and assistance consistent with sound principles and practice of self-direction.

(2) Financial management supports to meet the following requirements:

(i) Manage Federal, State, and local employment tax, labor, worker's compensation, insurance, and other requirements that apply when the individual functions as the employer of service providers.

(ii) Function as employer of record when the individual elects to exercise supervisory responsibility without employment responsibility.

(iii) Make financial transactions on behalf of the individual when the individual has personal budget authority.

(iv) Maintain separate accounts for each individual's budget and provide

periodic reports of expenditures against budget in a manner understandable to the individual.

§ 441.577 State plan HCBS administration: State responsibilities and quality improvement.

(a) *State plan HCBS administration*—(1) *State responsibilities.* The State must carry out the following responsibilities in administration of its State plan HCBS:

(i) *Number served.* The State will annually provide CMS with the projected number of individuals to be enrolled in the benefit and the actual number of unduplicated individuals enrolled in State plan HCBS in the previous year. If the State chooses to limit the number to be served at any point in time, as provided in § 441.577(a)(1)(ii), the State will annually provide to CMS the maximum number enrolled at one time.

(ii) *Optional limit to number served.* If the State chooses to set a limit for the maximum number of individuals to be enrolled in the State plan HCBS benefit (either annually or at any point in time), the following conditions must be met:

(A) The maximum number of individuals to be enrolled in the benefit is established and adjusted by a State plan amendment.

(B) If the State elects to maintain a waiting list for State plan HCBS, the State establishes and adheres to policies and procedures for formation and maintenance of a waiting list that complies with all applicable Federal and State requirements. Waiting list criteria and a formally established schedule and procedure for reevaluation and revision must be made public.

(iii) *Access to services.* The State must grant access to all State plan HCBS assessed to be needed, to individuals who have been determined to be eligible for the State plan HCBS benefit. The State may not limit access to one or more State plan HCBS according to type of disability or other characteristic, or limit the number of persons served by particular services. The State must not restrict the number of State plan HCBS that enrolled individuals may receive, or the scope and frequency of the HCBS (up to the approved service limitations, if any,) for reasons other than medical necessity as determined by the plan of care according to § 441.565.

(2) *Administration*—(i) *Option for presumptive payment.* (A) The State may provide for a period of presumptive payment, not to exceed 60 days, for Medicaid eligible individuals the State has reason to believe may be eligible for the State plan HCBS benefit. FFP is available as administration of the approved State plan for evaluation of eligibility for the State plan HCBS benefit under § 441.559(d) and assessment of need for specific HCBS under § 441.562(a), prior to an individual's receipt of State plan HCBS services or determination of ineligibility for the benefit.

(B) If an individual the State has reason to believe may be eligible for the State plan HCBS benefit is evaluated and assessed under the presumptive payment option and found not to be eligible for the benefit, FFP as administration of the approved State plan will be available for the evaluation and assessment. The individual so determined will not be considered to have enrolled in the State plan HCBS benefit for purposes of determining the annual number of participants in the benefit.

(ii) *Reimbursement methodology.* The State plan amendment to provide State plan HCBS must contain a description of the reimbursement methodology for each covered service. To the extent that the reimbursement methodologies for any self-directed services differ from those descriptions, the method for setting reimbursement methodology for the self-directed services must also be described.

(iii) *Operation.* The State plan amendment to provide State plan HCBS must contain a description of the State Medicaid agency line of authority for operating the State plan HCBS benefit, including distribution of functions to other entities.

(b) *Quality improvement strategy: Program performance and quality of care*—(1) *Quality improvement strategy.* States will maintain an HCBS quality improvement strategy that includes methods for ongoing measurement of program performance, quality of care, and mechanisms for remediation and improvement proportionate to the scope of services in the State plan HCBS benefit and the number of individuals to be served.

(2) *Program performance measures.* The States' quality improvement strategy must be designed to measure and provide evidence of program performance. Program performance measures must be made available to CMS upon request and include indicators approved or prescribed by the Secretary.

(3) *Quality of care measures.* The State's quality improvement strategy must be designed to measure outcomes associated with the receipt of home and community-based services, particularly with respect to the health and welfare of the recipients of these services. Quality of care measures must be made available to CMS upon request and include indicators approved or prescribed by the Secretary.

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

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Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 20, 2007.

Michael O. Leavitt,

Secretary.

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