

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 431, 435, 436, 440, 441, and 447

[CMS-2249-P2]

RIN 0938-AO53

Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise Medicaid regulations to define and describe State plan home and community-based services (HCBS) under the Social Security Act (the Act) as added by the Deficit Reduction Act of 2005 and amended by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act¹). This proposed rule offers States new flexibility in providing necessary and appropriate services to elderly and disabled populations and reflects CMS' commitment to the general principles of the President's Executive Order released January 18, 2011, entitled "Improving Regulation and Regulatory Review." In particular, this rule does not require the eligibility link between HCBS and institutional care that exists under the Medicaid HCBS waiver program. This regulation would describe Medicaid coverage of the optional State plan benefit to furnish home and community-based services and receive Federal matching funds. As a result, States will be better able to design and tailor Medicaid services to accommodate individual needs. This may result in improved patient

¹Affordable Care Act: Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010, Pub.L. 111-152

outcomes and satisfaction, while enabling States to effectively manage their Medicaid resources.

This proposed rule would also amend Medicaid regulations consistent with the requirements of the Affordable Care Act, which amended the Act to provide authority for a 5-year duration for certain demonstration projects or waivers under the Act, at the discretion of the Secretary, when they involve individuals dually eligible for Medicaid and Medicare benefits.

In addition, this proposed rule would provide an additional limited exception to the general requirement that payment for services under a State plan must be made directly to the individual practitioner providing a service when the Medicaid program is the primary source of reimbursement for a class of individual practitioners. This exception would allow payments to be made to other parties to benefit the providers by ensuring health and welfare, and training. We are including the payment reassignment provisions in this HCBS proposed rule because State's Medicaid programs often operate as the primary or only payer for the class of practitioners that includes HCBS service providers.

Finally, this proposed rule would also amend Medicaid regulations to provide home and community-based setting requirements of the Affordable Care Act for the Community First Choice State plan option.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m., e.d.t., on [OFR--insert date 30 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-2249-P2. 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 "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2249-P2,
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 to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2249-P2,
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 before the close of the comment period to either of the following addresses:
 - a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey 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. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
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 will also 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.

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Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding terms in alphabetical order below.

ADA	Americans with Disabilities Act of 1990 (Pub. L. 110-325)
ADLs	Activities of daily living
AHRQ	Agency for Healthcare Research and Quality
ANPRM	Advance Notice of Proposed Rulemaking
CFC	Community First Choice (1915(k) State plan Option)
CHIPRA	Children's Health Insurance Program Reauthorization of 2009 (Pub. L. 111-3)

CMS	Centers for Medicare & Medicaid Services
DRA	Deficit Reduction Act of 2005 (Pub. L. 109-171)
EPSDT	Early and Periodic Screening, Diagnosis and Treatment
FBR	Federal benefit rate
FFP	Federal financial participation
FPL	Federal poverty line
FY	Federal fiscal year
HCBS	Home and Community-Based Services
HHS	Department of Health and Human Services
IADLs	Instrumental activities of daily living
ICF/MR	Intermediate care facility for the mentally retarded
LOC	Level of care
NF	Nursing facility
OBRA '81	Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35)
OT	Occupational therapy
PT	Physical therapy
RFA	Regulatory Flexibility Act
SPA	State Plan Amendments
SSI	Supplemental Security Income
SSI/FBR	Supplemental Security Income Federal Benefit Rate
UPL	Upper payment limit

I. Executive Summary

A. Purpose

This proposed rule would amend the Medicaid regulations to define and describe State plan home and community-based services (HCBS). This regulation outlines the optional State plan benefit to furnish home and community-based State plan services and draw Federal matching funds. As a result, States will be able to design and tailor Medicaid services to better accommodate individual needs. This may result in improved patient outcomes and satisfaction, while enabling States to effectively manage their Medicaid resources.

This proposed rule would also amend Medicaid regulations consistent with the requirements of section 2601 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), which added section 1915(h)(2) to the Act to provide authority for a 5-year duration for certain demonstration projects or waivers under sections 1115, 1915(b), (c), or (d) of the Act, at the discretion of the Secretary, when they involve individuals who are dually eligible for both Medicaid and Medicare benefits.

In addition, this proposed rule would provide an additional limited exception to the general requirement that payment for services under a State plan must be made directly to the individual practitioner providing a service when the Medicaid program is the primary source of reimbursement for a class of individual practitioners. This exception would allow payments to be made to other parties to benefit the providers by ensuring workforce stability, health and welfare, and trainings, and provide added flexibility to the State. We are including the payment reassignment provision in the HCBS proposed rule because States' Medicaid programs often operate as the primary or only payer for the class of practitioners that includes HCBS service providers.

This proposed rule would also amend Medicaid regulations to provide home and community-based setting requirements related to section 2401 of the Affordable Care Act for the section 1915(k) Community First Choice State plan option.

B. Summary of the Major Provisions

1. Section 1915(i) State Plan Home Community-Based Services

The Deficit Reduction Act (DRA) added a new provision to the Medicaid statute entitled "Expanded Access to Home and Community-Based Services for the Elderly and Disabled." This provision allows States to provide HCBS (as an optional program) under their State Medicaid plans. This option allows States to receive Federal financial participation for services that were previously eligible for Federal funds only under waiver or demonstration projects. This provision was further amended by the Affordable Care Act. The statute now provides additional options for States to design and implement HCBS under the Medicaid State Plan. In April 4, 2008, we published a proposed rule to amend Medicaid regulations to implement HCBS under the DRA. That proposed rule was not finalized, and with the passage of section 2402 of the Affordable Care Act, some previously proposed regulations would no longer be in compliance with the current law under section 1915(i) of the Act. In addition, several new provisions were added. Specifically, the Affordable Care Act amended the statute by adding a new optional categorical eligibility group for individuals to provide full Medicaid benefits to certain individuals who will be receiving HCBS. It also authorized States to elect not to comply with section 1902(a)(10)(B) of the Act pertaining to comparability of Medicaid services. After closely analyzing the Affordable Care Act provisions, we concluded that a new proposed rule was necessary. This proposed rule retains a large portion of the policies contained within the April 4, 2008 proposed rule, and updates some of our previous proposals to reflect comments

that we received on the April 4, 2008 proposed rule as well as the statutory changes that were made by the Affordable Care Act.

2. Section 2601 of the Affordable Care Act: 5-Year Period for Certain Demonstration Projects and Waivers

This proposed rule also provides for a 5-year approval or renewal period, subject to the discretion of the Secretary, for certain Medicaid waivers. Specifically, this time period would apply for demonstration and waiver programs through which a State serves individuals who are dually eligible for both Medicare and Medicaid benefits.

3. Provider Payment Reassignments

Section 1902(a)(32) of the Act provides that State plans can allow payments to be made only to certain individuals or entities. Specifically, payment may only be made to an individual practitioner who provided the service. The statute provides several specific exceptions to the general principle of direct payment to the individual practitioner.

Over the years, some States have requested that we consider adopting additional exceptions to the direct payment principle to permit withholding from the payment due to the individual practitioner for amounts paid by the State directly to third parties for health and welfare benefits, training costs and other benefits customary for employees. These amounts would not be retained by the State, but would be remitted to third parties on behalf of the practitioner for the stated purpose.

While the statute does not expressly provide for additional exceptions to the direct payment principle, we believe the circumstances at issue were not contemplated under the statute. Therefore, we are proposing that the direct payment principle should not apply because we think its application would contravene the fundamental purpose of this provision. The

apparent purpose of the direct payment principle was to prohibit factoring arrangements, and not to preclude a Medicaid program that is functioning as the practitioner's primary source of revenue from fulfilling the basic responsibilities that are associated with that role. Therefore, we are proposing an additional exception to describe payments that we do not see as within the intended scope of the statutory direct payment requirement, that would allow the State to claim as a provider payment amounts that are not directly paid to the provider, but are withheld and remitted to a third party on behalf of the provider for health and welfare benefit contributions, training costs, and other benefits customary for employees.

4. Section 2401 of the Affordable Care Act: Community First Choice State Plan Option: Home and Community-Based Setting Requirements

Section 1915(k)(1)(A)(ii) of the Act provides that home and community-based attendant services and supports must be provided in a home and community-based setting. The statute specifies that home and community-based settings do not include a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded². We propose to adopt this statutory language in our regulations. Additionally, to provide greater clarity, we are proposing language to establish that home and community-based settings must exhibit specific qualities to be eligible sites for delivery of home and community-based services.

After consideration of comments received in response to the Community First Choice (CFC) proposed rule published on February 25, 2011, we decided to revise the setting provision and publish our proposed definition as a new proposed rule to allow for additional public comment before finalizing. Since CFC and section 1915(i) both pertain to home and community-based services, we have aligned this CFC proposed language with the section

² Although we recognize that the language used here is outdated, and that "intellectual disability" is the appropriate way to discuss this type of disability, the Social Security Act still refers to these types of facilities in this manner.

1915(i) proposed home and community-based setting requirements also included in this rule.

We find the public comment process to be valuable in our attempt to develop the best policy on this issue for Medicaid beneficiaries. Therefore, we plan to fully consider all comments received, and align decision making and language pertaining to home and community-based setting requirements across CFC, section 1915(i) State plan HCBS, as well as section 1915(c) HCBS waivers.

C. Summary of Costs and Benefits

Provision Description	Total Costs	Total Benefits
1915(i) State Plan Home Community-Based Services	We estimate that, adjusted for a phase-in period during which States gradually elect to offer the State plan HCBS benefit, in fiscal year (FY) 2012 the estimated Federal cost would be \$80 million, and the estimated State cost would be \$60 million.	We anticipate that States will make varying use of the State plan HCBS benefit provisions 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.
Section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects (Waivers)	No impact on Federal or State Medicaid funding. This rule is voluntary on the part of States.	As this provision elongates the time period under which States may operate certain waiver programs without renewal, it will help States to minimize administrative and renewal requirements in order to better focus on program implementation and quality oversight.

Provision Description	Total Costs	Total Benefits
<p>Provider Payment Reassignments</p>	<p>We do not anticipate any impact on Federal Medicaid funding. This rule is voluntary on the part of States.</p>	<p>This rule proposes additional operational flexibilities for States to ensure a strong provider workforce. There is also no impact on individual practitioners, even though the proposed rule would allow States to deduct or withhold portions of such payments under the specific circumstances described in the proposed rule. State budgets will not likely be significantly affected because the operational flexibilities in the proposed rule would only facilitate the transfer of funds between participating entities, rather than the addition or subtraction of new funds.</p>
<p>Section 2401 of the Affordable Care Act: Community First Choice State Plan Option: Home and Community-Based Setting Requirements</p>	<p>We do not believe there is an impact on Federal or State Medicaid funding as the purpose of the rule is merely to define home and community-based settings in which CFC services may be provided.</p>	<p>This rule will provide States with necessary guidance to support compliance with the requirement that CFC services are provided in a home or community based-setting. This rule also provides beneficiary protections to support an individual’s choice to receive home and community-based services in a manner that allows for integration with the greater community.</p>

II. Background

A. Expanded Access to Home and Community-Based Services for the Elderly and Disabled

under Section 1915(i) of the Social Security Act: History of Section 1915(i) of the Act

Section 6086 of the Deficit Reduction Act of 2005 (Pub. L. 109-171, enacted February 8, 2006) (DRA) entitled "Expanded Access to Home and Community-Based Services for the Elderly and Disabled," added section 1915(i) to the Social Security Act (the Act) to allow States, at their option, to provide home and community-based services (HCBS) under their State Medicaid plans. This option allows States to receive Federal financial participation (FFP) for services that were previously only eligible for FFP under waivers or demonstration projects, such as those authorized under sections 1915(c) and 1115 of the Act. Section 1915(i) of the Act was

later amended by sections 2402(b) through (g) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148, enacted March 23, 2010) (Affordable Care Act) to provide additional options for States to design and implement HCBS under the Medicaid State Plan.

In the April 4, 2008 **Federal Register** (73 FR 18676), we published a proposed rule to amend Medicaid regulations to implement HCBS under section 1915(i) of the Act. This rule was never finalized, and with the passage of the Affordable Care Act some of the proposed regulations would no longer be in compliance with the statute, as several new provisions were added to the statute. Therefore, we concluded that a new proposed rule and a new period of public comment were necessary. This proposed rule retains a large portion of the policies contained within the April 4, 2008 proposed rule. However, we have updated some of our proposals to reflect the statutory changes that were made by the Affordable Care Act.

B. Overview of the State Plan Home and Community-Based Services (HCBS) Benefit to Provide HCBS for the Elderly and Individuals with Disabilities

The following overview describes the provisions of section 1915(i) of the Act as established by the DRA and amended by the Affordable Care Act.

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"³. We refer to the "State plan HCBS 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 section 1915(c) HCBS waiver programs. The State plan HCBS benefit shares many features with section 1915(c) waiver

³ 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).

programs, but it is a State plan benefit, although one with very unique features not common to traditional State plan services.

Under section 1915(i) of the Act, States can provide HCBS to individuals who require less than institutional level of care (LOC) and who would, therefore, not be eligible for HCBS under section 1915(c) waivers, in addition to serving individuals who have needs that would meet entry requirements for an institution. As it is a State plan benefit, section 1915(i) of the Act also does not require cost neutrality compared to institutional services. Section 1915(i) of the Act differs from section 1915(c) waivers in other ways. As with other State plan services, the benefits must be provided Statewide, and States must not limit the number of eligible people served.

1. Services

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. 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.
- Other services requested by the State as the Secretary may approve.

In addition, the following services may be provided for individuals with chronic mental illness:

- Day treatment
- Other partial hospitalization services.
- Psychosocial rehabilitation services.
- Clinic services (whether or not furnished in a facility).

The HCBS may not include payment for room and board (see additional discussion in section II.E.3. of this proposed rule).

Section 1915(c)(4)(B) of the Act also permits States to request, and the Secretary to approve, coverage of other services not specifically designated in the list of specific services in the subparagraph. This authority was not included under section 1915(i) when it was created in the DRA. However, section 2402(c) of the Affordable Care Act amended section 1915(i)(1) of the Act to permit States to request, and the Secretary to approve, coverage for such other services in a 1915(i) benefit.

We interpret the statute as authorizing States to cover in their 1915(i) benefit both the services specifically identified in section 1915(c)(4)(B) of the Act, and any other services States request to include and which the Secretary approves. Therefore, we would expect States to define State plan HCBS with sufficient specificity so that we can determine whether the nature and scope of the service clearly relates to those listed in section 1915(c)(4)(B) of the Act. These services are described in §440.180 of this proposed rule. However, we would not require the same standard for “other services” under section 1915(i) State plan HCBS that we would apply under section 1915(c) of the Act. Since section 1915(i) of the Act does not require an individual to meet the criteria for institutional LOC, there is no authority to apply the standard that the “other services” defined and provided through State plan HCBS be necessary to prevent institutionalization. We note that for all services, including those in the “other services”

category, States must include a specific and complete description of the scope of the service, and not include open-ended statements.

We propose to review and approve these “other services” not specifically listed in section 1915(c)(4)(A) of the Act based upon the applicability to and consistency with the support needs as indicated in the needs-based criteria that a State defines for the HCBS benefit, and with assurance that the service will not duplicate other services available to individuals through the State’s Medicaid State plan. Additionally, these services must be offered in a manner that would comply with section 1902(a)(23) of the Act regarding free choice of providers, and that permits individuals to receive services in the most integrated setting possible and consistent with the best interests of the beneficiaries and the requirements of the Americans with Disabilities Act (ADA). Section 1915(i) does not incorporate waiver authority or other exceptions from these legal requirements. Therefore, the services offered cannot have the impact of limiting the pool of qualified providers from which individuals would receive services, or have the impact of requiring/only allowing individuals to receive services from the same entity from which they purchase or who provide their housing. For example, we would not allow States to establish residential HCBS in provider-owned and/or operated settings only, when they do not have comparable HCBS available to individuals residing in their own homes.

2. Eligibility

Eligibility for this option is based upon several different factors that are either specified by the statute or that a State may define. These include financial eligibility, the establishment of needs-based criteria, and the State option to target the benefit and to offer benefits differing in type, amount, duration or scope to specific populations. Due to the complex interaction between

these provisions, the following section is divided into subsections that address eligibility for the benefits. These include:

- Eligibility Overview.
 - Income Eligibility.
 - Needs-Based Criteria Overview.
 - Option to Disregard Comparability.
 - Establishing Needs-Based Criteria.
- a. Section 1915(i) of the Act: Eligibility Overview

Section 1915(i) of the Act explicitly provides that State plan HCBS may be provided without determining that, but for the provision of these services, individuals would require the LOC provided in a hospital, a nursing facility (NF), or an intermediate care facility for the mentally retarded⁴ (ICF/MR) as is required in section 1915(c) HCBS waivers. While HCBS services provided through section 1915(c) waivers must be "cost-neutral" as compared to institutional services, 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 for cost savings in NFs, ICFs/MR, or hospitals.

One particular result of this distinction is that, through the section 1915(i) benefit, States have the ability to provide a full array of HCBS to adults with mental health and substance use disorders. The benefit also creates an opportunity to provide HCBS to other individuals with

⁴ Although we recognize that the language used here is outdated, and that "intellectual disability" is the appropriate way to discuss this type of disability, the Social Security Act still refers to these types of facilities in this manner.

significant needs who do not qualify for an institutional LOC, such as some individuals with Autism Spectrum Disorder, diabetes, acquired immune deficiency syndrome, or Alzheimer's disease. In many cases, without the provision of HCBS, these conditions may deteriorate to the point where the individuals become eligible for more costly facility-based care.

State plan HCBS are intended 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 II.E.2. of this proposed rule regarding institutions not considered to be in the community, and in which State plan HCBS will not be available.)

b. Income Eligibility

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 under the State's Medicaid plan. In determining whether either of the relevant income requirements (discussed) is met, the regular rules for determining income eligibility for the individual's eligibility group apply, including any less restrictive income rules used by the State for that group under section 1902(r)(2) of the Act. Section 1915(i)(3) of the Act permits States to not apply the requirements of section 1902(a)(10)(C)(i)(III) of the Act relating to income and resource rules in the community for the medically needy. Under this authority States are permitted to use institutional eligibility rules in determining eligibility for the medically needy. The nonapplication requirements are described in section II.B.14 of the preamble. This eligibility criterion was not changed by the Affordable Care Act.

Section 2402(b) of the Affordable Care Act added a new option at section 1915(i)(6) of the Act, to allow States to provide section 1915(i) services to certain individuals who meet the

needs-based criteria, who would be eligible for HCBS under section 1915(c), (d) or (e) waivers or a section 1115 waiver approved for the State, and who have income up to 300 percent of the Supplemental Security Income Federal Benefit Rate (SSI/FBR).

Section 2402(d) of the Affordable Care Act also amended section 1902(a)(10)(A)(ii) of the Act by adding a new optional categorically needy eligibility group specified at section 1902(a)(10)(A)(ii)(XXII) of the Act to provide full Medicaid benefits to certain individuals who will be receiving section 1915(i) services. This eligibility group has two parts, and States can cover individuals under either or both parts of the group. Under this group, States can elect to cover individuals who are not otherwise eligible for Medicaid who meet the needs-based criteria of the section 1915(i) benefit, have income up to 150 percent of the Federal poverty line (FPL) with no resource test and who will receive section 1915(i) services, or individuals with income up to 300 percent of the SSI/FBR, who would be eligible under an existing section 1915(c), (d) or (e)⁵ waiver or section 1115 waiver approved for the State and who will receive section 1915(i) services. These individuals do not have to be receiving services under an existing section 1915(c), (d) or (e) waiver or section 1115 waiver; the individual just has to be determined eligible for the waiver.

c. Needs-Based Criteria Overview

In contrast to the institutional LOC 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. Institutional level of care criteria must be more stringent than the needs-based criteria for the State plan HCBS benefit. Additionally, the State may establish

⁵ 1915(d) and (e) waivers are State options to provide HCBS to the elderly and to individuals with disabilities, respectively. Currently, no State elects to provide services under either of these authorities.

needs-based criteria for each specific State plan home and community-based service that an individual would receive.

Thus, under section 1915(i) of the Act, States determine eligibility for State plan HCBS based on the following:

- Individuals eligible for medical assistance under the State plan whose income is below 150 percent of FPL, as determined by the State under the methodology applicable to the group, including any less restrictive income rules in place through section 1902(r)(2) of the Act.

- At the State option, individuals eligible under the new optional categorical needy group 1902(a)(10)(A)(ii)(XXII) of the Act. This includes:

- ++ Individuals with income below 300 percent of the SSI/FBR who are eligible for HCBS through a waiver approved for the State under sections 1115, 1915(c), 1915(d), or 1915(e) of the Act and will receive section 1915(i) services.

- ++ Individuals who are not otherwise eligible for medical assistance who have income below 150 percent and who will receive section 1915(i) services. There will be no resource test for this group.

- The individual resides in the home or community.
- The individual meets the needs-based criteria established by the State.
- The individual meets any targeting criteria in accordance with CMS requirements that the State elects to establish.

For more information about the optional eligibility category for individuals who receive services through the State plan HCBS benefit, please see section II.B.18. of this proposed rule.

The needs-based criteria for coverage of individual services provided within a State's section 1915(i) benefit are subject to the same requirements as the needs-based eligibility criteria

for the benefit, and may not limit or target any service based on age, nature or type of disability, disease, condition, or residential setting, but could include risk factors or take into account service history. However, section 1915(i)(7) of the Act provides States with the option to target eligibility for the benefit to specific populations.

d. Option to Disregard Comparability

Effective October 1, 2010, section 2402(f) of the Affordable Care Act, amended section 1915(i)(3) of the Act to permit States to elect not to comply with the requirement of section 1902(a)(10)(B) of the Act relating to comparability of services. A waiver of comparability is a key feature of section 1915(c) HCBS waivers, permitting a 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. With this change, States may exercise the authority to target the section 1915(i) benefit similarly, but are not required to do so. A State must establish needs-based criteria for eligibility for and receipt of State plan HCBS regardless of whether it elects the option to not comply with the comparability requirement. For additional information regarding the option for targeting in the benefit, please see the discussion at (section II.B.19 of the proposed rule).

e. Establishing Needs-Based Criteria

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 be likely to 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 permitted under the statute as a State option and are distinct from the needs-based criteria. We propose to provide States with the flexibility to define the specific needs-based criteria they will establish.

We believe that the statute distinguishes needs-based criteria from other possible descriptors of an individual's medical condition or 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. However, as discussed in section II.B.19. of this proposed rule, States may also disregard comparability requirements contained in section 1902(a)(10)(B) of the Act, and thus, target the section 1915(i) benefit (or multiple benefits) to individuals with specific diagnoses and conditions. We interpret the statute to mean that, when a State elects to disregard comparability in order to target the benefit to individuals with specific diagnoses, those individuals must meet both the targeting criteria, as well as the State's needs-based criteria.

Section 1915(i)(1)(B) of the Act additionally requires that the needs-based criteria for determining whether an individual requires the LOC 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. Institutional/waiver LOC criteria in some States do not include needs-based criteria. Since the two must be comparable, we interpret this to mean that States without a needs-based component to their institutional LOC evaluation must establish needs-

based criteria for those services, as well as for the State plan HCBS benefit. We also believe that States electing to implement a section 1915(i) benefit 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.

“Stringency” is not defined in the statute. The requirement is simply that there be a differential between the threshold of need for the State plan HCBS benefit as compared to the threshold of need for institutional services. The required difference in criteria will be relative, specific to each State’s unique institutional levels of care, and can be constructed in several ways. Because we have received many questions on the stringency requirements of the statute we will illustrate some of the possible options. We want to be clear, however, that the requirement of section 1915(i) of the Act is simply that the needs-based criteria for institutions and for the State plan HCBS benefit be set so that the latter are lower at the time the benefit is implemented. There is no requirement that institutional criteria be higher, lower, or unchanged from their level prior to implementing the State plan HCBS benefit. The only test is that the result of all the needs-based criteria must be that some individuals will be served under the State plan HCBS benefit who are not eligible to be served by Medicaid institutional services. If institutional LOC criteria are changed in implementing the benefit, States may provide protections for individuals who lose eligibility due to the application of those new criteria (see section II.B.16. of this proposed rule).

There are issues for States to consider other than section 1915(i) of the Act that will influence decisions on levels of care and needs-based criteria, that are far beyond the scope of this document, for example, statutory requirements for maintenance of effort (MOE) in effect at the time of this proposed rule, requirements of the Americans with Disabilities Act and the

Olmstead decision, and funding constraints⁶. In this proposed rule, we focus on the choices a State may make in setting up a State plan HCBS benefit in ways that are consistent with requirements of section 1915(i) of the Act. As an illustration, this proposed regulation would permit a State to define the needs-based criteria for a new HCBS benefit at a lower level than the State's existing institutional levels of care, and leave the institutional criteria unchanged (if they already include needs-based criteria). This would satisfy the requirement that the institutional criteria be more stringent than the State plan HCBS benefit, meet a goal to service individuals who have not previously had access to HCBS because they have not yet reached the level of need for admission to an institution, without making any change to existing services. This proposed regulation would also permit States to take other approaches. A State could raise one or more institutional levels of care, and provide HCBS under the State plan benefit for some or all of the individuals who would have not yet reached the level of need for admission to an institution. The State could choose (or not) to also include in the benefit individuals below the former institutional level of care. This scenario would also satisfy the stringency requirement, but would be more complex and would require analysis of some of the other relevant issues mentioned above.

We note that section 1915(i) of the Act does not modify the statutory coverage provisions governing 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

⁶ Under section 2001(b) of the Affordable Care Act, States are not permitted to establish eligibility standards, methodologies, or procedures that are more restrictive than those in place on the date of the Affordable Care Act's enactment (March 23, 2010). For adults, this requirement lasts until the Secretary determines that a health insurance exchange is fully operational in the State; for children under the age of 19, the requirement lasts until September 30, 2019.

Because the application of LOC requirements for institutions and HCBS waivers may have an impact on Medicaid eligibility for some individuals, we encourage States interested in using the State plan HCBS to contact CMS for technical assistance in meeting these statutory requirements.

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 an individual has a medical need for such health-related care and services which are only available in an institutional setting because that needed home or community-based health-related care and services are not available, 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 mean facilities certified by Medicaid as hospitals that are providing long-term care services. General acute care Medicaid hospital services are not subject to LOC 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), 1915(d) and 1915(e) waivers, as well as those section 1115 waivers that include HCBS, as specified in section 1915(i)(6)(a) of the Act. Sections 1915(c), (d) and (e)⁷ of the Act will have more stringent minimum criteria than the State plan HCBS benefit, as the waivers are required to use LOC assessments equivalent to one or more of the institutional levels of care. If a State has an approved section 1115 demonstration with multiple levels of care for institutional and/or HCBS, we interpret this requirement to apply to the least stringent institutional LOC criteria within that demonstration that would likely be the comparison for purposes of section 1915(i) of the Act.

⁷ Although the statute references waivers under Section 1915(d) and (e), no State currently operates a waiver under either authority. In the event that a State elects to include a (d) or (e) waiver, these requirements would apply.

In summary, the needs-based eligibility criteria for the State plan HCBS benefit must have the effect of allowing some individuals who do not meet the needs-based criteria for institutionalized care to access HCBS through the section 1915(i) benefit, but may also allow access to individuals who meet the institutional needs-based eligibility criteria. States may also enroll individuals in both a section 1915(i) benefit, and a section 1915(c) waiver, as discussed earlier in this rule.

3. Number Served

Section 1915(i)(1)(C) of the Act, as amended by section 2402(e) of the Affordable Care Act, does not permit States to limit the number of eligible individuals receiving services and to establish waiting lists. Instead, the benefit 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) of the Act permits the State to constrict its needs-based eligibility thresholds for State plan HCBS (see the discussion on Adjustment Authority in I.B.5. of this proposed rule).

Section 1915(i)(1)(C) of the Act requires that the State submit projections, in the form and manner, and upon the frequency as the Secretary specifies, of the number of individuals to be provided HCBS. We 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 further propose to specify that, during the application process, States would project the total number of individuals to be served by the benefit during the initial year. We further propose to specify that States with an approved State plan HCBS benefit 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.

4. Independent Evaluation

Section 1915(i)(1)(D) of the Act sets forth a requirement for an individual evaluation of need for each person seeking coverage of 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 is separate from, but related to, the independent assessment (as discussed below).

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.

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, difficulty with instrumental activities of daily living (IADLs) or the need for cueing in order to perform a task could be considered. A State could choose to use a person-centered functional assessment tool or strategy to fulfill this requirement.

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 within parameters as noted above. The purpose of an adjustment would be to revise the State's needs-based criteria to reduce the number of individuals who would be eligible for the HCBS benefit. To preserve the requirement of section 1915(i)(1)(B) of the Act 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 in the State plan institutional benefit, and thus, in any HCBS waivers that require participants to meet an institutional LOC. If the State chooses to

make this adjustment, it must provide at least 60 days written notice to the Secretary and to 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 (SPA) that fails to comply with the statute and regulations. This provision of the law must be interpreted in light of existing Medicaid requirements not waived by section 1915(i) of the Act. We have, therefore, incorporated within the proposed regulation those relevant requirements in addition to the statutory provisions within section 1915(i)(1)(D)(ii) of the Act. Section 441.559(c) provides the greatest degree of authority for adjustment possible within the constraints of other requirements. The Secretary will 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 requires that individuals served under the previous State plan HCBS needs-based criteria would continue to receive HCBS. As amended by section 2402(e) of the Affordable Care Act, 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 until the individual no longer meets the needs-based criteria, and targeting criteria if applicable, under which they were originally provided the benefit. Any changes to the institutional LOC criteria under this section are subject to the same requirements as described in 1915(i)(5) (see section II.B.16. of this proposed rule).

However, we would remind States of the maintenance of efforts requirements discussed in section II.B.2. of this proposed rule.

We note that the required processes for individual notification and appeals, contained within part 431, subpart E, remain in effect whenever a State modifies its needs-based criteria. Furthermore, section 1915(i)(5) of the Act provides protections for individuals who are receiving services in waivers or institutional settings prior to the modification of the LOC requirements, as discussed below.

It is important to note that the adjustment authority is a State option; there is nothing in the law that requires a State to constrict its needs-based criteria if enrollment exceeds projections.

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) of the Act, 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 any additional targeting criteria the State elects to require; 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 the State has adopted such criteria). Like the eligibility evaluation, the independent assessment is based on the individual's needs and strengths. The Act requires that both physical and mental needs and strengths are assessed. These requirements describe a person-centered assessment including behavioral health, which will take into account the individual's total support needs as well as the need for the HCBS to be offered. Section 1915(i)(1)(E)(ii) of the Act requires that States 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 service plan.

To achieve the three purposes of the assessment listed above, the assessor must be independent; that is, free from conflict of interest with regard to providers, to the individual and related parties, and to budgetary concerns. Therefore, we are proposing specific requirements for independence of the assessor in accordance 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 person-centered service plan, 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:

- A face-to-face evaluation of the individual by an assessor trained in the assessment and evaluation of persons whose physical or behavioral health conditions trigger a potential need for HCBS. To fulfill this statutory requirement, we would propose that the State must 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.

Additionally, we recognize that many States are developing infrastructure and policies to support the use of telemedicine and other ways to provide distance-care to individuals in order to increase access to services in rural areas or other locations with a shortage of providers. To support these activities, we propose that the “face-to-face” assessment can include any session(s) performed through telemedicine or other information technology medium if the following conditions apply:

- ++ The health care professional(s) performing the assessment meet the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology;

- ++ The individual receives appropriate support during the assessment, including the use of any necessary on-site support-staff; and

- ++ The individual is provided the opportunity to request an in-person assessment in lieu of one performed via telemedicine.

- An objective evaluation of the individual’s inability to perform two or more ADLs, or the need for significant assistance to perform the 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 in order to ensure that the assessments were applied uniformly across individuals in the section 1915(i) benefit. For example, an occupational therapy (OT) or physical therapy (PT) evaluation or a trauma screening 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 inability 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 in order to inform the development of the service plan required by section 1915(i)(1)(G) of the Act. Because States may define very diverse needs-based criteria and HCBS service definitions, we do not believe it is possible to be more specific in regulation about the criteria for assessment. However, we would note that a functional assessment tool could be used to measure objectively an individual's needs to establish eligibility as well as to develop an appropriate service plan.

We note that we are currently engaged in an initiative to develop universal core elements to be included in an assessment, through work being done under the Balancing Incentives Payment Program, created under section 10202 of the Affordable Care Act. For consistency

across Medicaid programs, we therefore, intend to move toward States including any finalized universal core elements developed from this work in carrying out independent assessments under 1915(i), as well as under 1915(k) Community First Choice, and in performing other HCBS assessments as determined by CMS.

- 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, the 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. For example, telephone communications with parties not available for an in-person meeting would be permitted.

- 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, and knowledge of the adult and child public service systems. At section 1915(i)(1)(F)(v) of the Act, 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 service plan development in a comprehensive, coordinated manner. Since the individualized service plan must be based upon the independent assessment, these requirements for the assessment should be used to inform and strengthen the service plan and, subsequently, the services provided to the individual.

- 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 independent eligibility evaluation, independent assessment, and developing the person-centered service plan, 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. Person-Centered Service plan

Section 1915(i)(1)(G) of the Act requires that the State plan HCBS benefit be furnished under an individualized care plan based on the assessment. The terms “care plan” and “service plan” are used interchangeably in practice. We will adopt the term “service plan” in this regulation for two reasons. First, to be consistent with the terminology in use with other HCBS, including §1915(c) HCBS waivers, we wish to avoid the misunderstanding that the plan is a different type of requirement in the State plan HCBS benefit than in other HCBS authorities. We note the reference to “service plan” for self-directed HCBS at 1915(i)(1)(G)(iii)(II)(bb). Second, some individuals and advocates have commented that “care plan” has a medical or dependent

connotation, inconsistent with a person-centered approach. Since we see no technical difference between the two terms, we propose to adopt “service plan”.

Underpinning all aspects of successful HCBS is the importance of a complete and inclusive person-centered planning process that addresses health and long-term services and support needs in a manner that reflects individual preferences. The person-centered approach is a process, directed by the individual with long-term support needs, and may also include a representative whom the individual has freely chosen.

To fully meet individual needs and ensure meaningful access to their surrounding community, systems that deliver HCBS must be based upon a strong foundation of person-centered planning and approaches to service delivery. Thus, we propose to require such a process be used in the development of the individualized service plan for all individuals to be served by section 1915(i) benefit. This can be achieved when States affirmatively and creatively support individuals in the planning process. We would propose certain requirements for developing the service plan, 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, which should include substantial feedback provided by individuals who received or are receiving services.

The person-centered service plan must identify the strengths, preferences, needs (clinical and support), and desired outcomes of the individual. The person-centered planning process is conducted in a manner that reflects what is important for the individual to meet identified clinical and support needs determined through a person-centered functional needs assessment process and what is important to the individual to ensure delivery of services in a manner that reflects personal preferences and choices.

In addition to being driven by the individual receiving services, the person-centered planning process would--

- Include people chosen by the individual;
- Provide necessary support to ensure that the individual has a meaningful role in directing the process to the maximum extent possible, and is enabled to make informed choices and decisions;
- Is timely and occurs at times and locations of convenience to the individual;
- Reflects cultural considerations of the individual;
- Include strategies for solving conflict or disagreement within the process, including clear conflict of interest guidelines for all planning participants;
- Offers choices to the individual regarding the services and supports they receive and from whom.
- Includes a method for the individual to request updates to the plan.
- Records the alternative home and community-based settings that were considered by the individual.

The plan resulting from this process should reflect that the setting in which the individual resides is chosen by the individual. The plan should reflect the individual's strengths and preferences, as well as clinical and support needs (as identified through an assessment of functional need). The plan should include individually identified goals, which may include goals and preferences related to relationships, community participation, employment, income and savings, health care and wellness, education, and others (we note that not all goals will have comparable services covered under Medicaid). The plan should reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and who provides

them. The plan should reflect risk factors and measures in place to minimize them, including individualized back-up plans. The plan must be signed by all individuals and providers responsible for its implementation, and should reflect the approach in place to ensure that it is implemented as intended. A copy of the plan must be provided to individuals and others involved in the plan.

Consistent with these person-centered principles and the requirements for community integration under the Americans with Disabilities Act, we are proposing that the service plan should be constructed in a manner that promotes service delivery and independent living in the most integrated setting possible. Therefore, we propose that the plan must not only address medical and support needs, but should also reflect other individual goals related to community living to the extent that services covered under the State Medicaid plan would be available to support such goals. Although these goals may include activities that may not themselves be funded through medical assistance, the coordination of Medicaid services with other activities in which the individual would be engaged as part of community living is an essential part of ensuring community integration. These activities might include employment, education, recreation or social activities, and/or other activities that occur regularly for individuals living in the community.

Subject to any additional needs-based criteria established for individual services, the State must make the services available to all eligible individuals who 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 needs, not based on available funds. Just as significantly, individuals who qualify for HCBS may not be compelled to receive them.

Individuals may also exercise their freedom to choose among qualified providers in the planning process.

The State Medicaid agency may delegate other agents to develop the service plan, but remains responsible for ensuring compliance with all requirements for each service plan developed. While the agency may delegate the authority for plan development and approval, the Medicaid agency is ultimately responsible for ensuring that the plans are completed according to the requirements of this regulation. This can be done through the establishment of appropriate controls, including monitoring and a quality improvement process.

Section 1915(i)(1)(G)(ii)(I)(aa) of the Act requires that the service plan is developed in consultation with the individual. The requirements for who is consulted in developing the service plan parallel those describing who may be consulted during the assessment process as determined by the State. As with the assessment, providers or others who may be responsible for providing services identified in the plan may be involved in the process. For example, providers may contribute to these processes by providing portions of an assessment and recommending a service plan, so long as the entity that retains final responsibility for the assessment or service plan meets all of the requirements of this final rule, including meeting the conflict of interest standards (See section II.B.10. for further discussion of conflict of interest).

Section 1915(i)(1)(G)(ii)(I)(bb) of the Act requires that the development of the service plan take into account the extent of family or other supports, which we refer to as “natural supports,” for the individual, and section 1915(i)(1)(G)(ii)(II) of the Act requires that such plan identify needed services. We interpret these provisions to indicate that to the extent available, natural supports should be explicitly included in the service plan. This means that individuals with equivalent needs 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 service plan 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 service plan. Changes in external factors such as gain or loss of other supports may trigger a review. Additionally, an individual may request a review of the plan at any time. We would require revision of the service plan 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 the development or revision of the service plan is based on the assessment. Therefore, we would propose that the independent assessment (See section II.B.6.) is required at least annually, and when needed upon a 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, without regard to their support needs. With the release of an updated, revised section 1915(c)

waiver application in 2008, 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 section 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 service plan. We do not interpret these requirements to indicate assessments and plans in addition to those generally required in sections 1915(i)(1)(F) and (G) of the Act. Accordingly, we would propose that the requirements for a self-directed service plan under section 1915(i)(1)(G)(iii)(III) of the Act be incorporated as components of the assessment and service plan 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 service plan, for which we describe proposed regulations in section III. 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 service plan be developed with a person-centered process, which, as noted above, we would propose to require of all service plans 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, and/or dismissing of providers of the State plan HCBS, which we term “employer authority.” We interpret selecting to include the authority to hire a provider, as well as to direct an agency to hire a specific provider. Currently, section 1915(c) HCBS waivers include varying degrees of self-direction. 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, at a minimum, information and assistance consistent with sound principles and practice of self-direction, and financial management supports to serve as fiscal/employer agents or co-employers. The availability of an independent advocate to assist the individual with the access to and oversight of their waiver services, including self-direction, is also an important component of a strong self-directed system. We note that the adequacy of supports for successful self-direction will be important elements of the State’s quality assurance strategy, which is required by section 1915(i)(1)(H) of the Act.

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 services and support and prevent or minimize problems prior to occurrences. Guidelines for quality improvement have been made available through CMS

policies governing section 1915(c) HCBS waivers available at www.hcbswaivers.net and published manuscripts available at www.nationalqualityenterprise.com.

Consistent with recent legislation with considerable focus on evidence-based quality and measurement, we would require States to have a quality improvement strategy, and to measure and maintain evidence of quality improvement including system performance, individual quality of care, and individual experience of care indicators approved and/or prescribed by the Secretary. These measures must take into account the relevant, targeted assurances, and include measures established through the DRA, CHIPRA, Affordable Care Act, and/or any other relevant health care indicators or quality measures developed by HHS, as applicable to the population(s) served by the section 1915(i) benefit. We would require States to make this information on their identified measures available to CMS upon request. In the event that a State elects to target the section 1915(i) benefit to specific populations, the State must submit evidence of quality improvement no later than 180 days before the end of each 5-year approval period. (See the discussion at I.B.19 of this proposed rule for more information regarding targeting and approval periods).

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 person-centered service plan. In this discussion, we will refer to persons or entities responsible for the independent evaluation, independent assessment, and the service plan as “agents” to distinguish them from “providers” of home and community-based services.

Conflicts can arise from 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 issues that focus on the convenience of the agent or service provider rather than being person-centered. Many of these conflicts of interest may not be conscious decisions on the part of individuals or entities responsible for the provisions of service.

To mitigate any explicit or implicit conflicts of interest, the independent agent must not be influenced by variations in available funding, either locally or from the State. The service plan must offer each individual all of the HCBS that are covered by the State that the individual qualifies for, and that are demonstrated to be necessary through the evaluation and assessment process. The service plan must be based only on medical necessity (for example, needs-based criteria), not on available funding. When local entities directly expend funds or direct allocated resources for services, in accordance with section 1902(a)(2) of the Act, the State must have a mechanism to ensure that availability of local funds does not affect access to services, such as using State resources to compensate for variability in local funding.

In this proposed regulation, we would require States to define conflict of interest standards to include criteria that reflect State and Federal experience with the issue in administering HCBS waivers, and that reflect the principles of section 1877 of the Act. Section 1877 of the Act prohibits certain types of referrals for services when there is a financial relationship between the referring entity and the provider of services.

We are aware that in certain areas there may only be 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 HCBS. 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 understand that the development of appropriate plans of care often requires the inclusion of individuals with expertise in the provision of long-term services and supports or the delivery of acute care medical services. As discussed previously, this rule is not intended to prevent providers from participating in these functions, but to ensure that an independent agent retains the final responsibility for the evaluation, assessment, and service plan functions.

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 FFP 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 HCBS 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. The phrase "if the individual is so eligible" indicates that payment is available once the individual is determined eligible, and not prior to that point.

- In section 1915(i)(1)(J) of the Act, we interpret the term "medical assistance for carrying out the independent evaluation and assessment under subparagraph E" to mean expenditures for both costs of evaluative services that are described in section 1905(a), such as physician or other practitioner services, as well as administrative costs to determine eligibility for the State plan HCBS benefit. 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 individuals the State has reason to believe may be eligible for the State plan HCBS benefit. FFP would be available for both medical services and administrative costs incurred for evaluation and assessment activities. During the period of presumptive payment, the individual would not receive State

plan HCBS, and would not be considered to be enrolled in Medicaid or eligible for the 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 that 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" may 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 the representatives conform to good practice concerning free choice of the individual, and assess for abuse or excessive control. States should also ensure that the person-centered planning process continues to be focused on the individual with HCBS support needs and his or her preferences and goals, and supports are provided so the individual can meaningfully participate and direct the process to the maximum extent possible. We are proposing to provide that the State may not refuse to recognize an authorized representative that the individual chooses, unless the State discovers and can document evidence that the representative is not acting in the best interest of the individual or cannot perform the required functions.

14. Nonapplication

As amended by the Affordable Care Act, 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)(10)(B) of the Act, regarding comparability; 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, it is important to reiterate that the choice not to apply these requirements applies only with regard to the provision of State plan HCBS.

Nonapplication of the requirement of comparability allows States to furnish the State plan HCBS benefit to specific targeted populations, similar to section 1915(c) waivers. Regardless of whether a State chooses to apply comparability requirements, it must define needs-based criteria to establish eligibility for the section 1915(i) benefit. If a State chooses not to apply comparability and to target the benefit, individuals must meet both the targeting criteria and the needs-based criteria in order to receive services through the section 1915(i) benefit. See the discussion in I.B.19 of this proposed rule for more detail regarding the option not to apply Medicaid comparability requirements and to target the benefit to a specific population or populations.

The nonapplication of 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 the individuals as if they are living in an institution for purposes of determining income and resources. This would result in the State not deeming/counting income and resources from an ineligible spouse to an applicant or from a parent to a child with a disability.

However, nonapplication of the income and resource rules applicable in the community applies only to the medically needy and only for the purposes of providing HCBS in accordance with the State plan amendment implementing section 1915(i) of the Act. Based on this language, we are interpreting the statute to mean that individuals made eligible on the basis of nonapplication of section 1902(a)(10)(C)(i)(III) of the Act may only be eligible for section 1915(i) services. In other words, for medically needy applicants, the State can elect not to deem income from an ineligible spouse, or from a parent to a child. If the State elects not to apply the requirements of section 1902(a)(10)(C)(i)(III) of the Act for the medically needy, it would determine Medicaid eligibility for section 1915(i) eligible medically needy individuals using institutional rules rather than community rules. Once the individual has been determined to be eligible as medically needy using institutional rules, and has been determined to meet the 150 percent of the FPL limit, the individual would only be eligible for State plan HCBS under section 1915(i) of the Act. The individual would not be eligible for any other Medicaid State plan services. However, individuals who are eligible for Medicaid as medically needy under income and resource rules applicable in the community, and whose income does not exceed the 150 percent of the FPL limit, would be eligible for State plan HCBS as well as all Medicaid State plan services.

15. No Effect on Waiver Authority

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. We further note that States may consider including 1915(i) services as a part of capitation under section 1915(b) waivers or other authorities for managed care arrangements. A State could use joint authority of 1915(b) and 1915(i) to provide HCBS to individuals eligible for the 1915(i) benefit.

16. Continuation of Federal Financial Participation (FFP) For Institutional Level of Care For Individuals Receiving Services As of the Effective Date of the State Plan HCBS Amendment

If the State modifies institutional LOC 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 permits States the option to continue receiving FFP for individuals who are receiving institutional services in NFs, ICFs/MR, and applicable hospitals or who are receiving services under a section 1915 waiver or through an 1115 HCBS demonstration project that is in effect at the time of the modification. We interpret the reference to section 1915 waivers to include waivers under sections 1915(c), 1915(d) or 1915(e) of the Act, which are the section 1915 waivers explicitly identified in section 1915(i)(6)(A) of the Act. Individuals receiving institutional care or HCBS under these authorities at the time that the institutional LOC is modified would not have to satisfy the more stringent criteria in order to continue receiving that care.

FFP under the unmodified criteria would continue to be available until such time as the individual is discharged from the institution, waiver program, or demonstration, or no longer requires this LOC. Moving between a waiver and an institution at the same LOC, or vice versa, by definition is not a change in LOC. Therefore, individuals who transition between waivers and institutions (for example, transitioning from an institution to waiver through the Money Follows the person program) would retain eligibility for institutional care and HCBS until they no longer meet the less stringent LOC requirements or until they lose eligibility for Medicaid or for institutional or waiver services due to a reason other than the application of the modified LOC criteria. An example of this would be if the individual aged out of a waiver, or if an increase in income or resources caused the individual to lose Medicaid eligibility.

In section 1915(i)(5) of the Act, the statute indicates that FFP remains available for individuals who meet the previous institutional criteria. We note that this does not create a requirement for States to continue to serve these individuals; rather, it creates an option for States to continue to receive FFP in order to provide care for individuals who would otherwise lose eligibility due to the implementation of the new criteria.

Due to the current requirements on maintaining eligibility standards, methodologies and procedures, we encourage States to consult with CMS before instituting any changes to LOC requirements.

17. State Option to Provide HCBS to Individuals Eligible for Services under a Waiver

Section 2402(b) of the Affordable Care Act added section 1915(i)(6) to the Act, specifying that States may elect to provide HCBS to an individual who is eligible for an approved waiver under sections 1915(c), (d), (e), or 1115 of the Act. Section 1915(i)(6)(A) specifies that individuals who are eligible for a waiver may receive State plan HCBS under the authority of section 1915(i) if they satisfy the needs-based criteria under such section and if their income is less than 300 percent of the supplemental security income (SSI) Federal benefit rate (FBR), as established by section 1611(b)(1) of the Act.

We interpret this statute as creating an option for States to increase the income limit for the State plan HCBS benefit, but only for individuals who are eligible for HCBS through an approved waiver within the State. We interpret “eligible” to mean that the individual meets all of the criteria required for entrance into a HCBS waiver that is approved within the State, regardless of whether the individual is actually enrolled and receiving services through that waiver. As discussed below, if a State elects this option, the State must cover the new optional categorically needy eligibility group specified at section 1902(a)(10)(A)(ii)(XXII) of the Act,

and individuals who are eligible for a waiver with income above 150 percent of the FPL, but below 300 percent of the SSI benefit rate, may receive State plan HCBS.

When establishing whether an individual's income is below 300 percent of SSI, under section 1915(i)(6)(B), the State should use the same rules that are applied for the special income level group specified at section 1902(a)(10)(A)(ii)(V) of the Act. Regardless of whether a State elects the option established by this section, the State could provide HCBS through both the section 1915(i) benefit, as well as through a HCBS waiver to any individual who meets the financial and needs-based criteria for both programs (that is, if an individual meets the waiver LOC criteria, and the needs-based criteria for the State plan HCBS benefit, and has income below 150 percent of the FPL, the individual could receive services under both authorities, provided that the services are not duplicative, whether or not the State elects to include the higher income level in their section 1915(i) benefit).

When a State elects to include this option, section 1915(i)(6)(C) of the Act allows services to differ in type, amount, duration, or scope from services provided to individuals who are eligible for the section 1915(i) benefit without also being eligible for a waiver. A State may choose to provide additional 1915(i) State plan HCBS to individuals who are eligible for HCBS under an approved waiver. If a State does so, it may also elect to establish additional needs-based criteria for those services. The establishment of additional criteria would be under the State authority to establish needs-based criteria for any service in the 1915(i) benefit (see the discussion in I.B.2 of this proposed rule for more discussion).

Any additional service(s) provided through this subsection must be allowable under section 1915(c)(4)(B) and may not include room and board. A State may also include "other" services, as defined by the State and approved by the Secretary, within the package of

section 1915(i) services that are limited to individuals who are eligible for a waiver. However, because individuals eligible for a waiver must also satisfy the needs-based criteria established for the section 1915(i) benefit to receive State plan HCBS, a State may not restrict access to benefits that are available to other individuals who receive the State Plan HCBS, except through a targeting criteria, or through the establishment of a needs-based criteria that applies uniformly to all individuals.

18. Establishment of Optional Eligibility Group to Provide Full Medicaid Benefits to Individuals Receiving State Plan HCBS

Section 2402(d) of the Affordable Care Act creates a new optional categorically needy eligibility group, specified at section 1902(a)(10)(A)(ii)(XXII) of the Act, for individuals “who are eligible for HCBS under the needs-based criteria established under (1)(A) of 1915(i), or who are eligible for home and community-based services under paragraph (6) of such section, and who will receive home and community-based services pursuant to a State plan amendment under such subsection.”

Under this group States can elect to cover individuals who are not otherwise eligible for Medicaid. For example, an individual age 65 or older, who has chronic needs but not at an institutional level of care and has too much income and/or resources to qualify for Medical Assistance under a State’s Medicaid plan, could be eligible for section 1915(i) services if he/she meets the needs-based criteria for the section 1915(i) benefit, has income up to 150 percent of the FPL and will receive section 1915(i) services. Under this group, States may also elect to cover individuals with income up to 300 percent of the SSI/FBR who would be eligible under an existing section 1915(c),(d),(e) waiver or section 1115 waiver and who will receive section 1915(i) services. These individuals do not have to be receiving services under an existing

section 1915(c),(d),(e) waiver or section 1115 waiver; the individual only has to be eligible for the waiver. Individuals eligible for Medicaid under this group would be eligible for full Medicaid benefits. The State must also elect the option under section 1915(i)(6) of the Act if the State intends to cover individuals with income up to 300 percent of the SSI/FBR.

19. State Option to Offer HCBS to Specific, Targeted Populations

The Affordable Care Act added section 1915(i)(7) to the Act, which allows States to target the section 1915(i) benefit to specific populations. In addition, as of October 1, 2010, States may design section 1915(i) benefits without regard to the comparability requirements contained in section 1902(a)(10)(B) of the Act. As a result, the State may “target” services, that is, either provide the 1915(i) benefit only to individuals in certain Medicaid eligibility groups, or provide different services within the 1915(i) benefit to different groups. Due to the ability to define targeted populations, a State may now propose more than one set of section 1915(i) benefits, with each benefit package targeted toward a specific population. A State may also propose one set of section 1915(i) benefits that targets multiple populations, and may offer different services to each of the defined target groups within the benefit. Additionally, a State may propose a section 1915(i) benefit that does not choose nonapplication of comparability and instead uses only the needs-based criteria to establish eligibility for the benefit. States may find this to be a less administratively burdensome approach, as there is no renewal requirement or limit to the approval period if the State does not target the HCBS benefit (see below for a discussion on limits to the approval period).

We propose to require that a State that elects to target the benefit to specific groups of individuals must submit objective targeting criteria in the SPA implementing the HCBS benefit, subject to approval by CMS. These targeting criteria may define a target population or multiple

target populations within parameters of diagnosis, disability, Medicaid eligibility groups, and/or age. Within these parameters, targeting criteria may be similar to those available through section 1915(c) waivers, as defined in §441.301, but we note that based on experience, these target groups may not aptly capture the universe of individuals who could benefit from section 1915(i) of the Act. Therefore, a State may also establish broader criteria that encompass more than one of the three groups defined in §441.301, or that target enrollees based on separate criteria. However, we note that the section 1915(i) benefit is described in the statute as “HCBS for Elderly and Disabled Individuals.” Therefore, we would expect any targeting criteria to apply to eligibility groups serving those individuals. We would also expect targeting criteria to align with the needs-based criteria established for the benefit.

For example, a State could target the benefit package to any children under the age of 21 with an intellectual disability, a developmental disability, autism, or a behavioral health condition. A State could also target the benefit using traditional section 1915(c) groups. An example of this would be to target the benefit to individuals age 65 and up. Further, this targeting option does not permit States to target the benefit in a manner that would not comply with section 1902(a)(23) of the Act regarding free choice of providers, or that forestalls the opportunity for individuals to receive services in the most integrated setting possible. Therefore, targeting criteria cannot have the impact of limiting the pool of qualified providers from which an individual would receive services, or have the impact of requiring an individual to receive services from the same entity from which they purchase their housing. For example, we would not allow States to establish targeting criteria that would restrict eligibility to only individuals who reside in provider-owned and/or operated settings.

If a State elects to target the benefit to a specific population or populations, it must still establish needs-based criteria that individuals must meet in order to be eligible for section 1915(i) services and the State may also establish needs-based criteria for individual services within the benefit. The needs-based criteria may include specific needs that are applicable to the targeting criteria, but may also include general needs that apply across all of the populations included in the benefit.

20. Five-Year Approval for Targeted Section 1915(i) HCBS Benefits and Renewal Requirements

Under sections 1915(i)(7)(B)(i) and (C) of the Act, if a State chooses to target State plan HCBS, the SPA approval will last for a 5-year period with the option for 5-year renewal periods. There is no statutory limit on the number of renewal periods available under this section. At the end of the initial 5-year period, and any subsequent renewals, CMS will review the State's approved SPA and evaluate State performance based upon the requirements contained within that SPA and the State plan HCBS quality outcomes.

We propose that a State must provide a written request for renewal at least 180 days prior to the end of the approval period. The request must be accompanied by a description of any proposed changes to the benefit, if applicable. Prior to renewal, CMS will request evidence of implementation of the State's quality improvement strategy in order to verify compliance with State plan HCBS requirements. Results of the quality monitoring process will be used to identify and make recommendations on areas of a State's section 1915(i) benefit that require modification prior to renewal. In accordance with section 1915(i)(7)(C) of the Act, we will approve renewals based upon adherence to Federal requirements, including adherence to the State's phase-in plan, as approved by CMS.

21. Phase-in of Services and Eligibility

Section 1915(i)(7)(B)(ii) allows States to phase-in the enrollment of individuals and/or the provision of services if the State elects to target the benefit to specific populations. The statute indicates that the State must enroll all eligible individuals and provide all of the services it has elected to include in the benefit by the end of the initial 5-year approval. Although the option to phase-in services and/or eligibility may seem contradictory with the requirements that the benefit be statewide and not limit enrollment, we interpret this section to provide States with the flexibility to prioritize enrollment to individuals with the highest need and/or to develop adequate infrastructure to ensure quality of care, and the health and safety of participants, prior to the provision of services. We do not interpret this option as providing States the authority to limit statewideness or to set a numerical limit on enrollment.

As an example, a State could elect to begin the provision of services to individuals with higher needs prior to the enrollment of all eligible individuals, based upon the assessment for eligibility to the benefit. In this instance, the needs-based criteria would allow States to identify individuals at greatest risk for health and safety, and to prioritize services to those individuals. Services would then be phased-in to individuals who qualify for the benefit but who have less assessed need.

States are permitted to modify the available services in a section 1915(i) benefit through a SPA at any time. Therefore, we do not believe that this option permits a State to include a service within the benefit without providing it to at least some enrolled individuals. However, at the option of a State, a phase-in plan might temporarily limit the provision of the entire benefit package, or of some specific services, based upon infrastructure considerations, such as the need to enroll an adequate number of qualified providers.

We propose that a State that elects to target the State plan HCBS benefit and to phase-in enrollment and/or services must submit a phase-in plan for approval by CMS that describes, at a minimum:

- The criteria used to phase-in enrollment or service delivery;
- The rationale for phasing-in services and/or eligibility; and
- Timelines and benchmarks to ensure that the benefit is available Statewide to all eligible individuals within the initial 5-year approval.

If a State elects and CMS approves a phase-in of services and/or eligibility in the section 1915(i) SPA, the statute indicates that the State must enroll all eligible individuals and provide all of the services it has elected to include in the benefit by the end of the initial 5-year approval. Therefore, if a State does not meet its phase-in plan by the end of the initial 5-year approval of the section 1915(i) benefit, the State will not be able to renew the benefit.

States are also prohibited from having a phase-in period longer than 5 years, and from receiving approval for a new section 1915(i) submission of a similar design with a phase-in period when a similar benefit with phase-in is discontinued before full implementation.

We are soliciting comments on alternative strategies and approaches for evaluating and approving the option to phase-in eligibility and enrollment.

C. Effective Date

The effective date on which States may provide HCBS through the State plan, as set forth by the DRA, is January 1, 2007. The effective date of the amendments to the section 1915(i) benefit, as established by the Affordable Care Act, is October 1, 2010.

D. 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 and that are not explicitly referenced in the regulation.

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, including if the State elects, the new eligibility group defined at section 1902(a)(10)(A)(ii)(XXII) of the Act. Each individual must meet all financial and non-financial criteria set forth in the plan for the applicable eligibility group.

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. States may also choose to target the benefit in a manner that either excludes children, or limits the benefit solely to children. HCBS benefits that are not otherwise available through 1905(a) State plan services under the Medicaid Early and Periodic Screening, Diagnostic, 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. In addition to meeting EPSDT requirements through the provision of 1905(a) services, a State may also meet a particular child's needs under EPSDT through services that are also available through the 1915(i) benefit. However, all Medicaid-eligible children must have full access to services required under EPSDT, and the provision of 1915(i) State plan HCBS should in no way hinder their access to such services.

We further note that the mandate under EPSDT applies only to services authorized by section 1905(a) of the Act. Therefore, HCBS under section 1915(i) of the Act are not required

under 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 1915(i) State plan HCBS as part of its EPSDT program. 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 §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.

States may also elect to include 1915(i) benefits as part of a managed care contract. In the event that State plan HCBS are included in a managed care contract, they must meet all applicable requirements contained in §438, including actuarial soundness of rates, cost effectiveness of services, and CMS contract review and approval.

Additionally, since this benefit is established through a State plan amendment process, section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5, enacted on February 17, 2009) requires the State to seek advice from Indian health programs and Urban Indian Organizations on the establishment of or modification to any State plan HCBS benefits.

FFP for the 1915(i) benefit is also subject to deferrals, withholding and disallowances in accordance with the requirements of subpart C of 42 CFR part 440. In the event that CMS determines a State to be out of compliance with the requirements of the HCBS benefit, standard Medicaid compliance actions will apply.

E. Other Background

1. Serving all eligible individuals while targeting limited resources

As noted above, section 1915(i) of the Act applies the general Medicaid requirements regarding statewideness and, like other State plan options, does not allow States to limit enrollment. Nevertheless, the law offers significant discretion for defining the population served. Specifically, States may limit utilization of the State plan HCBS benefit through application of the following provisions of section 1915(i) of the Act:

- 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 under this provision.

- The option to target the benefit to specific populations. States may combine needs-based criteria with targeting criteria in order to create a very specific benefit that applies to defined groups of individuals.

- The option to establish needs-based criteria to determine eligibility for each State plan HCBS. These 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 choice to offer a limited number of services under the State plan HCBS benefit. 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) of the Act.

- The option to limit the amount or duration of each service, in accordance with all Medicaid rules and requirements.

Since all State plan HCBS must be provided under a written service plan, States have the opportunity to review an individual's service plan to ensure that HCBS continue to be responsive to the needs of the individual.

Additionally, as a reminder, general Medicaid requirements also apply to the State plan HCBS benefit. All Medicaid services are to be provided only to those who need them according to medical necessity and needs-based criteria, as defined by the State. Prior authorization is available to the State.

2. HCBS Provided in the Community, Not in Institutions

Section 1915(i) provides States the option to provide home and community-based services, but does not define "home and community-based." Along with our overarching interest in making improvements to Medicaid HCBS, we seek to ensure that Medicaid is supporting needed strategies for States in their efforts to meet their obligations under the ADA and the Supreme Court decision in Olmstead v. L.C., 527 U.S. 581 (1999). In the Olmstead decision, the Court affirmed a State's obligations to serve individuals in the most integrated setting appropriate to their needs. A State's obligations under the ADA and section 504 of the Rehabilitation Act are not defined by, or limited to, the scope of requirements of the Medicaid program. However, the Medicaid program can provide an opportunity to obtain partial Federal funding that supports compliance with the ADA, section 504 of the Rehabilitation Act, and Olmstead through the provision of Medicaid services to Medicaid-eligible individuals.

In the April 4, 2008 **Federal Register** (73 FR 18676), we proposed to define home and community settings for this new benefit. Then in the June 22, 2009 **Federal Register** (74 FR 29453), we published an advance notice of proposed rulemaking (ANPRM) that solicited comments on potential rulemaking for a number of areas within the section 1915(c) HCBS

waiver program. Specifically, we requested public input on strategies to define home and community-based settings where waiver participants may receive services. Although the ANPRM is specific to section 1915(c) waivers, the services delivered and the settings they are available in are parallel to the section 1915(i) benefit. We recognize a need for a consistent definition of this term across Medicaid HCBS.

In response to the 1915(c) ANPRM, we received comments that supported the underlying goals to promote independence, community inclusion, and the goals of the Olmstead decision. However, many commenters also expressed concern about definitions of home and community-based settings that limited participant choice, and that excluded settings that may, in fact, promote independence and integration. Since that time, we have facilitated and participated in multiple stakeholder discussions related to this issue, and we also included proposed language for settings in which HCBS could be provided to elicit further comments on this issue in the section 1915(k) proposed rule published on February 25, 2011 and in the 1915(c) proposed rule published on April 15, 2011. We find the public comment process to be valuable in our attempt to develop the best policy on this issue for Medicaid beneficiaries. Therefore, with this rule, we again invite public comments on proposed language to establish the qualities for home and community-based settings under both sections 1915(i) State plan HCBS and the 1915(k) Community First Choice State plan option. It is our goal to align the final language pertaining to this topic across the sections 1915(k), 1915(i), and 1915(c) Medicaid HCBS authorities.

We have included proposed language for settings in which section 1915(i) services and supports could be provided to elicit additional comments on this issue. While it is not practical to create one singular definition that encompasses all settings that are home and community-based, with this rule we propose quality principles essential in determining whether a setting is

community-based. We expect States electing to provide HCBS benefits under section 1915(i) to include a definition of home and community-based setting that incorporates these principles and will review all SPAs to determine whether they propose settings that are home or community-based. We will permit States with approved section 1915(i) SPAs a reasonable transition period, a minimum of one year, to come into compliance with the HCBS setting requirements as promulgated in our final rule.

Recognizing the imperative to provide clear guidance to States and in consideration of recent proposals from States that have clearly exceeded reasonable standards for HCBS, we are proposing to clarify now that home and community-based settings must exhibit the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan, in order to be eligible sites for delivery of home and community-based services:

- The setting is integrated in, and facilitates the individual's full access to, the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, like individuals without disabilities;
- The setting is selected by the individual among all available alternatives and identified in the person-centered service plan;
- An individual's essential personal rights of privacy, dignity and respect, and freedom from coercion and restraint are protected;
- Individual initiative, autonomy, and independence in making major life choices, including but not limited to, daily activities, physical environment, and with whom to interact are optimized and not regimented; and

- Individual choice regarding services and supports, and who provides them, is facilitated.

In a provider-owned or controlled residential setting, the following additional conditions must be met. Any modifications of the conditions (for example to address the safety needs of an individual with dementia) must be supported by a specific assessed need and documented in the person-centered service plan:

++ The unit or room is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that the tenants have under the landlord/tenant laws of the State, county, city, or other designated entity. We are soliciting comments as to whether there are other protections, not addressed by landlord tenant law, that should be included;

++ Each individual has privacy in their sleeping or living unit:

--Units have lockable entrance doors, with appropriate staff having keys to doors;

--Individuals share units only at the individual's choice; and

--Individuals have the freedom to furnish and decorate their sleeping or living units;

++ Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;

++ Individuals are able to have visitors of their choosing at any time; and

++ The setting is physically accessible to the individual.

In addition to the aforementioned criteria there are two criteria that we have not included in the proposed regulation, but wish to solicit comment regarding whether they should be added.

The first is related to the proposed requirement that in a provider-owned or controlled residential setting, any modification of the conditions must be supported by specific assessed needs and documented in the person centered service plan. This requirement is meant to address two issues:

- Individuals receiving HCBS must not have their independence or freedoms abridged by providers for convenience, or well-meaning but unnecessarily restrictive methods for providing person-centered services and supports; and
- Individuals with cognitive disabilities and other impairments may require modifications of the aforementioned conditions for their safety and welfare.

This provision is meant to establish that service planning is the process in which these decisions are made, rather than ad hoc on a daily basis. While the proposed text establishes the requirement that any modification to the conditions are supported by a specific assessed need and documented in the person-centered service plan, we are also considering including language to explicitly set forth these activities. We are considering requiring the following points to be identified: identify a specific and individualized assessed safety need; document less intrusive methods that have been tried but did not work; include a clear description of the condition that is directly proportionate to the specific assessed safety need; include regular collection and review of data to measure the ongoing effectiveness of the modification; and establishing time limits for periodic reviews to determine if the modification can be lifted. We solicit comment on these points and any other potential requirements regarding modifications of the conditions set forth in this proposed rule. We also wish to solicit comment on a second criterion that would include a requirement that receipt of any particular service or support cannot be a condition for living in the unit. In discussing this specific criterion, we discovered that it could be read one of two

ways. One interpretation is that this language does not require an individual residing in a provider owned or operated setting to receive HCBS from the setting provider. Rather the individual could choose another qualified individual to provide HCBS. The other interpretation is that this language would prevent the owner of the setting from evicting an individual because the individual refused to accept a particular service. This interpretation could have an effect on residential settings, such as housing programs to address homelessness. Some of these settings include a structure in which individuals are required to participate in treatment (substance use, for example) as a condition of residing there. We acknowledge the complexities that arise, when trying to support an individual's right to choose while recognizing that there are programs and services that have been developed as a result of identified service needs. As indicated earlier, we are specifically soliciting comments on whether these two criteria should be included as regulatory requirements.

We note that home and community-based settings do not include nursing facilities, institutions for mental diseases, intermediate care facilities for mentally retarded, hospitals, or any other locations that have the qualities of an institutional setting as determined by the Secretary. In considering whether a setting has the qualities of an institutional setting, we will exercise a rebuttable presumption that a setting is not a home and community-based setting, and will engage in heightened scrutiny, for any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or disability-specific housing complex. We expect to issue further guidance regarding such settings. Other characteristics that could cause CMS to consider a setting as "institutional" or having the qualities of an institution would include, but not be limited to, settings which are isolated from

the larger community, do not allow individuals to choose whether or with whom they share a room, limit individuals' freedom of choice on daily living experiences such as meals, visitors, and activities, or limit individuals' opportunities to pursue community activities.

We have included these provisions to move toward a stronger articulation of the qualities that make a setting a home or truly integrated in the greater community for individuals living with disabilities. We believe that these principles of home and community-based settings will support the use of the Medicaid program to maximize the opportunities for individuals to access the benefits of home and community living.

We specifically invite comments on whether there are settings in addition to those currently enumerated in statute, that are, by their nature, location or administration inherently non-community based, and therefore, should be expressly excluded from HCBS. We also invite comments on the community-based qualities we have proposed in this rule to ascertain whether additional or different characteristics should be included.

In considering comments received pertaining to this provision of the rule, we will also include consideration of all comments received pertaining to the aligned home and community-based setting requirements being proposed in this rule for the section 1915(k) Community First Choice State Plan Option. In recognizing the need for a consistent definition of this term across Medicaid HCBS, it is our goal to align the final language pertaining to this topic across the regulations for sections 1915(i), 1915(k), and 1915(c) Medicaid HCBS authorities.

We note that this proposal in no way preempts broad Medicaid requirements, such as an individual's right to obtain services from any willing and qualified provider of a service.

We further note that States are not prohibited from funding institutional care under Medicaid. The exclusion of these settings from HCBS waivers and from the State plan HCBS

benefit does not limit the availability of institutional and facility-based care for those individuals who require long-term services and supports, and who freely choose to receive services in those settings. However, we believe that these types of services should not be funded through authorities that are intended to promote community-based alternatives to institutional care. Furthermore, we believe that the fundamental requirement that the needs-based criteria for section 1915(i) be less stringent than that for institutional care creates a mandate to ensure that services are provided in settings that are not institutional in nature.

While HCBS are not available while an individual resides in an institution, HCBS should be available to assist individuals to leave an institution. Recognizing that individuals leaving institutions require assistance to establish themselves in the community, we would allow States to include in a section 1915(i) benefit, as an “other” service, certain transition services to be offered to individuals to assist them in their return to the community. We propose that community transition services could be commenced prior to discharge and could be used to assist individuals during the period of transition from an institutional residence. Additionally, services could be provided to assist individuals transitioning to independent living in the community, as described in a letter to the State Medicaid Directors on May 9, 2002 (SMDL #02-008). We further recognize that, for short hospital stays, an individual may benefit from ongoing support through the HCBS State Plan for physical needs over and above such services available in a hospital, to ensure smooth transition from clinical setting to home, and to preserve a sense of continuity and normalcy (a notion particularly important for individuals with intellectual disabilities, cognitive disabilities associated with aging, and behavioral health support needs). Importantly, these services must be exclusively for the benefit of the individual, not the hospital, and must not substitute for services that the hospital is obligated to provide through its conditions

of participation or through its obligations under the ADA.

3. Home and Community-Based Services do not Include Room and Board

Payments for room and board are expressly prohibited by section 1915(i)(1) of the Act. Except for respite care furnished in a setting approved by the State that is not the individual's residence, no service or combination of services may be used to furnish room and board through the State plan HCBS benefit.

When an individual must be absent from his or her residence in order to receive a service authorized by the individualized service plan, it may be impractical to obtain a meal outside the venue in which the service is provided. Therefore, in some instances and when it does not constitute a full nutritional regimen, the provision of food may be included as an incidental part of service delivery. When meals are furnished as an integral component of the service, we are proposing to permit the State to consider the cost of food in the rate it pays 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.

4. Timing of Amendments

We seek to clarify expectations regarding timing of amendments when States propose modifications to the 1915(i) benefit. For the purposes of the 1915(i) benefit, we propose that amendments which result in a reduction of eligibility or services to 1915(i) participants must be submitted with a prospective, rather than retroactive, effective date.

F. Section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects

This proposed rule includes changes to §430.25 to implement section 2601 of the Affordable Care Act.

Section 2601 of the Affordable Care Act adds a new paragraph (2) to section 1915(h) to permit the Secretary, at her discretion, to approve a waiver that provides medical assistance for individuals dually eligible for Medicare and Medicaid (“dual eligibles”) for an initial period of up to 5 years and renewed for up to 5 years, at the State’s request. The statute defines a dual eligible as: “an individual who is entitled to, or enrolled for, benefits under part A of title XVIII, or enrolled for benefits under part B of title XVIII, and is eligible for medical assistance under the State plan under this title or under a waiver of such plan.” This new authority enhances existing tools available to improve and coordinate care and services for this particularly vulnerable group of beneficiaries. This change provides an important tool for States to design programs to better coordinate services for dual eligible individuals.

While section 2601 of the Affordable Care Act does not provide a new type of waiver, it does provide an important opportunity for States to simplify the operation of existing waivers that serve dually eligible individuals, especially important when States combine waiver authorities that have different approval periods.

A growing number of States provide care to dual eligible individuals in a managed care service system. To be successful, these systems often include community and institutional long-term services and supports, utilize or partner with Medicare managed care plans or fee-for-service providers to improve care continuity and individual outcomes, and minimize disincentives to community-based or preventive care.

The Medicaid tools available to establish such an arrangement vary, but many States seek to use a 1915(b) Managed Care waiver concurrently with a 1915(c) Home and Community-Based Services waiver. Some States interested in offering home and community-based supports to dual eligibles in a managed care delivery system raised concerns with the 2-year approval

period for the 1915(b) managed care waivers and the 3 and 5-year approval periods for the 1915(c) HCBS waiver program. These different approval periods present administrative challenges for States that pose hurdles to operational success.

Section 2601 of the Affordable Care Act provides a solution for these situations, and others where States may wish to minimize administrative and renewal requirements in order to better focus on program implementation and quality oversight. Section 2601 of the Affordable Care Act includes an opportunity for extended approval periods for sections 1915(b), 1915(c), 1915(d) and 1115 of the Act.

For a State to apply for the extended approval periods, the demonstration or waiver program must provide services for individuals who are dually-eligible for Medicare and Medicaid. The approval of such periods is at the Secretary's discretion, and determinations will be made regarding applications for 5-year waivers in a manner consistent with the interests of beneficiaries and the objectives of the Medicaid program.

We are proposing that if a demonstration or waiver program does not serve or excludes dually eligible individuals, the 5-year approval period will not be available, and existing approval period requirements will apply. In addition, we are proposing that in order for coverage-related waivers to be approved for 5 years periods, they must meet all necessary programmatic, financial, and quality requirements.

The statute provides that the State's request for extension of the waiver for additional 5-year periods will be approved unless the Secretary determines that one or more conditions of the waiver have not been met, that the waiver would no longer be cost neutral (for 1915(c) waivers), cost-effective (for 1915(b) waivers) or budget neutral (for 1115 demonstrations), that it would not be efficient to extend the waiver, or that it would no longer be consistent with the purposes of

the Medicaid program. We are proposing to require that quality oversight mechanisms must be in place and that the State must demonstrate compliance with applicable program requirements, as well as the terms and conditions of the waiver as specified by the Secretary.

G. Prohibition Against Reassignment of Provider Claims

1. Prohibition on Payment Reassignment

Section 1902(a)(32) of the Act provides generally that “no payment under the plan for care and services provided to an individual shall be made to anyone other than such individual or the person or institution providing such care or service, under an assignment or power of attorney or otherwise.”

The legislative history for this provision indicates that a primary purpose of the provision was to curb perceived abuses that stemmed from “factoring” of accounts receivable by physicians and individual practitioners. Factoring is when an individual or an organization, such as a collection agency or service bureau, purchases accounts receivable from a practitioner for a percentage of their face value.

Section 1902(a)(32) of the Act contains several specific exceptions to the general principle of direct payment to individual practitioners. There are exceptions for payments for practitioner services where payment is made to the employer of the practitioner, and the practitioner is required as a condition of employment to turn over fees to the employer; payments for practitioner services furnished in a facility when there is a contractual arrangement under which the facility bills on behalf of the practitioner; reassignments to a governmental agency, through a court order, or to a billing agent; payments to a practitioner whose patients were temporarily served by another identified practitioner; or payments for a childhood vaccine administered before October 1, 1994.

Similar provisions were enacted in title XVIII of the Act governing the Medicare program, at sections 1815(c) and 1842(b)(6) of the Act. Medicare payment assignment regulations are codified at 42 CFR part 424, subpart F (Limitations on Assignment and Reassignment of Claims). Because CMS is not proposing to amend or revise the regulations governing assignment of Medicare payments in this notice, we do not further discuss the Medicare rules. However, we are specifically soliciting public comment on the issue of consistency with Medicare payment policies, as discussed below.

2. Current Medicaid Payment Assignment Regulations

Medicaid regulations at §447.10 implement the requirements of section 1902(a)(32) of the Act by providing that State plans can allow payments to be made only to certain individuals or entities. Specifically, payment may only be made to the individual practitioner that provided the service or the recipient, if he or she is a non-cash recipient eligible to receive payment under §447.25, or under one of the limited exemptions. In addition, the regulations specifically state that "[P]ayment for any service furnished to a recipient by a provider may not be made to or through a factor, either directly or by power of attorney."

3. Medicaid Payment Reassignment

The regulations at §447.10 contain several enumerated exceptions to the general direct payment principle that implement and interpret the statutory exceptions. There is an exception for payment in accordance with a reassignment to a government agency, or by a court order. There is another exception for payment to a business agent, such as a billing service or accounting firm, that furnishes statements and receives payments in the name of the individual practitioner, if the business agent's compensation for this service is related to the cost of processing the billing, and not dependent on the collection of the payment.

There are also three exceptions for payments to individual practitioners that reflect statutory exceptions discussed above.

4. Individual Practitioner Workforce Stability and Development Concerns

Since the direct payment principle was originally enacted in 1972 and expanded in 1977, the definition of medical assistance under section 1905(a) of the Act has been changed to permit States to offer coverage of categories of practitioner services, such as personal care services, that may be viewed as unique to the Medicaid program. For these practitioners, the Medicaid program may be the primary, or only, source of payment. Some States have sought methods to improve and stabilize the workforce by offering health and welfare benefits to such practitioners, and by requiring that such practitioners pursue periodic training.

Several States have requested that we consider adopting additional exceptions to the direct payment principle to permit withholding from the payment due to the individual practitioner for amounts paid by the State directly to third parties for health and welfare benefits, training costs, and other benefits customary for employees. These amounts would not be retained by the State, but would be paid to third parties on behalf of the practitioner for the stated purpose.

While section 1902(a)(32) of the Act does not expressly provide for additional exceptions to the direct payment principle, we believe the circumstances at issue were not contemplated under section 1902(a)(32) of the Act and, therefore, that the direct payment principle should not apply. In light of the statutory silence in addressing this circumstance, we are proposing that the direct payment principle should not apply because we think its application would contravene the fundamental purpose of the provision. As noted above, the apparent purpose of the direct payment principle was to prohibit factoring arrangements. Therefore, we are proposing an

additional exception to describe payments that we do not see as within the intended scope of the statutory direct payment requirement. Under this exception, a State could claim as a provider payment amounts that are not directly paid to the provider, but are withheld and paid on behalf of the provider, such as health and welfare benefit contributions, training costs, or other benefits customary for employees.

H. Definition of Home and Community-Based Settings for the 1915(k) Community First Choice State plan Option

Section 1915(k)(1)(A)(ii) of the Act provides that home and community-based attendant services and supports must be provided in a home and community-based setting. The statute specifies that home and community-based settings do not include a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded. Through the application process of sections 1915(c) waivers, 1915(i) HCBS State plan amendments and section 1905(a) State plan amendments, we are aware of settings other than those specified in section 1915(k)(1)(A)(ii) of the Act that exhibit qualities of an institutional setting.

Over the past several years, we have sought input on how to define the characteristics of what makes a setting “home and community-based.” In the section 1915(i) proposed rule published on April 4, 2008 (73 FR 18676), we proposed to define home and community settings for this benefit. In the advanced notice of proposed rulemaking published on June 22, 2009 (74 FR 29453), we solicited comments on potential rulemaking for a number of areas within the section 1915(c) waiver program. Specifically, we sought public input on strategies to define home and community-based settings where waiver participants may receive services. Since that time, we have facilitated and participated in multiple stakeholder discussions related to this issue. In the proposed rule for section 1915(k) Community First Choice (CFC) State plan option

published on February 25, 2011 (76 FR 10736), we included the proposed language for settings in which CFC services and supports could be provided to elicit additional comments on this issue. In an effort to maintain consistency with this policy we also proposed similar language in the section 1915(c) proposed rule that published on April 15, 2011. We received many thoughtful comments on the proposed setting provisions published in the CFC proposed rule published on February 25, 2011. The comments received indicated to us that the proposed setting provisions caused more confusion and disagreement than clarity. In consideration of these comments, we decided to revise the setting provision and publish as a new proposed rule to allow for additional public comment before finalizing. We find the public comment process to be valuable in our attempt to develop the best policy on this issue for Medicaid beneficiaries.

Our policy regarding appropriate settings for the delivery of HCBS, as evidenced by our review of section 1915(c) waiver requests, has included a general prohibition on allowing HCBS in settings that are located on or adjacent to the campus of a public institution. We included this prohibition in the CFC proposed rule published on February 25, 2011. In response to the proposed rule, many commenters indicated strong support for this policy being incorporated into the final regulation, along with the proposal that buildings that included the delivery of inpatient services would not constitute acceptable settings for delivery of HCBS. Another commenter indicated that CMS should go a step further and in addition to excluding settings that are co-located with current institutions, also exclude settings on the grounds of former institutions to be clear that reorganizing and reclassifying an institution would not meet the criteria of a community-based setting. Many commenters believe that it is not possible for such a setting to ever be home and community-based. Others stated that all the characteristics of the setting should be given weight, and that we should not establish requirements based solely on the setting

locations or types (for example, size or the presence of institutional services offered within the same building), which would automatically disqualify a setting from being appropriate for delivery of HCBS.

In particular, we heard concerns that a general prohibition on setting locations or types could significantly restrict access to services in settings that promote aging in place for elderly individuals, disrupt effective treatment and support opportunities for individuals with significant brain injury, and potentially restrict access to services in rural areas. Commenters also expressed concerns that by focusing our policy on setting locations or physical characteristics, we were inappropriately implying that smaller or more scattered settings were automatically appropriate, regardless of the quality of care or degree to which individuals receiving services in those settings were actually able to participate in community life, be assured of health and safety, or able to control their own daily activities. Many commenters stated that listing the excluded settings created unintended consequences, and could exclude living arrangements for individuals receiving attendant services and supports that we did not intend to prohibit, as well as permit others that are not integrated and person-centered.

In response to public comment, we have developed proposed regulatory language to focus primarily on those qualities we deem essential in determining whether a setting of care is community-based. We believe the most effective and consistent way to assure that individuals with disabilities, regardless of age or type of disability, are offered home and community-based services in the most integrated setting appropriate to their needs and preferences, is to focus on the quality and characteristics of “home” and “community” that assure independence and integration from the individuals’ perspective. We agree with the many commenters who suggested this type of approach is most consistent with a person-centered system for delivering

care and services.

Some commenters stated that if an individual or his or her family “chooses” a residence, it is therefore a “home and community-based” setting. We disagree, as individuals can and do choose to receive services in institutional settings. In addition, this reasoning is especially suspect in situations where an individual may not be given the option of receiving services in a variety of settings outside of an institution (for example, in their own home or apartment or, depending on the service, in a competitive employment situation), but rather is offered services only in a provider-owned or operated congregate setting.

We received a range of responses as to whether disability-specific congregate settings are appropriate settings for delivery of HCBS. Some individuals and organizations are articulate about their right to live with anyone of their choosing, including those with disabilities. Others maintain that the only way to end unwanted segregation and forced “choices” is to forbid all segregation by disability, and that integration by definition means interaction with non-disabled individuals. All agree that unwilling segregation is a violation of civil rights. The Department of Justice has initiated a number of actions finding that States are violating the ADA by failing to provide more integrated alternatives to individuals in congregate settings whose residents are primarily or exclusively individuals with disabilities. States’ obligations under the ADA and Section 504 of the Rehabilitation Act are independent of, and are not limited by, their obligations under Medicaid, including the requirements of CFC, section 1915(c) of the Act, or section 1915(i) of the Act. States should carefully evaluate their strategies for offering services in community-based settings and consider whether individuals have meaningful options beyond a segregated option.

In addition, some commenters stated that community can be defined in many ways, and

therefore that home and community-based care could include integration into a community of peers; that is, in a disability-specific congregate or campus setting that includes a rich array of supports and activities within the setting of care. We acknowledge the importance of peer relationships but we do not agree that a community of one's peers is the same as "community based" in terms of settings in which HCBS is delivered. An important purpose of home and community-based services is to assist individuals to be able to live fully integrated in the greater, non-disabled community.

To provide greater clarity, we are proposing language to establish that home and community-based settings must exhibit specific qualities to be eligible sites for delivery of home and community-based services. We have included these provisions to move toward a stronger articulation of the qualities that make a setting a home or truly integrated in the broader community for individuals living with disabilities. These are the qualities most often articulated by persons with disabilities as key determinants of independence and community integration. We believe that these principles of home and community-based settings will support the use of the Medicaid program to maximize the opportunities for individuals to access the benefits of home and community living. We expect States electing to provide benefits under section 1915(k) to include a definition of home and community-based setting that incorporates these principles and will review all SPAs to determine whether they propose settings that are home or community-based. We will permit States with approved section 1915(k) SPAs a reasonable transition period, a minimum of one year, to come into compliance with the HCBS setting requirements as promulgated in our final rule. Under the regulation, settings must exhibit the following qualities, and such other qualities as the Secretary determines to be appropriate, based

on the needs of the individual as indicated in their person-centered service plan, in order to be eligible sites for delivery of home and community-based services:

- The setting is integrated in, and facilitates the individual's full access to, the greater community including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, like individuals without disabilities;
- The setting is selected by the individual among all available alternatives and is identified in the person-centered service plan;
- An individual's essential personal rights of privacy, dignity and respect, and freedom from coercion and restraint are protected;
- Individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact are optimized and not regimented; and
- Individual choice regarding services and supports, and who provides them, is facilitated.

In a provider-owned or controlled residential setting, the following additional conditions must be met. Any modification of the conditions, for example to address the safety needs of an individual with dementia, must be supported by specific assessed needs and documented in the person centered service plan:

- The unit or room is a specific physical place that can be owned, rented or occupied under another legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that the tenants have under the landlord tenant laws of the State, county, city, or other designated entity.

We are soliciting comments as to whether there are other protections, not addressed by landlord tenant laws that should be included.

- ++ Each individual has privacy in their sleeping or living unit:
- Units have lockable entrance doors, with appropriate staff having keys to doors;
- Individuals share units only at the individual's choice; and
- Individuals have the freedom to furnish and decorate their sleeping or living units;
- ++ Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;
- ++ Individuals are able to have visitors of their choosing at any time; and
- ++ The setting is physically accessible to the individual.

In addition to the aforementioned criteria there are two criteria that we have not included in the proposed regulation, but wish to solicit comment regarding whether they should be added. The first is related to the proposed requirement that in a provider-owned or controlled residential setting, any modification of the conditions must be supported by specific assessed needs and documented in the person centered service plan. This requirement is meant to address two issues:

(1) Individuals receiving HCBS must not have their independence or freedoms abridged by providers for convenience, or well-meaning but unnecessarily restrictive methods for providing services and supports; and

(2) Individuals with cognitive disabilities and other impairments may require modifications of the aforementioned conditions for their safety and welfare.

This provision is meant to establish that service planning is the process in which these decisions are made, rather than ad hoc on a daily basis. While the proposed text establishes the

requirement that any modification to the conditions are supported by a specific assessed need and documented in the person-centered service plan, we are also considering including language to explicitly set forth these activities. We are considering requiring the following points to be identified: identify a specific and individualized assessed safety need; document less intrusive methods of meeting that have been tried but did not work; include a clear description of the condition that is directly proportionate to the specific assessed safety need; include regular collection and review of data to measure the ongoing effectiveness of the modification; and establishing time limits for periodic reviews to determine if the modification can be lifted. We solicit comment on these points and any other potential requirements regarding modifications of the conditions set forth in this proposed rule. We also wish to solicit comment on a second criterion that would include a requirement that receipt of any particular service or support cannot be a condition for living in the unit. In discussing this specific criterion, we discovered that it could be read one of two ways. One interpretation is that this language does not require an individual residing in a provider owned or operated setting to receive HCBS from the setting provider. Rather the individual could choose another qualified individual to provide HCBS. The other interpretation is that this language would prevent the owner of the setting from evicting an individual because the individual refused to accept a particular service. This interpretation could have an effect on residential settings, such as housing programs to address homelessness. Some of these settings include a structure in which individuals are required to participate in treatment (substance use, for example) as a condition of residing there. We acknowledge the complexities that arise, when trying to support an individual's right to choose while recognizing that there are programs and services that have been developed as a result of identified service needs. As

indicated earlier, we are specifically soliciting comments on whether these two criteria should be included as regulatory requirements.

Additionally, in an effort to be consistent with other authorities providing home and community-based services, we propose to exclude hospitals as a community setting for the provision of Community First Choice Option. We believe this exclusion aligns with section 1915(k)(1)(A)(ii) of the Act requiring that services are provided in a home and community-based setting and section 1915(k)(3)(B) of the Act requiring services are provided in the most integrated setting appropriate to the individual's needs. We would like to clarify that the hospital prohibition applies to hospitals certified for the provision of long-term care services. We recognize that individuals with disabilities utilize personal attendant services and supports for various activities of daily living and instrumental activities of daily living. As a result, we understand that individuals will likely have a continued need for assistance while experiencing a short-term stay in general acute hospital settings. Therefore, while services provided in a general acute care hospital are not CFC services, individuals who have an assessed need for assistance with IADLs may continue to receive such services while an inpatient in an acute hospital setting. We would like to invite comment on this approach.

Lastly, we are proposing to include the list of the three prohibited institutional settings specified in statute, as settings in which CFC services and supports may not be provided, along with a general prohibition on any other locations that have qualities of an institutional setting, as determined by the Secretary.

In considering whether a setting has the qualities of an institutional setting for implementation of CFC, we will exercise a rebuttable presumption, as we will for the 1915(i) State plan HCBS benefit, that a setting is not a home and community-based setting, and will

engage in heightened scrutiny, for any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or disability-specific housing complex. We expect to issue further guidance regarding such settings. Other characteristics that could cause us to consider a setting as “institutional” or having the qualities of an institution would include, but not be limited to, settings which are isolated from the broader community, do not allow individuals to choose whether or with whom they share a room, limit individuals’ freedom of choice on daily living experiences such as meals, visitors, and activities, or limit individuals’ opportunities to pursue community activities.

Specifically, as with the 1915(i) proposed rule, we would invite comments on the specific qualities we have proposed. In addition, we are soliciting comments as to whether there are settings in addition to those currently enumerated in statute, that are, by their nature, location or administration inherently non-community based, regardless of the nature of an individual’s disability or age, and therefore, should be expressly excluded from HCBS. Issuing the revised setting provisions as a proposed notice will allow us to consider additional perspectives from the public on the modifications. In considering comments received pertaining to the setting provision of the section 1915(k) rule, we will also include full consideration of all comments received regarding the aligned home and community-based setting requirements being proposed in this rule and section 1915(i). In recognizing the need for a consistent definition of this term across Medicaid HCBS, it is our goal to align the final language pertaining to this topic across the regulations pertaining to sections 1915(i), 1915(k), and 1915(c) Medicaid HCBS authorities.

Along with our overarching interest in making improvements to Medicaid HCBS, we seek to ensure that Medicaid is supporting needed strategies for States in their efforts to meet

their obligations under the ADA and the Supreme Court decision in Olmstead v. LC, 527 US 581 (1999). In the Olmstead decision, the Court affirmed a State's obligations to serve individuals in the most integrated setting appropriate to their needs. A State's obligations under the ADA and section 504 of the Rehabilitation Act are not defined by, or limited to, the scope or requirements of the Medicaid program. However, the Medicaid program can provide an important opportunity to obtain Federal funding that supports compliance with the ADA, section 504 of the Rehabilitation Act, and Olmstead through the provision of Medicaid services to Medicaid-eligible individuals. Additionally, we expect States through the requirement at §441.677(b) to have a comprehensive quality assurance system, to develop individual outcome measures that would support the State's compliance with providing CFC services in accordance with the individual's person-centered plan and in a setting that meets the home and community-based setting criteria set forth in this regulation.

III. Provisions of the Proposed Rule

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

A. State Organization and General Administration (Part 431)

In §431.54, we are proposing to add paragraphs (a)(3) and (h) to include State plan HCBS as exceptions to comparability and community income and resource rules.

B. Eligibility in the States, District of Columbia, the Northern Mariana Islands, and American Samoa (Part 435) and Eligibility in Guam, Puerto Rico and the Virgin Islands (Part 436)

In §435.219 and §436.219, we are proposing to add a provision to implement the optional categorical eligibility group created by section 1902(a)(10)(A)(ii)(XXII) of the Act for individuals, "who are eligible for home and community-based services under the needs-based

criteria established under (1)(A) of 1915(i), or who are eligible for home and community-based services under paragraph (6) of such section, and who will receive home and community-based services pursuant to a State plan amendment under such subsection.” By using the word “or” we interpret that the statute creates two distinct eligibility groups under section 1902(a)(10)(A)(ii)(XXII) of the Act with two sets of requirements, as follows:

(1) Those who are eligible for HCBS under the needs-based criteria established under section 1915(i)(1)(A) of the Act; or

(2) Those who are eligible for HCBS under paragraph (6) of such section, and who will receive HCBS pursuant to a State plan amendment under such subsection.

We believe that we have the following flexibility in defining eligibility for the first subset of this group of individuals:

- The first subset is made up of individuals who are not otherwise eligible for Medicaid.

We believe that this interpretation is consistent with Congressional intent because this policy allows individuals who would not otherwise be eligible for Medicaid because they are not in a category (for example, certain adults prior to January 1, 2014) to become Medicaid eligible and receive section 1915(i) services. The early option established by section 1902(k)(2) of the Act covers individuals who are not otherwise categorically eligible for Medicaid. The new group defined in section 1902(a)(10)(A)(i)(VIII) of the Act, which goes into effect in 2014, also will cover individuals not eligible under the existing categorical groups listed in section 1902(a)(10) of the Act.

- Even though the description of the eligibility group in the statute at section 1902(a)(10)(A)(ii)(XXII) of the Act does not explicitly include an income cap we believe that a standard of 150 percent of the FPL, which is the same as the current income cap for individuals

eligible under the State plan receiving section 1915(i) services, is reasonable. The needs-based criteria are described in section 1915(i)(1)(A) of the Act, which provides additional conditions for the provision of State plan HCBS under section 1915(i)(1) to individuals who are eligible under the State Medicaid plan and whose income does not exceed 150 percent of the FPL. In addition, the amendments to section 1915(i) of the Act in section 2402(b) of the Affordable Care Act which establish a new option to cover individuals eligible for HCBS under a waiver, gives States this option “in addition to continuing to provide such services” to individuals satisfying the needs-based criteria. Prior to the effective date of the new eligibility group under section 1902(a)(10)(A)(ii)(XXII) of the Act, States could only provide HCBS under section 1915(i) to those eligible under an existing State plan group whose income did not exceed 150 percent of the FPL and who met the needs-based criteria.

- Section 1902 of the Act requires States to use methods of determining income that are reasonable, consistent with the objectives of the Medicaid program, simple to administer, and in the best interests of the beneficiary. For purposes of determining income for this group, we believe the SSI program’s rules (which are currently used in Medicaid for determining income eligibility for individuals aged 65 or older and people with disabilities) meet these criteria. Like the individuals covered under the SSI-related Medicaid eligibility category, many individuals eligible under this group will have disabilities or chronic illnesses. The SSI program provides for a number of income disregards specifically applicable to persons with disabilities that are not available under other program methodologies. States may also elect to use less restrictive income methodologies than are used under SSI. Any less restrictive methodology should apply to all members of the group.

- While the rules of the SSI program are an example of a methodology that we believe

meets the requirements for determining income eligibility for this group, this does not preclude States from describing other methodologies in their SPAs that they believe also meet those requirements. We encourage States considering the use of other methodologies to discuss them with CMS before actually submitting a SPA.

- The statute does not refer to any resource test for this group and we are proposing that States may not apply a resource test in determining eligibility for this subset of the new group. We believe that not applying a resource test for this subset would be consistent with the absence of a resource test for the eligibility group described under section 1902(a)(10)(A)(i)(VIII) of the Act and the option for States to cover such individuals prior to January 1, 2014.

- The section 1915(i) statute does require that these individuals must receive section 1915(i) services in order to be eligible for Medicaid.

- Once eligible for Medicaid in this group, the individual will be eligible for all Medicaid services, not just section 1915(i) services.

The second subset of this group consists of individuals eligible for home and community-based services under an existing State waiver or demonstration. In determining eligibility for individuals with income that does not exceed 300 percent of the SSI/FBR, individuals must be eligible for an existing section 1915(c), (d), or (e) waiver or a waiver under section 1115, even though they do not have to receive services under these authorities. For individuals with income that does not exceed 300 percent of the SSI/FBR, we believe that there is little flexibility under the statute in determining eligibility for this subset, therefore--

- The individual must be eligible for a section 1915(c) waiver;
- The State must follow eligibility and post eligibility rules of an approved section 1915(c) waiver. More information regarding HCBS waiver eligibility and post eligibility rules is

available in the HCBS waiver Technical Guide, online at www.hcbswaivers.net;

- Income and resource rules of the special income level group apply;
- Section 1902(r)(2) of the Act income disregards do not apply because income eligibility under the special income level group is determined using a gross income test that caps income at 300 percent of the SSI/FBR;

- Section 1902(r)(2) of the Act resource disregards apply;
- The individual must receive section 1915(i) services as a condition of Medicaid eligibility;

- If the State elects to cover individuals with income up to 300 percent of the SSI/FBR, it must elect the option under section 1915(i)(6) under the State plan; and

- The individual will be eligible for all Medicaid services, not just section 1915(i) services.

Additionally, when electing this new eligibility group States will have multiple options.

States can cover-

(1) Individuals who meet the needs-based criteria established under section 1915(i)(1)(A) of the Act with income up to 150 percent of the FPL and individuals who meet the needs-based criteria established under 1915(i)(1)(A) eligible for HCBS under a waiver with income up to 300 percent of the SSI/FBR; or

(2) The subset of individuals who meet the needs-based criteria established under section 1915(i)(1)(A) of the Act with income up to 150 percent of the FPL; or

(3) The subset of individuals who meet the needs-based criteria established under section 1915(i)(1)(A) of the Act eligible for HCBS under a waiver with income up to 300 percent of the SSI/FBR.

In order for States to elect any of the options listed above with respect to the new eligibility group, they must continue to cover individuals described in 1915(i)(1).

This is not the first time that an eligibility group has been treated in this manner; the aged or disabled poverty level group described at section 1902(m)(1) of the Act permits States to cover aged and disabled individuals, the aged only, or disabled only individuals.

We invite comment on the eligibility provisions of §435.219 and §436.219 of the regulation.

C. Services: General Provisions (Part 440)

In §440.1, we are proposing to add a reference to a new statutory basis to read "1915(i) HCBS furnished under a State plan to elderly and disabled individuals under the provisions of part 441, subpart L."

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.

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. 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, except for the "other" services which the Secretary has the authority to approve for an HCBS waiver. In HCBS waivers, other services must be cost-effective and must be necessary to prevent institutionalization. However, the State plan HCBS does not require cost-neutrality and some individuals will be eligible for section 1915(i) of the Act without meeting an institutional LOC. 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, except for "other" services. We require "other" services to be appropriate for individuals who meet the needs-based criteria that the State defines for the benefit. 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 and the State-defined "other services," we propose to require at §441.662(a)(7) and §441.662(a)(8) (regarding requirements for independent assessment), explanations of the manner in which non-duplication of services will be documented in the assessment of each individual receiving habilitation services or Secretary approved other services. Additionally, since some individuals may be simultaneously receiving services through a HCBS waiver and the section 1915(i) benefit, we require in §441.662(a)(9) documentation that the services provided through 1915(c) and 1915(i) authorities may not be duplicative for the same individual. This would also include coordination

of assessments, service plan development, and case-management to ensure that individuals receiving services under both authorities are not subject to multiple assessments and service plans.

Section 1915(i) of the Act prohibits reimbursement for room and board. At §440.182(c), we propose to state that, except for respite care furnished in a setting approved by the State that is not the individual's residence, no service or combination of services may be used to furnish room and board through the State plan HCBS benefit. When meals are furnished as an integral component of the service, we are proposing to permit the State to consider the cost of food in the rate it pays 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.

Finally, we propose that a State may claim FFP for a portion of the rent and food expenses 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 permitted in HCBS waivers under section 1915(c)(1) and §441.310(a)(2)(ii), that FFP is available only for the reasonable additional rent and food 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 rent and food costs when the residence is owned or leased by the caregiver.

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

In April 4, 2008, we issued a proposed rule in the **Federal Register** titled "Medicaid Program; Home and Community-Based State Plan Services." In that proposed rule, we specified that we would set forth our proposals in 42 CFR part 441 initially proposed in new

subpart K titled "State Plan Home and Community-Based Services for Elderly and Disabled Individuals," consisting of §441.650 through §441.677, 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. Subsequently, we published a proposed rule (76 FR 10736) on February 25, 2011 in the **Federal Register** titled "Medicaid Program; Community First Choice Option," which also proposed the addition of subpart K to part 441. Therefore, we are proposing to specify that the proposed provisions for the "State Plan Home and Community-Based Services for Elderly and Disabled Individuals" in subpart K under §441.550 through §441.577 be redesignated as subpart L (§441.650 through §441.677),

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.

E. Basis and purpose (§441.650)

We set forth in §441.650 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.

F. State Plan Requirements (§441.653)

In §441.653, we propose that a State plan that includes HCBS 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.

G. Eligibility for Home and Community-based Services under Section 1915(i)(1) of the Act (§441.656)

We propose in §441.656 (a)(1) to require that if the State Medicaid agency elects to provide the 1915(i) HCBS benefit, it must provide services to categorically needy individuals who are eligible for Medicaid under an eligibility group that is covered under its State Medicaid plan and who have income that does not exceed 150 percent of the FPL. The State may also elect to provide the section 1915(i) HCBS benefit to medically needy individuals.

To implement the intent of the Congress that the benefit be "home and community-based," we would require in §441.656(a) that the individual reside in the home or community, not in an institution, according to quality principles for community-based settings prescribed by the Secretary. As discussed in section II.E.2. of this proposed rule, there are a variety of living arrangements that promote independence and community integration, as well as arrangements that do not.

We would require in §441.656(b) that the individual must meet the needs-based eligibility criteria as set forth in §441.659. We propose in §441.656(c) 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 at a frequency identified by the State. Finally, we require that, in the event that a State

elects not to apply comparability requirements to the benefit, an individual must meet the State-defined and CMS approved targeting criteria in order to establish eligibility.

We propose in §435.219(b) and §436.219(b) that States may elect under section 1915(i)(6) of the Act the option to provide home and community-based State plan services to individuals eligible under a section 1915(c),(d),(e) or section 1115 waiver who have income up to 300 percent of the SSI/FBR.

We also propose in §441.656(e)(1) that States may elect to follow institutional income and resource eligibility rules for the medically needy living in the community. Nonapplication of 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 "not to apply" instead of "waive" since this is an election made by the State and does not require a waiver by the Secretary. We further propose that States may elect not to apply section 1902(a)(10)(B) of the Act, concerning comparability of services in Medicaid, which permits the State plan HCBS benefit to be targeted towards specific populations. In this section, we indicate that a State may elect to establish targeting criteria for the section 1915(i) benefit and for any specific services within that benefit, subject to CMS approval, based on factors such as age, diagnosis, and/or disability. These criteria provide States with the option to provide State plan HCBS services to specific populations, including specific Medicaid eligibility groups, but allows flexibility to combine multiple target groups within one benefit and to provide different services to each group. Targeting criteria cannot have the impact of limiting the pool of qualified providers from which an individual would receive services, or have the impact of requiring an individual to receive services from the same entity from which they purchase their housing.

H. Needs-based Criteria and Evaluation (§441.659)

The statute uses a number of terms at times interchangeably. In general, in §441.659 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."

1. Needs-based eligibility criteria

In §441.659(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, IADLs, or other risk factors defined by the State. We propose to require that State-defined risk factors affecting eligibility may 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 lack of availability of family members or other unpaid caregivers willing and able 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.

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.

2. More stringent institutional and waiver needs-based criteria

In §441.659(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 LOC criteria for institutions (that meet the requirements in §441.659(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 LOC criteria must add need-based requirements to their LOC assessments in order to establish the State plan HCBS benefit.

We propose in §441.659(b) to define by reference to statute and regulation the institutions for which section 1915(i) of the Act requires more stringent eligibility criteria. NF and ICF/MR are so cited. We interpret the 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 may not have the effect of limiting who can benefit from the State plan HCBS in an unreasonable way, as determined by the Secretary.

In §441.659(b), we further propose to require that the more stringent needs-based criteria for institutions and waivers be part of the State's LOC 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 §441.659(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 by the effective date of the State plan HCBS benefit⁸.

Finally, in §441.659(b)(2), we propose that if a State modifies its institutional level of criteria 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, the States may continue to receive FFP when serving individuals who were eligible under the previous criteria. Exemption from the more stringent criteria is indefinite, but ends when the individual is discharged from the facility or waiver, the individual becomes ineligible for Medicaid due to factors unrelated to the LOC determination, or the individual no longer meets the criteria for the applicable LOC. We

⁸ Although not included in the regulation, we would caution states against raising the LOC due to the maintenance of eligibility requirements included in the Affordable Care Act.

note that in long-term care facilities a transfer is not a discharge and would not cause the individual to lose this exemption. Similarly, if an individual transitions from an institution to a waiver it would not result in a separate LOC, and would not cause the individual to lose this exemption. States would determine the effect of any subsequent changes to general LOC requirements (unrelated to the more stringent criteria) upon individuals with this exemption. Additionally, nothing in this subsection would prevent the State from determining whether the person remains eligible for Medicaid based on other factors, such as income or residency.

3. Adjustment authority

In §441.659(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 §441.659(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 §441.659(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 propose to require, 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 established under this subsection would not apply to individuals already enrolled in the State plan HCBS. If the State also adjusts institutional levels of care, the adjusted institutional levels of care may not be less stringent than the institutional LOC prior to the effective date of the State plan HCBS benefit.

Additionally, in §441.659(b), we indicate that any changes to the institutional LOC criteria under the State adjustment authority contained in §441.659(c) are subject to the same

requirements as an adjustment to the institutional LOC criteria under §441.659(b).

In §441.659(c), we further propose to explicitly require that the adjusted needs-based eligibility criteria for the State plan HCBS benefit must be less stringent than needs-based institutional LOC 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 L. 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 in accordance with 42 CFR part 431, subpart E.

4. Independent evaluation and determination of eligibility

In §441.659(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 §441.656 of this subpart, and the needs-based criteria that the State has established under §441.659(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 assistance for ADLs.

We note that appraisal of whether an individual has need for, and meets additional needs-based criteria (if any) for specific HCBS offered under the benefit, is part of the independent assessment and service plan development process. However, this assessment affects eligibility for the benefit in that we propose at §441.656(a)(ii)(5) 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.

5. Periodic redetermination

In §441.659(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 §441.659(d).

I. Independent assessment (§441.662)

In §441.662, 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 service plan. 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, including other services available through Medicaid and other State and Federal programs.

The assessment also applies the State's needs-based criteria (if any) for each service. 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; or for establishing Medicaid eligibility through the benefit

without actually receiving State plan HCBS services. Such a circumstance could, among other problems, be of no utility to the individual, and may make it difficult for the State to meet an assessed need. Furthermore, the eligibility group defined in section 1902(a)(10)(a)(ii)(XXII) of the Act requires an individual to receive State plan HCBS in order to establish Medicaid eligibility through that category.

We propose to require in §441.662(a)(1) 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). We further propose that a "face-to-face" meeting could be performed through telemedicine or other information technology medium, if the health care professional performing the assessment meets provider qualifications that includes additional training requirements for the operation of the information technology, the individual receives support during the assessment including the use of any necessary on-site staff, and the individual provides informed consent. In §441.662(a)(1)(i), we propose to require that the assessment is performed by an agent that is independent and qualified as defined in §441.668. 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 §441.674.

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. 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. We further propose that the assessment must ensure that services received through Secretary-approved “other” services are not duplicative of any other services provided through the Medicaid State-plan or through another State or Federal program. We note that extended State plan services would not be considered duplicative, since those services are not available to individuals through the State plan. We further note that payments must also be in accordance with section 1903(c) of the Act. Finally, we require that the assessment must ensure that any individual simultaneously enrolled in State plan HCBS and receiving HCBS through a waiver does not receive duplicative services. We would include case management, assessment, and service plan development in the services that may not be duplicative. This does not necessarily mean that an individual cannot have more than one case manager, but instead is meant to ensure that services are coordinated across multiple programs, and that individuals are not required to develop multiple service plans.

Finally, in §441.662(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 service plan.

J. Service plan (§441.665)

In §441.665 we propose to require that based on the independent assessment specified in §441.662, the State develops (or approves, if the plan is developed by others) a service plan through a person-centered planning process.

We propose that the service plan must be developed jointly with the individual. While we propose several specific requirements for the process of developing a service plan, 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. While we include examples, we do not propose any required or excluded category of persons to consult. When the service plan is finalized between the parties, a written copy is provided to the individual.

Also, in §441.665(a), we propose certain content to be required in the service plan. The person-centered service plan must identify the specific State plan HCBS to be provided to the individual, that take into account the individual's strengths, preferences, needs (clinical and support), and desired outcomes. We are proposing that the service plan should be constructed in a manner that promotes service delivery and independent living in the most integrated setting possible. Therefore, we propose that the plan must not only address medical and support needs, but should also reflect other individual goals related to community living to the extent that services covered under the State Medicaid plan would be available to support such goals. 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 service plan provides for all needed services to the individual while preventing provision of duplicative or unnecessary services.

We propose a single service plan for both self-directed and non self-directed services. When individuals self-direct some or all of their HCBS, the service plan includes the information required in §441.674.

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

Finally, we propose that the individual must share the authority for developing and implementing the service plan. This shared authority increases the individual's self-efficacy and involvement in the activities and outcomes contained within the service plan.

K. Provider qualifications (§441.668)

In §441.668, 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 service plan.

We propose at §441.668(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 service plan. 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 service plan development, these qualifications must include training in assessment of individuals whose physical or mental condition may trigger a need for HCBS 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 agent is not a relative of the individual or responsible for the individual's finances or health-related decisions. The standards also require that the agent must not hold financial interest in any of the entities that provide care. 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 service plan development should not be performed by providers of the services prescribed. However, we recognize 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.

L. Definition of Individual's Representative (§441.671)

In §441.671, 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. We note that States must not refuse to allow a freely-chosen person to serve as a representative unless the State has tangible evidence that the representative is not acting in the best interest of the individual, or that the representative is incapable of performing the required functions.

M. Self-directed Services (§441.674)

We propose in §441.674 to permit States to offer an election for self-directing HCBS. We propose regulations containing the specific requirements for self-direction found in section 1915(i)(1)(G)(iii) of the Act. In §441.674(a), we define "self-direction." Provisions related to self-direction apply to an individual or an individual's representative. In §441.674(b), we propose that when an individual chooses self-direction, the independent assessment and person-centered planning required under §441.662 and §441.665 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.

These regulations are consistent with our policy for self-direction under section 1915(c) HCBS waivers. We propose to require in §441.674(b) that the service plan 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 service plan describe the process for facilitating voluntary and involuntary transition from self-direction. When the service plan is finalized between the parties, a written copy is provided to the individual, as required in the proposed plan on care requirements at §441.665(a).

In §441.674(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 §441.674(c), employer authority is defined as the ability to select, manage, or dismiss providers of the State plan HCBS. We propose that the service plan 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 §441.674(e).

In §441.674(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 service plan must specify the method for calculating the dollar values in the budget, a process for adjusting the budget to reflect changes in assessment and service plan, a procedure to evaluate expenditures under the budget, and the financial management supports, as required in §441.674(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 §441.674(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.

N. State Plan HCBS Administration: State Responsibilities and Quality Improvement
(§441.677)

1. State responsibilities

We would require in §441.677(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.

Section 1915(i) of the Act authorizes a State to elect not to apply comparability requirements, thus permitting States to target the entire 1915(i) benefit, specific services within the benefit, or both. We clarify in §441.677(a)(1)(ii) that the State may not limit enrollee access to services in the benefit for any reason other than assessed need or targeting criteria. This includes the requirement that services be provided to all individuals who are assessed to meet the targeting criteria and needs-based criteria, regardless of income. 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 II.E.1 of this proposed rule, States have a number of permitted methods to control utilization. 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 needs-based criteria, as evaluated by the independent assessment and person centered service plan. 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, HCBS than they are determined to require. We note that one function of the service plan as proposed at

§441.665(a)(3) is to prevent the provision of unnecessary, duplicative, or inappropriate care.

2. Administration

We propose in §441.677(a)(2)(i) an option for presumptive payment. In accordance with section 1915(i) of the Act, 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 §441.677(a)(2)(ii), we indicate that a State may elect to phase-in the provision of services or the enrollment of individuals if the State also elects not to apply comparability requirements and to target the benefit to specific populations. However, there is no authority to limit the numerical enrollment in the benefit or to create waiting lists. Therefore, we propose that any phase-in of services may not be based on a numerical cap on enrollees. Instead, a State may choose to phase-in the benefit or the provision of specific services based on the assessed need of individuals, the availability of infrastructure to provide services, or both. Infrastructure is defined as the availability of qualified providers or of physical structures and information technology necessary to provide any service or set of services.

A State that elects to phase-in the benefit must submit a plan, subject to CMS approval, that details the criteria used for phasing in the benefit. In the event that a State elects to phase-in the benefit based on needs, all individuals who meet the criteria described in the phase-in plan must receive services. If a State elects to phase-in services based upon infrastructure, the plan must describe the capacity limits, strategies to increase capacity, and must assure that services will be provided to all individuals who are able to acquire a willing and qualified provider. Any phase-in plan must provide assurance that the benefit, and all included services, will be available statewide to all eligible individuals within the first 5-year approval period.

In §441.677(a)(2)(iii), 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 §441.677(a)(2)(iv), 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 service plan. 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.

In §441.677(a)(2)(v), we include a provision regarding the effective dates of amendments with substantive changes. Substantive changes may include, but are not limited to changes in eligible populations, constriction of service amount, duration or scope, or other modifications as

determined by the Secretary. We would add regulatory language reflective of our guidance that 1915(i) amendments with changes that CMS determines to be substantive may only take effect on or after the date when the amendment is approved by CMS, and must be accompanied by information on how the State has assured smooth transitions and minimal adverse impact on individuals impacted by the change.

In §441.677(a)(2)(vi), we indicate that State plan amendments including targeting criteria are subject to a 5-year approval period and that successive approval periods are subject to CMS approval, contingent upon State adherence to Federal requirements. In order to renew State plan HCBS for an additional 5-year period, the State must provide a written request for renewal to CMS at least 180 days prior to the end of each approval period.

3. Quality improvement strategy

We propose in §441.677(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, for quality assurance purposes, 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.

We propose that the State plan HCBS benefit include a quality improvement strategy consisting of a continuous quality improvement process, and outcome measures for program performance, quality of care, and individual experience, as approved and prescribed by the Secretary, and applicable to the nature of the benefit.

In §441.677(b), we propose to require States to have program performance measures, appropriate to the scope of the benefit, designed to evaluate the State's overall system for providing HCBS. "Program performance" measures can be described as process and

infrastructure measures, such as whether plans of care are developed in a timely and appropriate manner, or whether all providers meet the required qualifications to provide services under the benefit. In §441.677(b)(1), we also propose to require States to have quality of care measures as approved or prescribed by the Secretary. Quality of care measures may focus on program standards, systems performance, and individual outcomes.

P. Section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects: Waiver Requirements (§430.25)

Section 2601 of the Affordable Care Act provides the opportunity for the Secretary to approve certain waivers for periods of up to 5 years. The proposed regulation includes an addition at §430.25(h)(2)(i) and §430.25(h)(2)(ii) to indicate the availability of extended approval periods for initial section 1915(c) waivers which are currently approved for 3-year periods (the renewals are already 5-year intervals), and for initial and renewal section 1915(b) waivers, which are currently approved for 2-year periods. In all cases, the extended approval period is only available for waivers that provide medical assistance to dual eligible individuals, and that meet all applicable statutory, regulatory, quality and programmatic requirements. The current §430.25(h)(2)(ii) also includes reference to section 1916 of the Act, which remains unchanged by the Affordable Care Act. As such, we have created a new §430.25(h)(2)(iii) to retain the original regulatory text specific to section 1916 of the Act.

Q. Prohibition Against Reassignment of Provider Claims (§447.10)

Under title XIX of the Act, State Medicaid programs generally can only pay for Medicaid-covered practitioner services through direct payments to the treating practitioners. States can develop payment rates that include considerations for costs related to health and welfare benefits, training, and other costs. Consistent with the statutory provision at

section 1902(a)(32) of the Act, and reflected in current regulations at §447.10, the entire rate must be paid to the individual practitioner who provided the service, unless certain statutory exceptions apply.

With respect to classes of practitioners for whom the State's Medicaid program is the only or primary payer, the ability of the State to ensure a stable and qualified workforce may be adversely affected by the inability to withhold funds and make payments on behalf of the individual practitioner for health and welfare benefit contributions, training costs, and other benefits customary for employees. Withholding funds for these purposes is an efficient and effective method for ensuring that the workforce has provision for basic needs and is adequately trained for their functions. Direct payment of funds to third parties on behalf of the practitioner may simplify program operations for the State and be viewed as advantageous by the practitioner. In addition, direct payment of funds to third parties on behalf of the practitioners may ensure that beneficiaries have greater access to such practitioners and higher quality services.

The statutory direct payment provision was intended to address the issue of factoring, and there is no indication that its purpose was to restrict State flexibility in investing in its workforce or quality improvement programs. In particular, we do not believe that the statutory direct payment provision addresses the unique circumstances that arise when the Medicaid program is the primary source of reimbursement for a class of practitioners.

We propose to interpret the scope of the direct payment provision to not include the circumstance when the Medicaid program operates as a primary payer for a class of practitioners, and assumes the ordinary responsibilities required in that circumstance to assure workforce stability and quality. This exception from the scope of the direct payment provision would be

limited to situations in which payment is made under a State law that authorizes payments on behalf of an individual practitioner to a third party for health and welfare benefit costs, training costs, or other benefits customary for employees. The legislative history of section 1902(a)(32) of the Act indicates that such a situation is not within the scope of “assignments” or “powers of attorney” that were considered at the time, or even of the same nature. Instead, such payments are more of an ordinary arrangement to further workforce stability and quality.

The proposed change would permit each State the option to elect such payment arrangements to the extent that the State determines that they would further State objectives; however, States would not be required to elect the payment arrangements. States will need to review their individual circumstances and workforce needs to determine if the measures would help ensure a stable, high-performing workforce for the benefit of the entire Medicaid population seeking the services.

Within broad Federal Medicaid law and regulation, CMS has long sought to ensure maximum State flexibility to design State-specific payment methodologies that help ensure a strong, committed, and well-trained work force. Currently, certain categories of Medicaid covered services, for which Medicaid is a primary payer, such as home health and personal care services, suffer from especially high rates of turnover and low levels of participation. This proposed rule would provide to States additional tools to help foster a stable and high-performing workforce. Medicaid programs would be able, as authorized under State law, to deduct from the practitioner’s reimbursement and remit to third parties amounts for health and welfare benefit contributions, training costs, and other benefits customary for employees.

We believe that permitting such payment arrangements would enhance the ability of the practitioners to perform their functions as health care professionals. The Medicaid program, at

both the State and Federal levels, has a strong interest in ensuring the development and maintenance of a committed, well-trained workforce.

We propose to provide States this flexibility by enumerating an additional exception to the payment limitations for individual practitioners at §447.10(g). Specifically, the proposed rule would add a new provision at §447.10(g)(4) to define permissible payments in the case of individual practitioners for whom the Medicaid program is the primary source of revenue to include payment authorized by State law to be made to a third party on behalf of the individual practitioner for health and welfare benefit contributions, training costs, and other benefits customary for employees.

To the extent that State laws require practitioners to participate in such a payment arrangement, a State could elect in its Medicaid State plan that the payment arrangement would be automatic. If, however, State law does not require participation by individual practitioners in such payment arrangements, but authorizes voluntary participation, the State would only be allowed to deduct amounts from the payment rate and forward them to a third party with the express permission of each individual practitioner. In that instance, the individual practitioner would need to authorize the payment arrangement on a voluntary basis, prior to any deduction from the provider payment. In either case, the amounts remitted to a third party would be on behalf of the individual practitioner.

As proposed, a State would not be able to claim as a separate expenditure under its approved Medicaid State plan amounts that are withheld from payments to individual practitioners for these cost categories (health and welfare benefit contributions, training, and similar benefits customary for employees). Under the proposed rule, should a State wish to recognize such costs, they would need to be included as part of the rate paid for the service in

order to eligible for Federal matching funds. No Federal matching funds would be available for such amounts apart from the Federal match available for rate paid by the State for the medical assistance service. These costs could not be claimed by the Medicaid agency separately as an administrative expense. As a result, the proposed rule would have little to no impact on Federal Medicaid funding levels.

We are specifically soliciting public comments on the extent to which the proposed payment arrangements would benefit States and practitioners, as well as any adverse impacts it may have that have not been anticipated. Additionally, we are seeking comments on other exceptions to the general prohibition on assignment of practitioner claims that might similarly simplify and streamline States' operations of their Medicaid plans and payment processes. Finally, we are specifically requesting comments on the intersection between Medicaid and Medicare regulations governing assignment of payments and any potential contradictions therein.

R. Section 2401 of the Affordable Care Act: Community First Choice State Plan Option: Home and Community-Based Setting Requirements (§441.530)

Section 1915(k)(1)(A)(ii) of the Act provides that a home and community-based setting does not include a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded. We propose at §441.530 to adopt this statutory language in our regulations. Additionally, to provide greater clarity, we are proposing language to establish that home and community-based settings must exhibit specific qualities to be eligible sites for delivery of home and community-based services.

IV. 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.

V. 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:

- A. ICRs Regarding Individuals Receiving State Plan Home and Community-based Services
(§435.219(b) and §436.219(b))

To cover the categorically needy eligibility group, the State would be required to submit a SPA and may elect to cover individuals who meet certain requirements in §435.219(a) or §436.219(a). The burden associated with this requirement is the time and effort put forth by the State to complete, review, process and transmit/submit the pre-print which describes the eligibility criteria for the group. We estimate it would take each State 30 hours to meet this one-time requirement. We estimate that on an annual basis, 3 States will submit a SPA to meet these requirements; therefore, the total annual burden hours for this requirement is 90 hours. We believe that a State employee, with pay equivalent to GS-13 step one (\$34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be \$1,030; this equates to an annual cost of \$3,091.

B. ICRs Regarding Eligibility for State Plan HCBS (§441.656)

If a State elects to target the benefit to specific populations, §441.656(b)(2) requires submission of targeting criteria to CMS. 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 10 hours to meet this one-time requirement. We estimate that on an annual basis, 3 States will submit a SPA to offer the State plan HCBS benefit that targets specific populations, and be affected by this requirement; therefore, the total annual burden hours for this requirement is 30 hours. We believe that a State employee, with pay equivalent to GS-13 step one (\$34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be \$343; this equates to an annual cost of \$1,030.

C. ICRs Regarding Needs-based Criteria and Evaluation (§441.659)

Section 441.659(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 SPA to offer the State plan HCBS benefit, and be affected by this one-time requirement; therefore, the total annual burden hours for this requirement is 72 hours. We believe that a State employee, with pay equivalent to GS-13 step one (\$34.34 per hour) would be responsible for this requirement. Thus, the cost for each responding State is anticipated to be \$824; this equates to an annual cost of \$2,472.

Section 441.659(b) reads that if a 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. Section 441.659(b)(1)(ii) requires the State to submit the more stringent criteria to CMS for inspection with the State plan amendment that establishes the State Plan HCBS benefit.

The burden associated with this requirement is the time and effort for the State to define the more stringent criteria and submit it to CMS along with the State plan amendment that establishes the HCBS benefit. We anticipate 3 States would be affected by this requirement on an annual basis and it would require 1 hour to prepare and submit this information. The one-time burden associated with this requirement is 3 hours. We believe that a State employee, with pay equivalent to GS-13 step one (\$34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be \$34; this equates to an annual cost of \$102. This would be a one time burden for each responding State.

Section 441.659(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 441.659(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 441.659(c)(2) requires the State notice to the Secretary be submitted as an amendment to the State plan.

The burden associated with the requirements found under §441.659(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 (§441.659(c), §441.659(c)(1), and §441.659(c)(2)) 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, thus there is no anticipated burden.

Section 441.659(d) states that eligibility for the State plan HCBS benefit is determined, for individuals who meet the requirements of §441.656(a)(1) through (5), through an independent evaluation of each individual that meets the specified requirements. Section 441.659(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 441.659(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. The individuals performing this assessment would vary based upon State benefit design, but will likely include individuals such as registered nurses, qualified mental retardation professionals, qualified mental health professionals, case managers, or other professional staff with experience providing services to individuals with disabilities or the elderly. While there is burden associated with this requirement, 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.

D. ICRs Regarding Independent Assessments (§ 441.662)

Section 441.662 requires the State to provide for an independent assessment of need in order to establish a service plan. At a minimum, the plan must meet the requirements as discussed under §441.665.

While the burden associated with the requirements under §441.662 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.

E. ICRs Regarding State Plan HCBS Administration: State Responsibilities and Quality Improvement (§441.677)

Section 441.677(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.

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 x 2 hours = 112 hours). We believe that a State employee, with pay equivalent to GS-13 step one (\$34.34 per hour) would be responsible for this requirement. Thus, the anticipated for each State is anticipated to be \$69; this equates to a maximum annual cost of \$3,864 if all 56 States elect to provide this benefit. There are currently six States with approved State plan HCBS benefits. Thus, we anticipate based on current benefits that the total annual aggregated burden will be \$414.

Section 441.677(a)(2)(iii) reads that the SPA 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. We believe that a State employee, with pay equivalent to GS-13 step one (\$34.34 per hour) would be responsible for this requirement. Thus, the cost to each State for each covered service is anticipated to be \$69; this would vary based upon the number of services covered. This would be an annual burden for each responding State. Since we have estimated

that 3 States will annually describe the reimbursement methodology, the total annual aggregated burden associated with this requirement is estimated to be \$207.

Section 441.677(a)(2)(iv) reads that the SPA 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 for each responding State. We believe that a State employee, with pay equivalent to GS-13 step one (\$34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be \$69.

Section 441.677(a)(2)(vi) limits the approval period for States that target the benefit to specific populations. If a State elects to target the benefit, this section requires a renewal application every 5 years in order to continue operation of the benefit. Actual time to meet this requirement will vary depending on the scope of the program and any changes the State includes. However, we estimate that it will take one State an average of 40 hours to meet this requirement. This includes reviewing the previous submission, making any necessary changes to the State plan document(s), and communicating with CMS regarding the renewal. This burden would occur once every five years and would be recurring. We estimate that, beginning in 2016, 3 States will annually request renewal and the total burden will be 120 hours. We believe that a State employee, with pay equivalent to GS-13 step one (\$34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be \$1,374; this equates to an

annual cost of \$4,122. This would be a burden for each State that targets its benefit once every 5 years; however, this burden will not take effect until 2016.

Section 441.677(b) requires States to develop and implement a 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, and make this information available to CMS upon the frequency determined by the Secretary or upon request.

The burden associated with this requirement is the time and effort put forth by the State to develop and implement a quality improvement strategy, and to make this information available to CMS upon the frequency determined by the Secretary or upon request. We estimate it will take one State 45 hours for the development of the strategy, and for making information available to CMS. 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 x 45 hours = 2,520 hours). We estimate that the burden associated with implementation of the quality improvement strategy will greatly vary, as the necessary time and effort to perform these activities is dependent upon the scope of the benefit and the number of persons receiving State plan HCBS. We believe that a State employee, with pay equivalent to GS-13 step one (\$34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be \$1,545; this equates to a maximum annual cost of \$86,537. Currently, there are six States with approved benefits, thus we anticipate an annual burden based on current States of \$9,270.

TABLE 1: Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response	Total Annual Burden	Hourly Labor Cost of	Total Labor Cost of	Total Capital/Maintenance	Total Cost (\$)
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				(hours)	(hours)	Reporting (\$)	Reporting (\$)	Costs (\$)	
435.219(b) and 436.219(b)	0938-1148	3	3	30	90	34.34	1,030	0	1,030
441.656(b)(2)	0938-1148	3	3	10	30	34.34	1,030	0	1,030
441.659(a)	0938-1148	3	3	24	72	34.34	2,472	0	2,472
441.659(b)	0938-1148	3	3	1	3	34.34	103	0	103
441.677(a)(1)(i)	0938-1148	6	6	2	12	34.34	414	0	414
441.677(a)(2)(iii)	0938-1148	3	3	2	6	34.34	207	0	207
441.677(a)(2)(iv)	0938-1148	3	3	2	6	34.34	207	0	207
441.677(b)	0938-1148	6	6	45	270	34.34	9,270	0	9,270
Total					489		14,733	0	14,733

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 have comments on these information collection and record keeping requirements, please do either of the following:

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

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-2249-P2.

Fax: (202) 395-5806; or Email: OIRA submission@omb.eop.gov.

VI. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct agencies to 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year). This proposed rule has been designated an “economically significant” rule under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

B. Statement of Need

The State plan HCBS benefit is authorized under section 1915(i) of the Act. Section 1915(i) was created by the Deficit Reduction Act of 2005 and was amended by the Affordable Care Act of 2010. The resulting statute provides States with authority to establish State plan HCBS benefits in their Medicaid program.

These regulations are necessary in order to include the State plan HCBS within the Code of Federal Regulations. Additionally, these regulations provide States with direction and clarity regarding the framework under which the programs can be established.

C. Overall Impacts

We estimate that, as a result of this proposed rule, the Medicaid cost impact for fiscal year (FY) 2012 would be \$80 million for the Federal share and \$60 million for the State share. The estimates are adjusted for a phase-in period during which States gradually elect to offer the State plan HCBS benefit.

D. Detailed Impacts

1. State Plan HCBS

State Medicaid programs will make use of the optional flexibility afforded by the State plan HCBS benefit to provide needed long-term care HCBS to eligible 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 most integrated 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, target the benefit to specific populations, and have the option to tighten needs-based criteria requirements if costs escalate too rapidly.

If States elect to include the new optional group, eligibility could be expanded because the group may include individuals who would not otherwise be eligible for Medicaid. However, 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 service plan, and the provision of needed HCBS in accordance with the individualized service plan, may discourage inappropriate utilization of costly services such as emergency room care for routine procedures, which may be beneficial to Medicare and Medicaid when individuals are eligible for both programs. If a State targets this benefit, only individuals who meet the targeting criteria would receive 1915(i) services and be eligible for the group, thus limiting Medicaid expansion.

After considering these factors, we assumed that, if all States adopted this measure, program expenditures would increase by 1 percent of current HCBS expenditure projections.

We further assumed that ultimately, States representing 50 percent of the eligible population would elect to offer this benefit, and that this ultimate level would be reached in FY 2014, with a phase-in period until then. Based on these assumptions, the Federal and State cost estimates are shown in Table 2.

TABLE 2: Medicaid Cost Estimates Resulting From Changes to the State Plan HCBS Benefit (FYs 2012-2016, in \$Millions)

	FY12	FY13	FY14	FY15	FY16
Federal Share	\$80	\$120	\$170	\$190	\$215
State Share	\$60	\$90	\$125	\$145	\$160

The effect on Medicaid beneficiaries who receive the State plan HCBS benefit will be substantial and beneficial in States where optional 1915(i) State plan HCBS are included, as it will provide eligible individuals with the opportunity to receive needed long-term care services and supports in their homes and communities.

The State plan HCBS benefit will afford business opportunities for providers of the HCBS. We do not anticipate any effects on other providers. Section 1915(i) of the Act delinks the HCBS from institutional LOC, and requires that eligibility criteria for the benefit include a threshold of need less than that for institutional LOC, 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.

This rule has no direct effect on the Medicare program; however, an indirect and beneficial effect may occur if individuals eligible for both Medicare and Medicaid are enrolled in a State plan HCBS program.

E. 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. We solicit comment on the analysis within the “Alternatives Considered” section.

Alternatives to this proposed rule include:

(1) Not Publishing a Rule: Section 1915(i) of the Act was effective January 1, 2007. States may propose SPAs 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 a State plan 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 an SPA.

We conclude that section 1915(i) of the Act establishes significant new features in the Medicaid program, and that it was important to provide States and the public 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 part 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 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.

F. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in the Table 3, we have prepared an accounting statement showing the classification of the transfers associated with the provisions of this proposed rule. This table provides our best estimate of the proposed increase in aggregate Medicaid outlays resulting from offering States the option to provide the State plan HCBS benefit established in section 1915(i) of the Act and proposed by CMS-2249-P (Medicaid

program; Home and Community-Based State Plan Services).

TABLE 3: Accounting Statement: Classification of Estimated Transfers, from FYs 2012 to 2016 (in \$Millions)

Category	TRANSFERS	
Annualized Monetized Transfers	3% Units Discount Rate \$153.0	7% Units Discount Rate \$150.4
From Whom To Whom?	Federal Government to Providers	
Category	TRANSFERS	
Other Annualized Monetized Transfers	3% Units Discount Rate \$114.5	7% Units Discount Rate \$112.5
From Whom To Whom?	State Governments to Providers	

G. 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 promote efficient and effective use of Medicaid expenditures for these services.

VII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), as modified by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104-121), requires agencies to determine whether proposed or final rules would have a significant economic impact on a substantial number of small entities and, if so, to prepare a Regulatory

Flexibility Analysis and to identify in the notice of proposed rulemaking or final rulemaking any regulatory options that could mitigate the impact of the proposed regulation on small businesses. For purposes of the RFA, small entities include businesses that are small as determined by size standards issued by the Small Business Administration, nonprofit organizations, and small governmental jurisdictions). Individuals and States are not included in the definition of a small business entity.

For purposes of the RFA, we assume that approximately 75 percent of Medicaid providers are considered small businesses according to the Small Business Administration's size standards (with total revenues of \$35 million or less in any one year), and 80 percent are nonprofit organizations. Medicaid providers are required, as a matter of course, to follow the guidelines and procedures as specified in State and Federal laws and regulations. Furthermore, 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 will have a business opportunity under this proposed rule. The Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security 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 metropolitan statistical area and has fewer than 100 beds. This proposed rule does not offer a change in the administration of the provisions related to small rural hospitals.

Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

VIII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately \$139 million. This proposed rule does not mandate any spending by State, local, or tribal governments, in the aggregate, or by the private sector, of \$139 million.

IX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) 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.

List of Subjects42 CFR Part 430

Administrative practice and procedure, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 431

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

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income, Wages.

42 CFR Part 436

Aid to Families with Dependent Children, Grant programs-health, Guam, Medicaid Puerto Rico, Supplemental Security Income (SSI), Virgin Islands

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 441

Aged, Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas

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 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation for part 430 continues to read as follows:

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

Subpart B—State Plans

2. Section 430.25 is amended by--

A. Revising paragraphs (h)(2)(i) and (ii).

B. Adding paragraph (h)(2)(iii).

The revisions and addition read as follows:

§430.25 Waivers of State plan requirements.

* * * * *

(h) * * *

(2) Duration of waivers. (i) Home and community-based services under section 1915(c) of the Act. The initial waiver is for a period of 3 years and may be renewed thereafter for periods of 5 years. For waivers that include individuals who are dually eligible for Medicare and Medicaid, 5-year initial approval periods may be granted at the discretion of the Secretary for waivers meeting all necessary programmatic, financial and quality requirements.

(ii) Waivers under section 1915(b) of the Act. The initial waiver is for a period of 2 years and may be renewed for additional periods of up to 2 years as determined by the Administrator. For waivers that include individuals who are dually eligible for Medicare and Medicaid, 5-year initial and renewal approval periods may be granted at the discretion of the Secretary for waivers meeting all necessary programmatic, financial and quality requirements.

(iii) Waivers under section 1916 of the Act. The initial waiver is for a period of 2 years and may be renewed for additional periods of up to 2 years as determined by the Administrator.

* * * * *

PART 431--STATE ORGANIZATION AND GENERAL ADMINISTRATION

3. 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

4. Section 431.54 is amended by adding paragraphs (a)(3) and (h) to read as follows:

§431.54 Exceptions to certain State plan requirements

(a) * * *

(3) Section 1915(i) of the Act provides that a State may provide, as medical assistance, home and community-based services under an approved State plan amendment that meets certain requirements, without regard to the requirements of sections 1902(a)(10)(B) and 1902(a)(10)(C)(i)(III) of the Act, with respect to such services.

* * * * *

(h) State plan home and community-based services. The requirements of §440.240 of this chapter related to comparability of services do not apply with respect to State plan home and community-based services defined in §440.182 of this chapter.

PART 435--ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

5. The authority citation for part 435 continues to read as follows:

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

Subpart C—Options for Coverage

6. Section 435.219 is added to subpart C to read as follows:

§435.219 Individuals receiving State plan home and community-based services.

If the agency provides home and community-based services to individuals described in section 1915(i)(1), the agency, under its State plan, may, in addition, provide Medicaid to any group or groups of individuals in the community who are described in one or both of the paragraphs under paragraphs (a) or (b) of this section.

(a) Individuals who--

(1) Are not otherwise eligible for Medicaid;

(2) Have income that does not exceed 150 percent of the Federal poverty line (FPL);

(3) Meet the needs-based criteria under §441.659 of this chapter; and

(4) Will receive State plan home and community-based services as defined in §440.182 of this chapter.

(b) Individuals who--

(1) Would be determined eligible by the agency under an existing waiver or demonstration project under sections 1915(c), 1915(d), 1915(e) or 1115 of the Act, but are not required to receive services under such waivers or demonstration projects;

(2) Have income that does not exceed 300 percent of the Supplemental Security Income Federal Benefit Rate (SSI/FBR); and

(3) Will receive State plan home and community-based services as defined in §440.182 of this chapter.

(c) For purposes of determining eligibility under paragraph (a) of this section, the agency may not take into account an individual's resources and must use income standards that are reasonable, consistent with the objectives of the Medicaid program, simple to administer, and in

the best interests of the beneficiary. Income methodologies may include use of existing income methodologies, such as the SSI program rules. However, subject to the Secretary's approval, the agency may use other income methodologies that meet the requirements of this paragraph (c).

PART 436--ELIGIBILITY IN GUAM, PUERTO RICO AND THE VIRGIN ISLANDS

7. The authority citation for part 436 continues to read as follows:

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

Subpart C—Options for Coverage

8. Section 436.219 is added to subpart C to read as follows:

§436.219 Individuals receiving State plan home and community-based services.

If the agency provides home and community-based services to individuals described in section 1915(i)(1) of the Act, the agency, under its State plan, may, in addition, provide Medicaid to any group or groups of individuals in the community who are described in one or both of paragraphs (a) or (b) of this section.

(a) Individuals who--

(1) Are not otherwise eligible for Medicaid;

(2) Have income that does not exceed 150 percent of the Federal poverty line (FPL);

(3) Meet the needs-based criteria under §441.659 of this chapter; and

(4) Will receive State plan home and community-based services as defined in §440.182 of this chapter.

(b) Individuals who--

(1) Would be determined eligible by the agency under an existing waiver or demonstration project under sections 1915(c), 1915(d), 1915(e) or 1115 of the Act, but are not required to receive services under such waivers or demonstration projects;

(2) Have income that does not exceed 300 percent of the Supplemental Security Income Federal Benefit Rate (SSI/FBR); and

(3) Will receive State plan home and community-based services as defined in §440.182 of this chapter.

(c) For purposes of determining eligibility under paragraph (a) of this section, the agency may not take into account an individual's resources and must use income standards that are reasonable, consistent with the objectives of the Medicaid program, simple to administer, and in the best interests of the beneficiary. Income methodologies may include use of existing income methodologies, such as the rules of the OAA, AB, APTD or AABD programs. However, subject to the Secretary's approval, the agency may use other income methodologies that meet the requirements of this paragraph (c).

PART 440 SERVICES: GENERAL PROVISIONS

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

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

Subpart A—Definitions

10. Section 440.1 is amended by adding the new statutory basis in alphanumerical order to read as follows:

§440.1 Basis and purpose.

* * * * *

1915(i) Home and community-based services furnished under a State plan to elderly and disabled individuals.

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

§440.180 Home and community-based waiver services.

* * * * *

12. Section 440.182 is added to subpart A to read as follows:

§440.182 State plan home and community-based services.

(a) Definition. State plan home and community-based services (HCBS) benefit means the services listed in paragraph (c) of this section when provided under the State's plan (rather than through an HCBS waiver program) for individuals described in paragraph (b) of this section.

(b) State plan HCBS coverage. State plan HCBS can be made available to individuals who--

(1) Are eligible under the State plan and have income, calculated using the otherwise applicable rules, including any less restrictive income disregards used by the State for that group under section 1902(r)(2) of the Act, that does not exceed 150 percent of the Federal Poverty Line (FPL); and

(2) In addition to the individuals described in paragraph (b)(1) of this section, to individuals based on the State's election of the eligibility groups described in §435.219(b) or §436.219(b) of this chapter.

(c) Services. The State plan HCBS benefit consists of one or more of the following services:

- (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) of this subpart.

(7) Respite care services.

(8) Subject to the conditions in §440.180 of this subpart, 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).

(9) Other services requested by the agency and approved by the Secretary as consistent with the purpose of the benefit.

(d) Exclusion. FFP is not available for the cost of room and board in State plan HCBS.

The following HCBS costs are not considered room or board for purposes of this exclusion:

(1) The cost of temporary food and shelter provided as an integral part of respite care services in a facility approved by the State.

(2) Meals provided as an integral component of a program of adult day health services or another service and consistent with standard procedures in the State for such a program.

(3) A portion of the rent and food costs 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

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

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

14. Section 441.530 is added to read as follows:

§441.530 Home and Community-Based Setting.

(a) States must make available attendant services and supports in a home and community-based setting consistent with both paragraphs (a)(1) and (2) of this section.

(1) Home and community-based settings shall have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in, and facilitates the individual's full access to, the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, in the same manner as individuals without disabilities.

(ii) The setting is selected by the individual from among all available alternatives and is identified in the person-centered service plan.

(iii) An individual's essential personal rights of privacy, dignity and respect, and freedom from coercion and restraint are protected.

(iv) Individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact are optimized and not regimented.

(v) Individual choice regarding services and supports, and who provides them, is facilitated.

(vi) In a provider-owned or controlled residential setting, the following additional conditions must be met. Any modification of the conditions, for example, to address the safety

needs of an individual with dementia, must be supported by a specific assessed need and documented in the person-centered service plan:

(A) The unit or room is a specific physical place that can be owned, rented or occupied under another legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord tenant law of the State, county, city or other designated entity;

(B) Each individual has privacy in their sleeping or living unit:

(1) Units have lockable entrance doors, with appropriate staff having keys to doors;

(2) Individuals share units only at the individual's choice; and

(3) Individuals have the freedom to furnish and decorate their sleeping or living units.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;

(D) Individuals are able to have visitors of their choosing at any time; and

(E) The setting is physically accessible to the individual.

(2) Home and community-based settings do not include the following:

(i) A nursing facility;

(ii) An institution for mental diseases;

(iii) An intermediate care facility for the mentally retarded;

(iv) A hospital providing long-term care services; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. The Secretary will apply a rebuttable presumption that a setting is not a home and community-based setting, and engage in heightened scrutiny, for any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional

treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or disability-specific housing complex.

15. A new subpart L, consisting of §§441.650 through 441.677, is added to read as follows:

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

Individuals

Sec.

441.650 Basis and purpose.

441.653 State plan requirements.

441.656 State plan home and community-based services under the Act.

441.659 Needs-based criteria and evaluation.

441.662 Independent assessment.

441.665 Person-centered service plan.

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441.671 Definition of individual's representative.

441.674 Self-directed services.

441.677 State plan HCBS administration: State responsibilities and quality improvement.

Subpart L State Plan Home and Community-Based Services for the Elderly and

Individuals with Disabilities

§441.650 Basis and purpose.

Section 1915(i) of the Act permits States to offer one or more home and community-based services (HCBS) under their State Medicaid plans to qualified individuals with disabilities or individuals who are elderly. 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 when the State elects to include the optional benefit, and defines State responsibilities.

§441.653 State plan requirements.

A State plan that provides 1915(i) State plan home and community-based services must meet the requirements of this subpart.

§441.656 State plan home and community-based services under the Act.

(a) Home and Community-Based Setting. Under section 1915(i)(1) of the Act, States must make State plan HCBS available in a home and community-based setting consistent with both paragraphs (a)(1) and (2) of this section.

(1) Home and community-based settings shall have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in, and facilitates the individual's full access to, the greater community including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, in the same manner as individuals without disabilities.

(ii) The setting is selected by the individual from among all available alternatives and is identified in the person-centered service plan.

(iii) An individual's essential personal rights of privacy, dignity and respect, and freedom from coercion and restraint are protected.

(iv) Individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact are

optimized and not regimented.

(v) Individual choice regarding services and supports, and who provides them, is facilitated.

(vi) In a provider-owned or controlled residential setting, the following additional conditions must be met. Any modification of the conditions, for example, to address the safety needs of an individual with dementia, must be supported by a specific assessed need and documented in the person-centered service plan:

(A) The unit or room is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord/tenant law of the State, county, city, or other designated entity;

(B) Each individual has privacy in their sleeping or living unit:

(1) Units have lockable entrance doors, with appropriate staff having keys to doors;

(2) Individuals share units only at the individual's choice; and

(3) Individuals have the freedom to furnish and decorate their sleeping or living units.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;

(D) Individuals are able to have visitors of their choosing at any time; and

(E) The setting is physically accessible to the individual.

(2) Home and community-based settings do not include the following:

(i) A nursing facility;

(ii) An institution for mental diseases;

(iii) An intermediate care facility for the mentally retarded;

(iv) A hospital; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. The Secretary will apply a rebuttable presumption that a setting is not a home and community-based setting, and engage in heightened scrutiny, for any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or disability-specific housing complex.

(b) Needs-Based Eligibility Requirement. Meet needs-based criteria for eligibility for the State plan HCBS benefit, as required in §441.659(a).

(c) Minimum State plan HCBS Requirement. Be assessed to require at least one section 1915(i) home and community-based service at a frequency determined by the State, as required in §441.662(a)(5).

(d) Target Population. Meet any applicable targeting criteria defined by the State under the authority of paragraph (b)(2) of this section.

(e) Nonapplication. The State may elect in the State plan amendment approved under this subpart not to apply the following requirements when determining eligibility:

(1) 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.

(2) Section 1902(a)(10)(B) of the Act, pertaining to comparability of Medicaid services, but only for the purposes of providing section 1915(i) State plan HCBS. In the event that a State elects not to apply comparability requirements:

(i) The State must describe the group(s) receiving State plan HCBS, subject to the Secretary's approval. Targeting criteria cannot have the impact of limiting the pool of qualified providers from which an individual would receive services, or have the impact of requiring an individual to receive services from the same entity from which they purchase their housing. These groups must be defined on the basis of any combination of--

- (A) Age;
- (B) Diagnosis;
- (C) Disability; or
- (D) Medicaid Eligibility Group.

(ii) The State may elect in the State plan amendment to limit the availability of specific services defined under the authority of §440.182(b) or to vary the amount, duration, or scope of those services, to one or more of the group(s) described in this paragraph.

§441.659 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. Needs-based criteria are factors used to determine an individual's requirements for support, and may include risk factors. 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.

(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))

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 for which the State has established long-term level of care (LOC) 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, it may not have the effect of limiting who can benefit from the State plan HCBS in an unreasonable way, as determined by the Secretary.

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

(i) Be included in the LOC 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 LOC criteria to meet the requirements under paragraph (b) or (c)(7) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, States may continue to receive FFP for individuals receiving institutional services or waiver HCBS under the LOC criteria previously in effect.

(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 for the State plan HCBS benefit are less stringent than needs-based institutional and waiver LOC 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 until such time as:
 - (i) The individual no longer meets the needs-based criteria used for the initial determination of eligibility; or
 - (ii) The individual is no longer eligible for or enrolled in Medicaid or the HCBS benefit.
- (5) 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.
- (6) In the event that the State also needs to modify institutional LOC 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 LOC criteria under this adjustment authority. The adjusted institutional LOC 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 §441.656(a)(1) through (5) of this subpart. The independent evaluation complies with the following requirements:

(1) Is performed by an agent that is independent and qualified as defined in §441.668 of this subpart.

(2) Applies the needs-based eligibility criteria that the State has established under paragraph (a) of this section, and the general eligibility requirements under §441.656(a)(1) through (3) and (b)(2) of this subpart.

(3) Includes consultation with the individual, and if applicable, the individual's authorized representative.

(4) Assesses the individual's 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 of this chapter 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.

§441.662 Independent assessment.

(a) Requirements. For each individual determined to be eligible for the State plan HCBS benefit, the State must provide for an independent assessment of needs, which may include the results of a standardized functional needs assessment, in order to establish a service plan. In applying the requirements of section 1915(i)(1)(F) of the Act, the State must:

(1) Perform a face-to-face assessment of the individual by an agent that is independent and qualified as defined in §441.668 of this subpart and with a person-centered process guided by best practice and research on effective strategies that result in improved health and quality of life outcomes.

(i) For the purposes of this section, a face-to-face assessment may include assessments performed by telemedicine, or other information technology medium, if the following conditions are met:

(A) The health care professional(s) performing the assessment meets the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology.

(B) The individual receives appropriate support during the assessment, including the use of any necessary on-site support-staff.

(C) The individual provides informed consent for this type of assessment.

(ii) [Reserved]

(2) Conduct the assessment in consultation with the individual, and if applicable, the individual's authorized representative, and include the opportunity for the individual to identify other persons to be consulted, such as, but not limited to, the individual's spouse, family, guardian, and treating and consulting health and support professionals responsible for the individual's care.

(3) Examine the individual's relevant history including the findings from the independent evaluation of eligibility, medical records, an objective evaluation of functional ability, and any other records or information needed to develop the service plan as required in §441.665 of this subpart.

(4) Include in the assessment the individual's physical and behavioral health care and support needs, strengths and preferences, available service and housing options, and when unpaid caregivers will be relied upon to implement the service plan, a caregiver assessment.

(5) 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 and receive at least one home and community-based service offered under the State plan for medical assistance.

(6) Include in the assessment, if the State offers individuals the option to self-direct a State plan home and community-based service or services, any information needed for the self-directed portion of the service plan, as required in §441.674(b) of this subpart, including the ability of the individual (with and without supports) to exercise budget or employer authority.

(7) Include in the assessment, 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 Education Improvement Act of 2004.

(8) Include in the assessment and subsequent service plan, for individuals receiving Secretary approved services under the authority of §440.182 of this chapter, documentation that

no State plan HCBS services are provided which would otherwise be available to the individual through other Medicaid services or other Federally funded programs.

(9) Include in the assessment and subsequent service plan, for individuals receiving HCBS through a waiver approved under §441.300 of this subpart, documentation that HCBS provided through the State plan and waiver are not duplicative.

(10) Coordinate the assessment and subsequent service plan with any other assessment or service plan required for services through a waiver authorized under section 1115 or section 1915 of the Social Security Act.

(b) Reassessments. 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 service plan.

§441.665 Person-centered service plan.

(a) Person-centered planning process. Based on the independent assessment required in §441.662 of this subpart, the State must develop (or approve, if the plan is developed by others) a written service plan 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 is driven by the individual. The process:

- (1) Includes people chosen by the individual.
- (2) Provides necessary information and support to ensure that the individual directs the process to the maximum extent possible, and is enabled to make informed choices and decisions.
- (3) Is timely and occurs at times and locations of convenience to the individual.
- (4) Reflects cultural considerations of the individual.
- (5) Includes strategies for solving conflict or disagreement within the process, including

clear conflict-of-interest guidelines for all planning participants.

(6) Offers choices to the individual regarding the services and supports they receive and from whom.

(7) Includes a method for the individual to request updates to the plan.

(8) Records the alternative home and community-based settings that were considered by the individual.

(b) The person-centered service plan. The person-centered service plan must reflect the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports. Commensurate with the level of need of the individual, and the scope of services and supports available under the State plan HCBS benefit, the plan must:

(1) Reflect that the setting in which the individual resides is chosen by the individual.

(2) Reflect the individual's strengths and preferences.

(3) Reflect clinical and support needs as identified through an assessment of functional need.

(4) Include individually identified goals and desired outcomes.

(5) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and the providers of those services and supports, including natural supports. Natural supports cannot supplant needed paid services unless the natural supports are unpaid supports that are provided voluntarily to the individual in lieu of State plan HCBS.

(6) Reflect risk factors and measures in place to minimize them, including Individualized backup plans.

(7) Be understandable to the individual receiving services and supports, and the individuals important in supporting him or her.

(8) Identify the individual and/or entity responsible for monitoring the plan.

(9) Be finalized and agreed to in writing by the individual and signed by all individuals and providers responsible for its implementation.

(10) Be distributed to the individual and other people involved in the plan.

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

(12) Prevent the provision of unnecessary or inappropriate care.

(13) Other requirements as determined by the Secretary.

(c) Reviewing the person-centered service plan. The person-centered service plan must be reviewed, and revised upon reassessment of functional need as required in §441.662 of this subpart, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual.

§441.668 Provider qualifications.

(a) Requirements. 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 standards for providers (both agencies and individuals) of HCBS services and for agents conducting individualized independent evaluation, independent assessment, and service plan development.

(b) Conflict of interest standards. 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) the independent evaluation of eligibility for State plan HCBS, who

are responsible for the independent assessment of need for HCBS, or who are responsible for the development of the service plan. 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) Holding financial interest, as defined in §411.354 of this chapter, in any entity that is paid to provide care for the individual.
- (5) 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 State demonstrates that 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, and individuals are provided with a clear and accessible alternative dispute resolution process.

(c) Training. 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.

§441.671 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.

(c) When the State authorizes representatives in accordance with paragraph (b) of this section, the State must have policies describing the process for authorization; the extent of decision-making authorized; and safeguards to ensure that the representative functions in the best interests of the participant. States may not refuse the authorized representative that the individual chooses, unless in the process of applying the requirements for authorization, the State discovers and can document evidence that the representative is not acting in the best interest of the individual or cannot perform the required functions.

§441.674 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 §441.671 of this subpart.

(b) Service plan requirement. Based on the independent assessment required in §441.662 of this subpart, the State develops a service plan jointly with the individual as required

in §441.665 of this subpart. If the individual chooses to direct some or all HCBS, the service plan must meet the following additional requirements:

- (1) Specify the State plan HCBS that the individual will be responsible for directing.
 - (2) 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 and/or authority over expenditures from the individualized budget.
 - (3) Include appropriate risk management techniques that explicitly 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.
 - (4) Describe the process for facilitating voluntary and involuntary transition from self-direction including any circumstances under which transition out of self-direction is involuntary.
- (c) Employer authority. If the service plan 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 service plan 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 service plan.

(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 offer the following individualized 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.

§441.677 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.

(ii) Access to services. The State must grant access to all State plan HCBS assessed to be needed in accordance with a service plan consistent with §441.665 of this subpart, to individuals who have been determined to be eligible for the State plan HCBS benefit, subject to the following requirements:

(A) A State must determine that provided services meet medical necessity criteria;

(B) A State may limit access to services through targeting criteria established by §441.656(b)(2) of this subpart; and

(C) A State may not limit access to services based upon the income of individuals, the cost of services, or the individual's location in the State.

(iii) Appeals. A State must provide individuals with the right to appeal terminations, suspensions, or reductions of Medicaid eligibility or covered services as described in part 431, subpart E.

(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 for both services that meet the definition of medical assistance and necessary administrative expenditures for evaluation of eligibility for the State plan HCBS benefit under §441.659(d) of this subpart and assessment of need for specific HCBS under §441.662(a) of this subpart, 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 and is evaluated and assessed under the presumptive payment option and found not to be eligible for the benefit, FFP is available for services that meet the definition of medical assistance and necessary administrative expenditures. 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) Option for Phase-in of Services and Eligibility. (A) In the event that a State elects to establish targeting criteria through §441.656(b)(2) of this subpart, the State may limit the enrollment of individuals or the provision services to enrolled individuals based upon criteria described in a phase-in plan, subject to CMS approval. A State which elects to target the State plan HCBS benefit and to phase-in enrollment and/or services must submit a phase-in plan for approval by CMS that describes, at a minimum:

- (1) The criteria used to limit enrollment or service delivery;
- (2) The rationale for phasing-in services and/or eligibility; and
- (3) Timelines and benchmarks to ensure that the benefit is available statewide to all eligible individuals within the initial 5-year approval.

(B) If a State elects to phase-in the enrollment of individuals based on highest need, the phase-in plan must use the needs-based criteria described in §441.659(a) of this subpart to establish priority for enrollment. Such criteria must be based upon the assessed need of individuals, with higher-need individuals receiving services prior to individuals with lower assessed need.

(C) If a State elects to phase-in the provision of any services, the phase-in plan must include a description of the services that will not be available to all eligible individuals, the rationale for limiting the provision of services, and assurance that all individuals with access to a willing and qualified provider may receive services.

(D) The plan may not include a cap on the number of enrollees.

(E) The plan must include a timeline to assure that all eligible individuals receive all included services prior to the end of the first 5-year approval period, described in paragraph (a)(2)(vi) of this section.

(iii) 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.

(iv) 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.

(v) Modifications. The agency may request that modifications to the benefit be made effective retroactive to the first day of a fiscal year quarter, or another date after the first day of a fiscal year quarter, in which the amendment is submitted, unless the amendment involves substantive change. Substantive changes may include, but are not limited to, the following:

(A) Revisions to services available under the benefit including elimination or reduction in services, and changes in the scope, amount and duration of the services.

(B) Changes in the qualifications of service providers, rate methodology, or the eligible population.

(1) Request for Amendments. A request for an amendment that involves a substantive change as determined by CMS--

(i) May only take effect on or after the date when the amendment is approved by CMS; and

(ii) Must be accompanied by information on how the State will ensure for transitions with minimal adverse impact on individuals impacted by the change.

(2) [Reserved]

(vi) Periods of approval. (A) If a State elects to establish targeting criteria through §441.656(b)(2) of this subpart, the approval of the State Plan Amendment will be in effect for a period of 5 years from the effective date of the amendment. To renew State plan HCBS for an additional 5-year period, the State must provide a written request for renewal to CMS at least 180 days prior to the end of the approval period. CMS approval of a renewal request is contingent upon State adherence to Federal requirements.

(B) If a State does not elect to establish targeting criteria through §441.656(b)(2) of this subpart, the limitations on length of approval does not apply.

(b) Quality improvement strategy: Program performance and quality of care. States must develop and implement an HCBS quality improvement strategy that includes a continuous improvement process and measures of program performance and experience of care. The strategy must be proportionate to the scope of services in the State plan HCBS benefit and the number of individuals to be served. The State will make this information available to CMS at a frequency determined by the Secretary or upon request.

(1) Quality Improvement Strategy. The quality improvement strategy must include all of the following:

(i) Incorporate a continuous quality improvement process that includes monitoring, remediation, and quality improvement.

(ii) Be evidence-based, and include measures as determined by the Secretary.

(iii) Provide evidence of program performance and the establishment of sufficient infrastructure to effectively implement the program.

(iv) Measure individual outcomes associated with the receipt of HCBS, related to the implementation of goals included in the individual service plan.

(2) [Reserved]

PART 447—PAYMENTS FOR SERVICES

16. The authority citation for part 447 continues to read as follows:

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

17. Section 447.10 is amended by adding paragraph (g)(4) to read as follows:

§447.10 Prohibition Against Reassignment of Provider Claims

(g) * * *

(4) In the case of a class of practitioners for which the Medicaid program is the primary source of revenue, payment may be made to a third party on behalf of the individual practitioner for benefits such as health insurance, skills training and other benefits customary for employees.

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CMS-2249-P2

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

Dated: April 24, 2012.

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: April 24, 2012.

Kathleen Sebelius,

Secretary.

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