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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

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RIN 0938–AO53; 0938–AP61

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

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

ACTION: Final rule.

SUMMARY: This final rule amends the Medicaid regulations to define and describe state plan section 1915(i) home and community-based services (HCBS) under the Social Security Act (the Act) amended by the Affordable Care Act. This rule offers states new flexibilities in providing necessary and appropriate services to elderly and disabled populations. This rule describes Medicaid coverage of the optional state plan benefit to furnish home and community based-services and draw federal matching funds.

This rule also provides for a 5-year duration for certain demonstration projects or waivers at the discretion of the Secretary, when they provide medical assistance for individuals dually eligible for Medicaid and Medicare benefits, includes payment reassignment provisions because state Medicaid programs often operate as the primary or only payer for the class of practitioners that includes HCBS providers, and amends Medicaid regulations to provide home and community-based setting requirements related to the Affordable Care Act for Community First Choice State plan option. This final rule also makes several important changes to the regulations implementing Medicaid 1915(c) HCBS waivers.

DATES: *Effective Date:* These regulations are effective on March 17, 2014.

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Acronyms

Because of the many terms to which we refer by acronym in this final 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
- HCB Home and community based
- HCBS Home and Community-Based Services
- HHS Department of Health and Human Services
- IADLs Instrumental activities of daily living
- ICF/IID Intermediate care facility for individuals with intellectual disabilities
- 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 final rule amends 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 provide medical assistance to individuals who are dually eligible for both Medicaid and Medicare benefits.

This final rule also provides 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 will 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, because states' Medicaid programs often operate as the primary or only payer for the class of practitioners that includes HCBS providers.

In addition, this final rule also amends Medicaid regulations to provide home and community-based setting requirements related to section 2401 of the Affordable Care Act for section

1915(k) of the Act, the Community First Choice State plan option.

This final rule further amends 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 final rule also revises the regulations implementing Medicaid home and community-based services (HCBS) waivers under section 1915(c) of the Social Security Act (the Act) by providing states the option to combine the existing three waiver targeting groups identified in § 441.301. In addition, this final rule will include other changes to the HCBS waiver provisions to convey expectations regarding person-centered plans of care, to provide characteristics of settings that are home and community-based as well as settings that may not be home and community-based, to clarify the timing of amendments and public input requirements when states propose modifications to HCBS waiver programs and service rates, and to describe the additional strategies available to CMS to ensure state compliance with the statutory provisions of section 1915(c) of the Act. The final rule also includes requirements for person-centered plans of care that document, among other things, an individual's choice of a HCB setting from among options that meet the individual's needs.

B. Summary of the Major Provisions

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

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 the April 4, 2008, **Federal**

Register, (73 FR 18676) 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 final rule also establishes home and community-based setting requirements. We will allow states a transition/phase-in period for current approved 1915(i) State plan HCBS to demonstrate compliance with these requirements.

2. 5-Year Period for Certain Demonstration Projects and Waivers

This final rule provides for a 5-year approval or renewal period, subject to the discretion of the Secretary, for certain Medicaid waivers. Specifically, this time period applies 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 proposed 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 proposed 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. Community First Choice State Plan Option: Home and Community-Based Setting Requirements (Section 1915(k) of the Act)

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 individuals with intellectual disabilities. We have adopted this statutory language in our regulations. Additionally, to provide greater clarity, we have established 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 in the **Federal Register** (76 FR 10736) 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 this final rule. The public comment process has been valuable in assisting us to develop the best policy on this issue for Medicaid beneficiaries. We have fully considered all comments received, and have aligned the requirements pertaining to home and community-based settings across CFC, section 1915(i) State plan HCBS, and section 1915(c) of the Act HCBS waivers.

5. Home and Community Based Services Waivers (Section 1915(c) of the Act)

Section 1915(c) of the Act authorizes the Secretary of Health and Human Services to waive certain Medicaid statutory requirements so that a state may offer Home and Community-Based Services (HCBS) to state-specified group(s) of Medicaid beneficiaries who otherwise would require services at an

institutional level of care. This final rule will give states the option to combine the existing three waiver targeting groups as identified in § 441.301. In addition, it will implement requirements regarding person-centered service plans, clarify the timing of amendments when states modify HCBS waiver programs and service rates, and describe the additional strategies available to us to ensure state

compliance with the provisions of section 1915(c) of the Act. This final rule also establishes home and community-based setting requirements. We will allow states a transition/phase-in period for current approved 1915(c) HCBS waivers to demonstrate compliance with these requirements.

C. Summary of Costs, Benefits and Transfers

Provision description	Total costs	Total benefits	Total transfers
1915(i) State Plan Home Community-Based Services.	The estimated total annual collection of information requirements cost to states is \$21,805..	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..	We estimate that, adjusted for a phase-in period during which states gradually elect to offer the state plan HCBS benefit, in FY 2014 the federal cost would be \$150 million, and the estimated state cost would be \$115million. (Some portion of these impacts would actually be societal costs rather than “transfers”, to the extent that new users of the HCBS in this rule are previously not receiving services.)
Section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects (Waivers).	N/A	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..	No impact on federal or state Medicaid funding. This rule is voluntary on the part of states.
Provider Payment Re-assignments.	N/A	This rule implements additional operational flexibilities for states to help ensure a strong provider workforce..	We do not anticipate any impact on federal Medicaid funding. This rule is voluntary on the part of states.
Section 2401 of the Affordable Care Act: Community First Choice State Plan Option: Home and Community-Based Setting Requirements.	N/A	This rule provides 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 HCBS in a manner that allows for integration with the greater community..	We do not anticipate 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.
1915(c) Home and Community-Based Services Waivers.	States may incur costs in coming into compliance with this rule. Given the variability in state programs, and the varying extent to which some are already complying, it is difficult to estimate these costs..	These changes will support beneficiaries by enabling services to be planned and delivered in a manner driven by the beneficiary and will maximize opportunities for beneficiaries to have access to the benefits of community living and receive services in the most integrated setting. These changes will also enable states to realize administrative and program design simplification and improve efficiency of operation..	We do not anticipate any impact on federal Medicaid funding.

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

A. Background

On February 8, 2006, the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109–171) was signed into law. Section 6086 of the DRA is entitled “Expanded Access to Home and Community-Based Services for the Elderly and Disabled.” Section 6086(a) of the DRA adds a new section 1915(i) to the Act that allows

states, at their option, to provide home and community-based services (HCBS) under their regular state Medicaid plans. This option allows states to receive federal financial participation (FFP) for services that were previously eligible for the funds only under waiver or demonstration projects, including those under sections 1915(c) and 1115 of the Act. Section 1915(i) of the Act 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 following discussion of this regulation, we refer to particular home and community-based service(s) offered under section 1915(i) of the Act as “State plan HCBS” or simply “HCBS”¹. We refer to the “State plan 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

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

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 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 with other state plan services, the benefits must be provided statewide, and states must not limit the number of eligible people served.

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 individuals with intellectual disabilities² (ICF/IID) as is required in section 1915(c) HCBS waivers. While HCBS 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.

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.

HCBS benefits that are not otherwise available through section 1905(a) of the Act 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, in part, 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.

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.

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 goal to improve 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 provide covered program services to eligible individuals with disabilities 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 services provided under the State’s Medicaid program. However, the Medicaid program can support compliance with the ADA, section 504 of the Rehabilitation Act, and *Olmstead* through the provision of Medicaid services to Medicaid-eligible individuals in integrated settings.

We noted in the May 3, 2012 proposed rule published in the **Federal Register** (77 FR 26362), that home and

community-based settings do not include nursing facilities, institutions for mental diseases, intermediate care facilities for the mentally retarded, hospitals, or any other locations that have the qualities of an institutional setting as determined by the Secretary.

While HCBS are not available while an individual resides in an institution, HCBS may be available to assist individuals to transition from an institution to the community. 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 transition to the community. We proposed 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 State plan HCBS benefit to meet needs not met through the provision of hospital services that are identified in the individual’s person-centered service plan, to ensure smooth transitions between acute care settings and home and community-based settings, and to preserve the individual’s functions. 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 under federal or state laws. However, 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.

Section 2601 of the Affordable Care Act adds a new paragraph to section 1915(h) of the Act 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

² While the Social Security Act still refers to these types of facilities as intermediate care facilities for the mentally retarded (ICFs/MR), the language used in this rule reflects “intellectual disability” as the appropriate way to discuss this type of disability, based on Rosa’s Law and we now refer to this types of facility as an intermediate care facility for individuals with intellectual disabilities (ICF/IID).

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.

Section 1902(a)(32) of the Act generally states 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.” However, 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.

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.³ We are aware of settings other than those specified in section 1915(k)(1)(A)(ii) of the Act that may exhibit qualities of an institutional setting, such as public hospitals. Over the past several years, we have sought input on how to define the characteristics of what makes a setting “home and community-based” (HCB). To provide greater clarity, we are establishing with this final rule that home and community-based settings must exhibit specific qualities to be eligible sites for delivery of HCBS under Medicaid. Any modifications to these qualities must be justified in an

individual’s person-centered plan, and we believe this gives states the flexibility to address specific needs of beneficiaries. We have included these provisions to move toward a stronger articulation of the qualities that make a setting a home and truly integrated in the broader community. These are the qualities most often articulated by persons with disabilities as key determinants of independence and community integration. We believe that these qualities 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), 1915(i), and/or 1915(c) to include a definition of home and community-based setting that incorporates these qualities and will review all SPAs and 1915(c) waivers to determine whether they propose settings that are home or community-based. We will permit states with approved section 1915(k) SPAs, 1915(i) SPAs, and 1915(c) waivers a reasonable transition period to come into compliance with the HCB setting requirements as promulgated in our final rule.

For a detailed description of the background of this rule, please refer to “State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice” proposed rule published in the May 3, 2012 **Federal Register** (77 FR 26362).

B. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

On May 3, 2012, we published a proposed rule (77 FR 26362) in the **Federal Register** entitled “Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice,” (hereinafter referred to as “HCBS proposed rule”) that proposed to amend the Medicaid regulations to define and describe state plan home and community-based services (HCBS) under the Affordable Care Act. This rule offers states new flexibilities in providing necessary and appropriate services to elderly and disabled populations. The rule also proposed to amend Medicaid regulations consistent with the requirements of section 2601 of the 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. In addition, the proposed rule includes payment reassignment provisions because states’ Medicaid programs often operate as the primary or only payer for the class of practitioners that includes HCBS providers. Finally, the rule proposed 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.

We received a total of 401 timely comments from state agencies, advocacy groups, health care providers, employers, health insurers, health care associations, and the general public. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding the proposed changes. We note that many expressed overall satisfaction with the benefit as a whole, in that it offers another opportunity for individuals served through the Medicaid program to return or remain in the community with family and friends. A couple stated that this opportunity offers additional flexibility and will not only provide people the opportunity to live and thrive where they choose, but also has the potential to save states’ dollars.

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

Brief summaries of each proposed provision, a summary of public comments we received (with the exception of specific comments on the paperwork burden or the economic impact analysis), and our responses to the comments follow. Comments related to the paperwork burden and the impact analyses are addressed in the “Collection of Information Requirements” and “Regulatory Impact Analysis” sections in this preamble.

³ 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.

1. 5-Year Period for Certain Demonstration Projects and Waivers (part 430)

In accordance with section 2601 of the Affordable Care Act, we proposed a 5-year approval or renewal period, subject to the discretion of the Secretary, for Medicaid waivers under sections 1915(b), 1915(c), 1915(d) and 1115 of the Act. Specifically, this time period applies for demonstration and waiver programs through which a state serves individuals who are dually eligible for both Medicare and Medicaid benefits. While section 2601 of the Affordable Care Act did not provide a new type of waiver, it did provide an important opportunity for states to simplify the operation of existing or future waivers under current authorities that serve dually eligible individuals, especially important when states combine waiver authorities that have different approval periods. 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 proposed that if a demonstration or waiver program does not serve or excludes dually eligible individuals, the 5-year approval period will not be available under this authority, and existing approval period requirements will apply. In addition, we proposed that in order for coverage-related waivers to be approved for 5 years periods, they must meet all necessary programmatic, financial, and quality requirements.

Comment: Commenters on this section expressed agreement with this provision. One also requested that we be mindful of the demonstrations under the Financial Alignment Initiative for dual eligibles. Another recommended clarification that this provision would also apply to other future waiver demonstration requests by states to combine Medicare and Medicaid funding at the state level for delivering care to Medicare-Medicaid eligibles.

Response: This provision is available for waivers that serve dually eligible individuals, under sections 1915(b), 1915(c), 1915(d) and 1115 of the Act, and that meet all necessary programmatic, financial, and quality requirements.

Comment: One commenter requested that CMS make wise and appropriate use of this authority. Another commenter recommended that CMS include a statement in the regulation language like one in the preamble to the proposed rule that determinations "be

made regarding applications for 5-year waivers in a manner consistent with the interests of beneficiaries and the objectives of the Medicaid program." This commenter stated that one example would be a waiver that effectively reduces services for dual eligibles, which should not be approvable as it would not be consistent with the purposes of Title XIX.

Response: We have added "and in a manner consistent with interests of the beneficiaries and the objectives of the Medicaid program" to the final regulation. In the event that the state finds a need to make reductions to its program, the state would have to explain to CMS how they will account for the interest of individuals before taking such action.

2. State Organization and General Administration (part 431)

In § 431.54, we proposed to add paragraphs (a)(3) and (h) to include state plan HCBS as exceptions to comparability and community income and resource rules. For specific discussion, see the published May 3, 2012 proposed rule (77 FR 2012 through 10385).

Comment: Commenters requested that we clarify that under section 1915(i)(3) of the Act noncompliance with comparability or community income and resource rules is optional, not mandatory. Specifically, they requested that we modify § 431.54 (a)(3) and (h) as follows:

□ For § 431.54 (a)(3): Section 1915(i) of the Act provides that if a state may provide, as medical assistance, home and community-based services under an approved state plan amendment that meets certain requirements, it may elect to do so 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 only.

□ For § 431.54(h): State plan home and community-based services. If the state so elects, 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.

Response: We believe that the language in the regulation is clear and we are finalizing the rule as proposed.

3. 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)

We received several comments that were in support of the eligibility policies pertaining to the new eligibility

group specified at § 435.219 and § 436.219. Commenters were pleased that the regulation offers states flexibility in providing HCBS to elderly and disabled populations who do not meet an institutional level of care. Commenters were also pleased that the methodology proposed for the new eligibility group described at § 435.219(a) & (c) did not have a resource test and that the income standard for this new eligibility group is set at 150 percent of the FPL. Comments on eligibility policies not contained in this rule are not addressed.

Comment: A few commenters believed that the language in the regulation should be more detailed to better reflect the language in the preamble.

Response: We do not believe that the regulatory language should be as detailed as the language in the preamble. The language in the preamble contains the rationale for the requirements described in the regulatory language. Therefore, we are not revising the regulatory language to be as detailed as the preamble. We will be revising the regulatory language to correct an error which inaccurately indicated that a State could cover some but not all people described in paragraph (a) or (b). The response to that comment is addressed separately.

Comment: A few commenters suggested that the regulation at § 435.219(c) should be revised to include a requirement that the methodology elected by the state can be no more restrictive than the SSI methodology.

Response: To provide states with flexibility, we are not prescribing a methodology. We will review the methodology proposed by the state to determine whether it meets the criteria set forth at § 435.219(c) and § 436.219(c). We believe that the current regulatory language is in the best interest of the beneficiary.

Comment: One commenter suggested revising the introductory language in § 435.219 and § 436.219 to make it clearer that a state may choose to cover persons described in paragraph (a), persons described in paragraph (b) or both sets of persons. The commenter suggested deleting the language "any group or groups of" because the language suggests inaccurately that a state might be able to cover some but not all of the persons described in either of paragraphs (a) or (b) of the regulation.

Response: We agree with the commenter. The state has the option to provide Medicaid to individuals described in one or both of the paragraphs under (a) or (b) of this

section but cannot cover some but not all of the individuals that may be eligible under either or both parts of the eligibility group. We are revising the regulatory language at § 435.219 and § 436.219 by removing the phrase “any group or groups of.”

Comment: A few commenters suggested that the language in § 453.219 should be revised to specify that any income methodologies must be applied to all members of the eligibility group.

Response: The state must use the same income methodology for all members within the eligibility group. Specifically, if a state elects to cover § 435.219(a) the income methodology must be the same for all members determined eligible under § 435.219(a). If the state elects § 435.219(b) the state must use the same income and resource methodologies and standards that it uses for the § 435.236 (the special income level) group. As described in the previous comment, states have the option to provide Medicaid to individuals described in one or both of the paragraphs under (a) or (b) of this section.

Comment: One commenter commended CMS for proposing regulations to implement optional categorical eligibility for Medicaid for individuals in need of section 1915(i) of the Act services. The commenter believes that this category has the potential to help secure coverage for uninsured and underinsured individuals and will provide states with a useful option to consolidate coverage groups.

Response: The intent of the regulation is to provide eligibility for more individuals needing State plan HCBS not to consolidate coverage groups.

Comment: One commenter urged CMS to retain the regulatory language that requires states to use income standards, which are, “reasonable, consistent with the objective of the Medicaid program . . . and in the best interest of the beneficiary.”

Response: We are not changing this regulatory language, which is specified at § 435.219(c) and § 436.219(c).

4. Services: General Provisions (part 440)

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 HCBS may not include payment for room and board. 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. Section 1915(i) of the Act 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 individuals with intellectual disabilities (ICF/IID) as is required in section 1915(c) HCBS waivers. While HCBS 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. 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.

Comment: A few commenters requested that CMS add additional services to § 440.182. One additional commenter requested that nursing services be added to the list of services specifically listed in section 1915(c)(4)(B) of the Act governing HCBS waivers.

Response: The services that section 1915(i)(1) of the Act authorizes states to include are the services and supports listed in section 1915(c)(4)(B) of the Act governing HCBS waivers. While we are unable to expand on this list of services, we note that the “other services” specifically referenced in the statute may include coverage of services not designated in the list of specific services, and gives states the flexibility to propose and define other specific services.

Comment: Many commenters requested that CMS add to the regulation text that “other services” can include services that have been, or could be, approved as “other services” under a 1915(c) waiver and to list specific examples, such as transition services or services for individuals with traumatic brain injury.

Response: “Other services” may include coverage of services not specifically designated, and states have the flexibility to propose and define other specific services. We will provide examples of “other services” in future guidance.

Comment: A couple of commenters requested revisions to § 440.182(c) to emphasize that the habilitation services that can be covered by the state include, but are not limited to, expanded habilitation services as specified in § 440.180(c).

Response: We have revised § 440.182(c) to add the phrase “may include expanded habilitation services” to specify that states can choose whether or not to include expanded habilitation services as defined in § 440.180(c).

Comment: One commenter expressed that the final regulation regarding home and community-based settings must continue to permit the full array of home and community-based services, as defined by the Medicaid HCBS statute and regulations and included in the individual’s person-centered service plan.

Response: We agree and, as in the proposed rule, the final regulation will continue to convey this flexibility for states.

Comment: Another commenter applauded the flexibility given to states to not only provide *specified* HCBS benefits under the state Plan, but to also provide other services at a state’s request with Secretary approval, and encourages CMS to work with states on an ongoing basis to educate, train, and support the use of this new state plan option.

Response: We appreciate this comment and believe that this option provides states with an opportunity to deliver long-term supports and services to individuals in need. Since implementation of this benefit, we have directly and indirectly provided states with technical assistance in the use of section 1915(i) of the Act, and we are committed to continuing to offer such assistance to states.

Comment: One commenter stated that CMS should not allow section 1915(i) of the Act to be used to provide instrumental activities of daily living (IADL) services while an individual is in a general acute hospital short-term stay, as this would be duplicative to the services received in the hospital and would be hard to administer without increased costs to the state.

However, another commenter was supportive of allowing HCBS to continue, as applicable for people who are temporarily hospitalized, stating that based on the needs of the individual, there could be a genuine necessity for HCBS while an individual is hospitalized in a short-term acute care setting and would not be a duplication of hospital care services:

“Some individuals may need assistance from their personal care provider to communicate their needs, medical history, redirect behaviors, and provide consistent person-directed physical assistance. Most hospitals do not have adequate, nor trained staff to provide the level and type of ongoing ‘personal care’ many people using HCBS

require. Providing continuation of HCBS while someone is in a hospital is not letting hospitals avoid their responsibilities, but rather acknowledging the reality that their focus/responsibility is on 'medical care', while HCBS' focus is on 'personal care'."

Response: We agree with the second commenter and believe that this should remain an option afforded to the state subject to the conditions and limitations stated in our rule. To support program integrity, states are required to perform claims edits or adopt other systematic approaches that prevent duplicate payment.

Comment: One commenter noted that the inclusion of "other services" including certain transition services can make a significant difference in addressing chronic homelessness.

Response: We agree.

Comment: One commenter suggested providing FFP for rent and food expenses reasonably attributed to a related caregiver providing State plan HCBS, just as CMS proposed in the proposed rule for unrelated caregivers.

Response: Section 1915(i) of the Act does not include authority that would allow payment for the costs of rent and food attributable to a related personal caregiver residing in the same household as the participant.

Comment: One commenter asked us to clarify if there can be differences in the amount, scope or duration of services provided under 1915(i) and similarly named services provided in a section 1915(c) HCBS waiver, and whether rates or rate methodologies could differ. The commenter also asked whether there could be different provider qualifications for a covered State plan HCBS benefit and a similar covered HCBS waiver service.

Response: States are permitted the flexibility to define the section 1915(i) of the Act services they will include under their benefit, including the amount, duration, and scope of those services. If a proposed section 1915(i) service is also available under another Medicaid authority, states must explain how the section 1915(i) services would not be provided in duplicate, or incur duplicate payment. However, we note that while 1915(i) services are not identified in 1905(a) and are not part of the EPSDT requirement, all Medicaid-eligible children must have full access to services required under EPSDT, and the provision of section 1915(i) of the Act State plan HCBS should in no way hinder their access to such services.

With regard to rate methodologies, while rate determination methods may vary, payments for Medicaid services must be consistent with the provision of section 1902(a)(30)(A) of the Act (that is,

"payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers") and the related federal regulations at § 447.200 through 205. If the state-established rates will vary for different providers of a service (including a service that is also available under a section 1915(c) of the Act waiver), the state must explain the basis for the variation.

Provider qualifications must be reasonable and appropriate to the nature of the service, reflect sufficient training, experience and education to ensure that individuals will receive services in a safe and effective manner, and not have the effect of limiting the number of providers by the inclusion of requirements that are unrelated to quality and effectiveness. If the state-established minimum provider qualifications will vary for a service that is also available under a section 1915(c) of the Act waiver, the state must explain the basis for the variation.

Comment: One commenter requested that CMS amend the language to ensure that the rule addresses individuals with disabilities across the lifespan, including children, in order to help states understand that they can serve children under the special population classification. They expressed concern that the proposed rule does not explicitly address children. They also requested that CMS add language to specify children with physical and sensory disabilities, not just those with cognitive and behavioral disorders.

Response: Our intention was not to exclude children with disabilities or any other population as we cited examples in the preamble to the proposed rules. The regulation text does not cite specific populations who can receive Medicaid HCBS, nor do we think it prudent to do so, as it may imply limitations on state flexibility.

Comment: One commenter requested that CMS allow federal financial payment for room and board costs to be included in payment for State plan HCBS, in order to make such alternatives viable for individuals who, without housing assistance, must seek institutional placement.

Response: The statute explicitly excludes coverage of room and board and our rule cannot override that exclusion.

Comment: For § 440.182(c)(8), which refers to conditions set forth at § 440.180 for persons with chronic mental illness, one commenter proposed instead a reference to § 440.180(d)(2).

Response: We agree that this reference is more precise and have incorporated this revision.

Comment: One commenter expressed support for not including the phrase "as cost effective and necessary to avoid institutionalization," which appears in § 440.180(b)(9) to describe the "other" services that might be authorized under section 1915(c) of the Act, in § 440.182(c)(9) pertaining to section 1915(i) of the Act.

Response: We agree that this phrase is not appropriate to include in § 440.182(c)(9), as State plan HCBS under 1915(i) are not subject to cost neutrality.

Comment: One commenter indicated that the regulation text should indicate that services must be furnished to individuals with an assessed need, and must not be based on available funds.

Response: This is reflected in § 441.725(b) regarding the person-centered service plan.

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 2402(b) of the Affordable Care Act added a new option at section 1915(i)(6) of the Act, to allow states, in addition to continuing to provide services to individuals described in section 1915(i)(1) of the Act, to provide section 1915(i) of the Act services to certain individuals who meet the needs-based criteria, who would be eligible for HCBS under sections 1915(c), (d) or (e) of the Act 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) of the Act benefit, have income up to 150 percent of the Federal poverty line (FPL) with no resource test

and who will receive section 1915(i) of the Act 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)⁴ 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.

Comment: One commenter indicated that there is not a lot of difference between 300 percent FBR and 150 percent FPL. In 2012 the amounts were \$2094 versus approximately \$1400 per month. The commenter believes that having two income levels to administer will cause more work for the states and make explaining the program more confusing. The commenter recommended that for all 1915(i) services, the income standard be 300 percent of the SSI/FBR.

Response: The statute does not permit the income standard to be raised to 300 percent of the SSI/FBR for all individuals receiving 1915(i) services. Electing the new eligibility group specified at § 435.219 and § 436.219 in order to provide state plan HCBS to individuals who were not previously eligible to receive these services is strictly a state option. Therefore, if a state believes that the requirements for this eligibility group are too burdensome, the state does not have to elect to cover this optional eligibility group.

Comment: One commenter believes that existing financial eligibility rules should remain in place.

Response: Electing any changes to financial eligibility set forth in this final rule are strictly a state option.

5. State Plan Home and Community-Based Services Under Section 1915(i)(1) of the Act (§ 441.710) (Proposed § 441.656) and Community First Choice State Plan Option: Home and Community-Based Setting Requirements (§ 441.530)

a. Home and Community-Based Settings Under 1915(i) and 1915(k) of the Act

To implement the statutory requirement that the benefit be “home and community-based,” we proposed to require in § 441.656(a) that the individual reside in the home or community, not in an institution, and

that the settings must have qualities of community-based settings prescribed by the Secretary. We stated our recognition of the need for a consistent definition of this term across Medicaid HCBS, and our goal to align the final language pertaining to this topic across the regulations for sections 1915(i), 1915(k), and 1915(c) of the Act Medicaid HCBS authorities.

Section 1915(i) of the Act 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). We proposed language defining the qualities and requirements for settings in which section 1915(i) of the Act services and supports could be provided and sought additional comments on this issue. Instead of attempting to provide one singular definition to encompass all settings that are home and community-based, we described the qualities that apply in determining whether a setting is community-based. We stated that we would expect states electing to provide HCBS under section 1915(i) of the Act to include a definition of home and community-based settings that incorporates these qualities, and that we would review all SPAs to determine whether they propose settings that are home and community-based.

In the proposed rule, we stated that we would permit states with approved section 1915(i) of the Act SPAs a reasonable transition period, a minimum of one year, to come into compliance with the HCBS setting requirements that are promulgated in our final rule.

Overall, we received 280 comments in response to the HCB settings section of the proposed rule regarding 1915(i) State plan HCBS and 1915(k) CFC. Commenters included advocacy organizations, individuals receiving services, family members, friends and guardians of individuals receiving services as well as providers, government entities and the general public. Because we are proposing the same requirements for home and community-based settings in regulations implementing 1915(i) and 1915(k), we are discussing comments pertaining to both in this section. The comments were mixed, with commenters providing both support and disagreement within subsections of the HCBS settings provision. A few of the issues that

elicited a substantial number of comments are: qualities, integration, providers, choice, accessibility and privacy in addition to general comments.

Comment: We received many comments related to this section of the proposed rule. These comments are reflected as follows:

Many commenters expressed concern about the effect the criteria will have on existing home and community-based services, and expressed concern that the proposed rule will eliminate community based-services that elderly individuals and people with disabilities are currently receiving. Several commenters suggested eliminating all provisions that restrict the consumer’s freedom of choice regarding the residential settings in which they can utilize their Medicaid funds, stating that the qualities and characteristics of home are determined by the individual.

Some commenters stated that affordable rental options, especially those in apartment complexes where home maintenance responsibilities are handled by the landlord, are hard to find or non-existent in some communities. They indicated that lack of affordable housing is a huge challenge for people seeking to live in the community while being supported for severe disabilities, and that many individuals who experience multiple disabilities need housing that is tailored for their specific physical needs. These commenters stressed that group homes that were built and owned by a third party, specifically for the purpose of serving people with disabilities, would not be available if they tried to rent on the open market and that ruling out such homes for HCBS funding imposes further hardship and segregation on the population in need of HCBS.

One commenter believes the requirements will drive up costs.

Some commenters believe that the changes would effectively eliminate their freedom to provide their adult child a setting that is protected from exposure to community members that do not understand the effect of a community’s environment on individuals with disabilities.

One commenter indicated that if adopted, the criteria would have a significant adverse impact on its ability to continue to serve individuals with the most significant disabilities in the community. The language included in the proposed regulation would: (1) Thwart informed choice by negating or severely restricting longstanding program options and opportunities to provide services and supports expressly authorized by the HCBS provisions of

⁴ 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.

the Medicaid statute and regulations; and (2) Significantly restrict state flexibility to respond to identified needs of Medicaid beneficiaries.

Some commenters stated within the broad disability community, different groups have different needs and desires and any definition of home and community-based needs to be broad enough to encompass these divergent needs and desires with one not outweighing others. They indicated that it may not be possible to have a single definition to meet these needs.

One commenter stated that the standards proposed for home and community-based settings are impractical, overly prescriptive, inappropriate for persons with cognitive impairments and neurobehavioral challenges, and cannot be delivered at a rate that states and taxpayers can afford.

Another commenter disagreed with eliminating congregate care options and requested CMS clearly state policies which encourage states to operate a range of services for people with disabilities which reflect the diversity of their care and that of their families, including congregate care.

Several commenters disagreed with the notion embedded in the CMS proposal that “community based” can only be defined as a totally independent setting or small stand-alone group home in an urban or suburban environment.

We received many comments supporting the proposed criteria. These indicate that the criteria are a step in the right direction and support the goal of HCBS to assist individuals to be able to live fully in the greater community. One of these commenters stated that the criteria proposed appropriately establish the essential elements of resident autonomy and person-centered care.

Many commenters stated their belief that the provisions are key to assisting states with complying with the *Olmstead* decision. One recommended that the regulation quote verbatim the conclusion of the *Olmstead* decision and that reference to the “integration mandate” in the final regulation restates actual language in the ADA regulations for instance, “most integrated setting appropriate to the needs of qualified individuals with disabilities.”

Another indicated that the requirements appropriately ensure that individuals have control over their care environment while also making allowances for serving people with cognitive disabilities. Several commenters stated that the rule offers appropriate flexibility to ensure that individuals can remain in the community for as long as possible.

Many commenters commended CMS for its efforts to promote the rights of people with disabilities to live in the most integrated setting possible. They stated that the proposed rule has the potential to improve the care of many adults and children in the public mental health and developmental disabilities system.

A few commenters stated that making an institutional setting more “homelike” does not mean that it becomes community-based, and that the intent is to ensure that people with disabilities have more self-direction and ability to govern and control important components of their personal living environment.

One commenter stated appreciation and support for criteria that support individual choice, the ability for a recipient to exercise control over his or her immediate environment and day to day activities, and that do not restrict the individual’s ability to live in the community in which his or her residence is located. However, the commenter is concerned that residency in some of the more creative congregated living arrangements may be disqualified. The commenter added that CMS should be as flexible as possible to ensure that these homes are able to continue to support individuals with disabilities and illnesses in the least restrictive environment possible.

Response: We appreciate all of the comments submitted. We believe the requirements we are finalizing are critical to ensure that individuals have the opportunity to receive services in a manner that protects individual choice and promotes community integration. Individuals who are elderly and/or disabled who commented made it clear that their personal rights should not be curtailed because of where they live or because there is a need to receive HCBS. It is not the intent of this rule to prohibit congregate settings from being considered home and community-based settings. State plan HCBS must be delivered in a setting that meets the HCB setting requirements as set forth in this rule (except for HCBS that may be delivered in an institutional setting, such as institutional respite). Also, since this authority provides states the opportunity to provide individuals HCBS and not institutional services, individuals must be living in settings that comport with the HCB setting requirements as set forth in this rule. We acknowledge that for some settings, implementing these requirements will require a change to operational protocol, and perhaps changes to licensure requirements, but we believe that the requirements are achievable and

provide for reasonable transition time to facilitate such changes as may be necessary. We are committed to working with states as they examine their systems and develop plans to bring their HCBS programs/benefits into compliance.

Comment: One commenter noted that Medicaid reimbursement for room and board is expressly prohibited, yet the criteria laid out in §§ 441.530 and 441.656(a) are primarily focused on considerations of what is a beneficiary’s room and board choice and therefore arguably outside CMS’ authority to regulate. This commenter stated that CMS lacks authority to regulate these features of alternative housing arrangements for which it does not provide reimbursement and requested that CMS clarify under what authority CMS can mandate physical structure alternative housing requirements and whether such authority extends to non-provider controlled alternative housing arrangements. Other commenters stated that creating an exhaustive list of potential requirements will be difficult and suggested that CMS carefully consider the wide range of states’ specific programs over the next year before providing guidance through a State Medicaid Director letter.

Response: While we do not regulate housing, we are required to determine whether Medicaid State plans and waivers comply with the statutes authorizing the provision of medical assistance. In authorizing HCBS Medicaid expenditures, we must ensure that such settings are home and community-based.

Comment: We received many comments in response to our request for input on whether the regulation should be modified to prohibit housing providers from requiring individuals to receive services from that provider, or requiring an individual to receive a particular service as a condition of living or remaining in the setting. Many commenters believe that housing should not be conditioned upon the acceptance of services and believe that individuals should have the right to choose their living environment, as well as their supports and services. Some commenters expressed concern that such an arrangement is inconsistent with the requirement that Medicaid beneficiaries have a free choice of provider. Other commenters believe that if assisted living facilities, and other congregate settings that bundle housing and services, were required to separate housing and services, those providers could maintain their customer base by providing services of a quality that appeals to individuals, not by taking

advantage of a captive pool of residents. Others expressed concern that people would become homeless or institutionalized because the services they require change, and individuals are not given the opportunity to age in place. Some commenters believe that individuals should have the opportunity to make their own decisions about where they live, free of any coercion. One commenter supporting the restriction acknowledged that compliance with such a provision would require monumental changes to certain business models and service delivery systems and that such a change may be beyond the scope of this regulation. Overall, the commenters supporting the prohibition believe that individuals with disabilities deserve choice among livable options and control over the space they call home. Alternatively, we received comments opposing a separation of housing services requirement, stating that it is too restrictive. Some commenters expressed concern that such a requirement would limit a provider's ability to evict tenants who become a threat to other tenants and staff or repeatedly refuse a particular service that would treat their medical condition. Other commenters believe that while the inclusion of this criterion is important in some settings, such as an individual's home or apartment, it should not be applied to settings such as group homes or assisted living residences, where the provision of services is inherent in the setting. Several commenters suggested that instead of modifying the regulation to require separating housing and services, this issue could be handled in a different manner, such as the use of resident agreements in specific residential settings or through the person centered planning process. Commenters believe that this regulation should not preclude reasonable conditions for residency that are consistent with the rules of the regulating agency. There is also concern with the effect such restriction could have on specialized programs, such as those targeted toward the homeless population. Such programs include residential services and require individuals to maintain sobriety. Other commenters expressed concern regarding how such a requirement would be operationalized in assisted living facilities whose model is to provide both housing and services. In such settings, multiple service providers and multiple staff with multiple lines of authority, sorting through oversight and management issues becomes very

complex. A few commenters suggested that CMS should provide guidance that as a matter of practice, individuals should not be locked into a particular service package as a condition of their receipt of housing services. Other commenters suggest that in arrangements where placement is contingent on acceptance of a specific program, it should be clearly specified as part of the person-centered planning process that individuals have been apprised of all alternatives and that the decision to accept the placement is free from coercion. The commenter notes that adult care and assisted living facilities are also guided by state regulations and in most cases these regulations indicate that residents may not reside in the facility if they are a threat to themselves or others. The commenter explains that if a facility fails to "discharge" a resident to a more appropriate environment, the facility may be in conflict with those state regulations, running the risk of being cited with a deficiency or endangerment, which can threaten its viability.

Response: Upon consideration of the thoughtful comments submitted, we are not requiring the separation of the housing provider from the provider of HCBS. Commenters provided compelling arguments both in support and against the proposed prohibition. We recognize that the needs of the individuals receiving HCBS vary greatly. Just as there should be a variety of service options to meet those needs, there should be a variety of residential options as well. We agree with commenters that the issue of choice regarding the provision of services can be addressed as part of the person-centered planning process and reflected in the individual's person-centered service plan. States must ensure that when an individual chooses a home and community based setting, the individual has made an informed choice among options. In the event the individual has made an informed choice to reside in a setting that provides both housing and services, the individual must acknowledge that he has also chosen that provider to be the service provider. Our decision not to require the separation of housing and services in the final rule does not preclude a state from structuring its service delivery system to promote separation. Nor does it preclude a provider from allowing for such an arrangement if all parties agree, and the arrangement does not violate state licensing requirements. At this time, we do not believe that there

should be a federal mandate requiring such a separation.

Comment: Several commenters requested that § 441.656(a)(1)(vi) be modified to include a "right to refuse service" provision. One commenter suggested the following modification "in a provider-owned or controlled residential setting, that receipt of any particular service or support either from the provider/owner or other qualified provider cannot be a condition for living in the unit and that this shall mean that the owner of the unit cannot terminate occupancy/tenancy of someone for not agreeing to participate in a particular service." A few commenters suggest that if CMS decides against including a "right to refuse service" provision, then a narrow exception should be provided, allowing the requirement to be waived only for substance abuse treatment services, on the grounds that such treatment services are distinct in character from other forms of service provision focused on ADLs, IADLs, etc. One commenter believes that while providers should receive adequate reimbursement for housing and services, the individual should be protected against restrictive (service utilization) requirements for tenancy and should maintain the right to elect, receive or deny services without risk of eviction. Another commenter indicated that this interpretation could have an effect on residential settings as 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 in the unit. Overall, the commenters believe that individuals should not be forced to move out of their homes because they do not want a particular service offered by the provider.

Response: We do not believe that a "right to refuse" provision is necessary as it is a basic tenet of the Medicaid program that individuals cannot be compelled to receive any Medicaid service. Additionally, we believe the requirements specified under the person-centered planning process, and the requirement at § 441.530(a)(1)(iii) and § 441.710(a)(1)(iii) that an individual is free from coercion and restraint, achieve the same purpose as a "right to refuse" provision. Although Medicaid beneficiaries have the right to refuse a service, we recognize that depending on the setting, rules other than those of the Medicaid program may be applicable and may reflect health and safety concerns related to the refusal of services. We plan to issue additional guidance on how other components of this regulation can be useful tools in addressing such concerns.

Comment: Several commenters recommend that the proposed regulation be amended to reference the ADA, which generally requires a provider to accommodate a resident's needs by making necessary services available to the extent that those accommodations are setting-appropriate and are not legally prohibited. Commenters believe that this type of accommodation should be required in a community-based setting, as it values the individual's interest in staying in the home over the facility's interest in limiting the care needs that must be met.

Response: The requirements of this rule do not replace or override the requirements of the ADA. There are already a few general provisions in our regulations that prohibit discrimination in State Medicaid programs on the basis of nationality, disability, etc., (§ 430.2, § 435.901, § 435.905, and § 435.908). As these regulations apply in determining eligibility and administering the Medicaid program generally, it is not necessary to add a regulation on this subject specific to section 1915(i) of the Act.

Comment: One commenter suggested that clear contracts and boundaries need to be defined in order to recognize that no matter the setting, that location is the individual's home.

Response: We agree with the commenter that regardless of the type of setting, the location is the person's home.

Comment: One commenter suggested CMS include the concept of "aging in place," as defined by the Center for Disease Control. The commenter believes that regardless of whether or not the setting is provider-owned or controlled, individuals should be protected by a reasonable accommodation requirement in their current settings as their needs change in order to prevent individuals from being evicted or losing their home. The commenter further suggests that individuals should also have access to an appeals process through an objective third party to dispute decisions about terminations of agreements and evictions.

Response: We do not believe this support requires a change to the regulations. The requirements set forth in this final rule also address the commenters' additional suggestion regarding an appeals process for evictions and terminations of agreements.

Comment: One commenter indicated that their state has a long history of providing services that are institutionally-based, with

misplacement of younger people in adult care homes that are for the frail elderly. This commenter urged CMS to ensure that individuals have assessments of need to ensure they are not placed in the wrong settings.

Response: Sections 1915(c), 1915(i) and 1915(k) of the Act all require that individuals have an individual assessment of needs that includes the individual's needs, strengths, preferences and goals for services and supports provided under the respective authorities.

Comment: One commenter appreciates CMS noting in the preamble to the proposed rule the other authorities for providing Medicaid services in certain institutional care settings (such as SNFs and ICFs), but notes that this should not be construed to mean that assisted living can or should be lumped with SNFs simply because both provide regulated services in a congregate setting. The commenter does not support the premise that residents of assisted living settings should "fall back" on the institutional model in order to access Medicaid services.

Response: It is not our intent to imply that all congregate settings should be categorized as nursing facilities and/or intermediate care facilities for individuals with intellectual disabilities. State plan HCBS must be delivered in a setting that meets the HCB setting requirements as set forth in this rule (except where HCBS are permitted to be delivered in an institutional setting, such as institutional respite). Also, since this authority provides states the opportunity to provide individuals with HCBS and not institutional services, individuals must be living in settings that comport with the HCB setting requirements as set forth in this rule. Settings that do not meet the requirements may be qualified to provide institutional services.

Comment: One commenter suggests that states should consider whether individuals have meaningful options among settings located in the community, which afford them the choices that are integral to some of the qualities that define HCB settings. The commenter suggests that states should collect data on the choices and expressed preferences of Medicaid beneficiaries who require HCBS and set goals to build adequate infrastructure to meet these needs.

Response: We appreciate the commenters' thoughtful suggestions. The regulation already requires that the setting be selected by the individual from among housing options, and that

the individual's choice is documented in the person-centered service plan. We will not revise the regulation to include the commenter's suggestion to require states to use the data on the choices and expressed preferences to set goals to build adequate infrastructure to meet these needs; however, we will consider that suggestion as we develop future guidance.

Comment: One commenter agreed that these requirements should apply to other HCBS funding streams such as the section 1915(c) waiver program.

Response: We appreciate the commenter's support. As stated in the preamble of the proposed regulation, these requirements will also apply to section 1915(c) of the Act Home and Community Waiver programs and the section 1915(k) of the Act Community First Choice state plan option.

Comment: One commenter stated that individuals should not be forced to live in the community, as this might not always be the individual's preference.

Response: This requirement does not require individuals to live in the community to receive necessary Medicaid services. Medicaid services are available in a variety of settings. This regulation sets forth requirements that must be met for individuals to receive services under sections 1915(i), (c) and (k) of the Act.

Comment: We received many comments supporting the proposed language. Several commenters support CMS' efforts in aligning HCBS setting qualities under sections 1915(i) and 1915(k) of the Act and agree with the proposed list of qualities for home and community based settings at § 441.656(a)(1) of the proposed rule that promote patient autonomy, dignity, choice and preference. Several commenters believe the provisions are strongly reflective of the belief that home- and community-based services should be organized in a person-centered manner, driven by the needs and preferences of the individual and that those services acknowledge the rights of the individual to "privacy, dignity and respect". Several commenters generally believe that the provisions establish the essential elements of autonomy and person-centered care in a way that promotes choice and independence. Many commenters believe that the list of qualities promotes integration of people with disabilities into the greater community and does not restrict individuals with disabilities. One commenter recognized the policy on this issue is complicated and believes that the proposed language is a big improvement over previous proposals.

Response: We agree and appreciate the commenters' support.

Comment: A few commenters asked if the rule applies to private homes and non-residential community settings where services may be provided, such as adult day settings or day habilitation settings.

Response: 1915(i) State plan HCBS and 1915(k) CFC services (for example, residential, day or other) must be delivered in a setting that meets the HCB setting requirements as set forth in this rule. We will provide further guidance regarding applying the regulations to non-residential HCBS settings. In addition, since this authority provides states the opportunity to provide individuals HCBS and not institutional services, individuals receiving 1915(i) State plan HCBS or 1915(k) CFC services must be living in settings that comport with the HCB setting requirements as set forth in this rule regardless of whether they are receiving HCBS in that residence. This is consistent with CMS' longstanding policy regarding 1915(c) HCBS. We are unsure what the commenter means by the term "private home" but a residence owned or leased by an individual for his or her personal use would generally meet these criteria.

Comment: One commenter suggests that CMS should consider requiring and monitoring state reporting on measures related to the qualities of home and community-based settings. The commenter suggests alignment with section 1915(i) of the Act quality and reporting standards. An alternative approach also suggested by the commenter is for CMS to require a Memorandum of Understanding (MOU) between state agencies documenting how they will work together to ensure consistency with the quality requirements.

Response: Sections 1915 (c), (i) and (k) of the Act all require states to demonstrate at the time of approval that they have a quality improvement strategy that includes performance and outcome measures for the HCBS, including measures for the HCB setting requirements. We are currently working towards a streamlined approach to be used across Medicaid HCBS.

Comment: One commenter recommended the rule be revised to include a requirement that individual choice regarding supplementation of services and supports and who provides them is facilitated, if providers meet all applicable requirements of the licensed entity.

Response: We do not believe it is necessary to add language addressing provider qualifications to this provision.

Implementing regulations for sections 1915(c), 1915(i) and 1915(k) of the Act all include provisions that address provider qualification requirements.

Comment: Several commenters indicated that people with disabilities should have the same rights, responsibilities and protections as nondisabled people have under every state's Landlord and Tenant Law. One commenter indicated that their state's landlord and tenant laws currently in place are sufficient to satisfy the requirements of the regulation (absent a court order, a person may not be involuntarily evicted even if they need a higher level of care, are delinquent in payment or create significant disruption for others living in the congregate setting). Another commenter indicated that their state's landlord tenant law must operate equally for everyone.

Response: We believe these comments are consistent with the intent of this regulation. We note that we do not have the authority to require states to modify their landlord and tenant laws.

Comment: One commenter suggested that CMS should clarify that all settings in which the individual does not have a regular lease or full ownership rights should be considered "provider-controlled."

Response: Any setting where the provider of HCBS also owns and operates an individual's residential service is considered provider-controlled.

Comment: A few commenters indicated that because there is no definition of an individual's "sleeping or living unit" it is unclear what area the individual's rights pertain to. The commenters requested clarification that the "unit or room" to which the person is legally entitled is at least the space to which the rights in § 441.530(a)(1)(vi)(B)(1-3) should apply.

Response: The requirements set forth at § 441.530(a)(1)(vi)(B)(1-3) apply to the sleeping or living unit that is used by the individual, and is not a common area used by others residing in the setting.

Comment: One commenter indicated that their state's landlord-tenant laws and their housing with services regulations both apply to their housing with services settings and the commenter wants to ensure that anything that is finalized by CMS does not negatively impact the consumer based system developed over the last two decades in that state.

Response: The proposed language specified that "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." However, we heard from many commenters that depending on the state, tenant law may not apply to congregate settings, such as group homes or assisted living facilities. To address such situations, we revised § 441.530 and § 441.710(a)(1)(vi)(A) to add the following language: "For settings in which landlord tenant laws do not apply to such units or dwellings, the state must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS participant that provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law". In all instances, these agreements must address eviction processes and appeals. In summary, we believe that our language creates a minimum requirement, but allows states to use existing laws or establish new laws as long as they meet our minimum requirements.

Comment: One commenter found it difficult to support this requirement based on the fact that each designated entity in the same state can have different tenant laws.

Response: It is expected that states would establish policy and procedures to assure compliance with this provision.

Comment: One commenter indicated that it might not be appropriate to require all provider-owned and operated settings be subject to local landlord and tenant laws or to meet all the requirements in § 441.530(a)(2)(v) adding that for some individuals with chronic mental illness or cognitive impairment, this strict requirement may exclude the least restrictive environment in which they can reside. The commenter indicated that CMS and state Medicaid agencies can use the other provisions in § 441.530 to insure that settings in which residents receive services are designed to facilitate the actual integration of the individual in the surrounding community without prohibiting some residences that are provider-owned or controlled from providing residential support to recipients.

Response: We have modified the regulation to include language to address situations in which state landlord/tenant rules do not apply.

Comment: One commenter requested clarification as to whether the provider has to hold the space when the terms of the lease are broken and there is no payment of rent and suggested that CMS use the typical landlord tenant language.

Response: It is beyond the scope of this regulation to address issues such as when the terms of a lease are broken or rent is not paid. This regulation defers to the state and local law, as applicable. Absent applicable state or local law, the regulation provides minimum requirements that the state must make sure are in place to inform individuals of the eviction process and the process to appeal the eviction.

Comment: One commenter noted that if the provider cannot evict the individual from provider controlled housing all the other residents may suffer and require new housing arrangements. The commenter stated that providers of services have experience balancing the rights of multiple residents and added that there are circumstances when eviction is in the best interest of all residents.

Response: This regulation is not intended to override existing rules governing adherence to proper eviction procedures. This rule requires that individuals receiving Medicaid HCBS who are in provider owned or controlled settings have the same or comparable protections related to evictions as individuals not receiving Medicaid HCBS.

Comment: One commenter asked about situations where the individual decides to participate in an activity that is contrary to the person-centered plan, putting the individual in danger, and asked who is liable for the outcome of the risky behavior. The commenter also wanted to know if, when all parties have agreed to a plan and the individual receiving supports departs from that to which s/he has agreed, the provider has standing to require the individual to adhere to the plan and may take steps to ensure compliance.

Response: We appreciate the commenter's questions. There is an expectation that individuals and providers will adhere to the services and activities identified in the person-centered service plan. If individuals place themselves or those around them in danger, we expect the state and provider to take the appropriate action necessary to address the situation. However, after the immediate crisis is resolved, we would expect a reassessment of needs to occur using the person-centered service planning process and an update to the person-centered service plan.

Comment: Many commenters expressed concern that the application of landlord/tenant law would create a conflict with state licensing laws governing assisted living providers or other congregate settings, and indicated that the state licensure laws protect

individuals from arbitrary eviction and define the circumstances in which a provider may and may not discharge an individual. The commenter added that providers have an obligation to take all reasonable steps to accommodate an individual before seeking a discharge, and recommended that CMS consider the logistical and technical difficulties in referring to state, county or city landlord/tenant laws, as these vary significantly and would subject providers in different areas of the same state to different standards depending on where they are located. The commenter indicated that it would be burdensome for a state to create an HCBS program that would take into account all the variations when trying to meet these requirements, and suggested that providers that are not licensed under an existing state licensing law be required to only adhere to the state landlord/tenant law, to create uniformity and avoid the administrative difficulties created by including county and city laws. One commenter added that the legal relationship between a provider and a resident is very different than that of a landlord tenant relationship, as landlords typically do not provide, nor are required by law to provide, food, housekeeping or assistance with ADLs pursuant to a rental agreement. The commenters recommend that in lieu of mandating eviction protections under landlord tenant laws, assisted living facility resident protections be provided through specific disclosure provisions as part of the resident agreement and approved by the applicable state licensing authority. The commenter added that such provision would specify the terms and conditions for move-in, including conditions for discharge or transfer and an appeals process for resolving disputes that are non-emergency in nature.

Response: We are pleased to hear that states have robust beneficiary protections included in the licensing requirements of certain settings. It is not our intent to replace a state's current system. The intent of the language was to assert the expectation that for a setting to be considered home and community-based, residents of provider-owned or controlled residential settings must have comparable protections available to them as those provided under the landlord tenant law of the state, county, city or other designated entity. As a result of the comments received, we have added to this requirement, for settings in which landlord tenant laws do not apply, that the state must ensure that a lease,

residency agreement or other form of written agreement is in place for each participant and that such agreements provide protections that address the eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law.

Comment: One commenter believes the § 441.530 (a)(1)(vi)(A) should be revised to permit discharge when an individual's condition changes and care needs can no longer be met under the license of the dwelling they occupy adding that there is nothing in the regulation that abolishes the Keys amendment requirements for SSI recipients or HCB waiver recipients.

Response: While we understand that there may be circumstances in which an individual's needs require a different level of service, we expect that the assessment of functional need, the person-centered plan and the availability of HCBS will be able to address an individual's changing needs. If it is determined that eviction or an involuntary discharge is necessary, the state must ensure that proper procedures for such actions are followed and individuals are fully informed of their rights.

Comment: One commenter wanted to know if it is the responsibility of the provider to assist the individual in finding other housing, services, and supports.

Response: The state is responsible for addressing this assistance through the person-centered planning process.

Comment: One commenter recommends the regulation require that states and providers delineate (a) the conditions under which an individual may be involuntarily moved from a setting he or she prefers, and (b) the methods by which the individual will be informed of such conditions at the time the individual chooses the setting.

Response: The regulation has been modified to provide that, in circumstances where tenant landlord tenant laws do not apply, a lease, residency agreement or other form of written agreement must be in place that provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law. Under circumstances where tenant landlord rules do apply, the state will ensure compliance with those rules.

Comment: One commenter indicated that their state requires a contract between the residents and providers and wanted to know if it could be used in lieu of a lease.

Response: It is possible that this arrangement would comply with the revised language allowing other forms of

written agreements to implement protections that are at least minimally comparable to the protection provided under the jurisdiction's landlord tenant law. A final determination of whether such contracts comply with the regulatory requirements will be made through the state plan amendment or waiver review process.

Comment: One commenter indicated that current requirements in their State allow for adequate service planning and transition (30-day notice) when a provider is unable to meet the needs of an individual, and the State suggested that the proposed rule reflect a similar requirement.

Response: We believe it is a good protection to include, however, we do not propose to amend the regulation to require a specific timeframe. We would like the state to retain flexibility in establishing timeframes.

Comment: Two commenters indicated that in their state, the assisted living model separates the assisted living services from housing. The commenters noted that providers of assisted living services are licensed and the services must be provided in a "Managed residential community" consisting of individual apartments where residents can continue to live and maintain personal autonomy. The commenters added that residents are considered tenants and are protected under the state's landlord tenant laws and that under this arrangement the assisted living services provided within the managed residential community are regulated by state licensure laws. The commenters requested that the rule recognize laws and state licensure laws and regulations that govern the provision of HCBS in their state.

Response: We believe the regulation allows for this.

Comment: Many commenters requested further clarification of the "specific physical place" language. In general, the commenters support the idea that individuals in congregate settings should have agreements for a specific room or unit and should not be arbitrarily moved around by providers. However, the commenters note that landlord tenant laws vary tremendously by state and their application to specific residential arrangements tends to be fact specific and subject to complex statutory and judicial interpretation. The commenters also note that the federal Fair Housing Act prohibits discrimination in almost all housing activities based on disability and requires housing providers to make reasonable accommodations to rules and policies when such accommodations are needed for the individual to use and

enjoy the housing. The application of the fair housing laws to residential settings that are also subject to state licensure and regulatory schemes can be complex, and the law in this area is continuing to develop. Additionally the state's "level of care" licensure standards that require the discharge of residents with certain types or acuity of conditions are at odds with civil rights protections designed to allow consumers to live and receive services in places they choose. Providers are not required to make accommodations where to do so would result in an undue financial and administrative burden or would fundamentally alter the nature of the provider's operations. However, providers and state licensing agencies are required to make reasonable accommodations to enable people to remain in the homes that they choose if the accommodations meet those tests. The commenters suggest that state plan amendments and waiver applications should specify processes by which they would make "reasonable accommodations" decisions without forcing residents to make claims in court or forcing providers to jeopardize their licensure by reasonably accommodating residents whose service needs have intensified, for example. Reasonable accommodations processes should provide plenty of notice and be easily used. A number of states have enacted interactive processes to provide appeals and individual determinations of the ability to remain, even if their continued residency represents a violation of the level of care requirements. Finally, a legally enforceable agreement under this subsection should include a right to appeal decisions affecting tenancy. Agreements should clearly specify the conditions that would trigger a termination, including conditions related to the person's health status or level of disability that would necessitate a move. The individual should have the right to appeal termination decisions to an objective third party in a timely manner, such as 30 days, which should be defined in the state's waiver application. This appeals process should be accompanied by the reasonable accommodation process noted above. Other commenter's recommended that if a state's licensing standards do not include such protections, then the landlord tenant statutes should be the default law. Several commenters recommended the following language: "An individual has, under state licensing law, protections from evictions. If these protections are not provided, the individual shall have,

at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord/tenant law of the state, country, city or other designated entity."

Response: We appreciate the commenter's thoughtful comments highlighting the complexities of applying tenant landlord rules to settings that normally do not have such an application. The regulation has been modified to specify that in circumstances where landlord tenant laws do not apply, a lease, residency agreement or other form of written agreement must be in place that provides at least comparable protections to those provided under the jurisdiction's landlord tenant law. At a minimum, these agreements must address eviction processes and appeals. Under circumstances where tenant landlord rules do apply, the state will ensure compliance with those rules. We are not amending the regulation to include specific language referencing state licensing laws. Rather we have amended the language to add "For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS participant and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law."

Comment: One commenter recommended replacing the proposed language "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" with the following:

(A) Individual has a lease, residency agreement or other form of written agreement that includes the ability to appeal move-out decisions to an objective third-party. Reasonable accommodations are made both by the provider and the state to accommodate aging in place. An appeal of a move-out decision should not prevent the move-out when there is a significant risk of harm to the resident, other residents, or staff. The appeal process will include nonpayment of fees unless the state has a demonstrated alternative process for addressing payment disputes. All appeals should be pursued expeditiously and should not take longer than 30 days.

Response: We appreciate the commenter's recommendation, however we do not believe it is appropriate to include as a requirement. We note that the suggested language represents some good practice, and would encourage states to include such protections in

their policy and procedures if they do not already exist.

Comment: One commenter recommended the following changes to the proposed language: “The unit or room is a specific physical place that, if a ‘family care home’, includes a private bedroom, and if not a ‘family care home’, includes, at a minimum, its own kitchen facilities, sleeping area, and private bathroom with toilet, sink and shower or bathtub, that can be owned, rented or occupied . . .”

Response: We appreciate the commenter’s suggestions, however, we will not revise the rule to include these types of specifications as they would be overly prescriptive.

Comment: One commenter requested that we revise the regulation to specify that the unit can be owned, rented or occupied under another legally enforceable agreement by the individual receiving services “or his/her chosen surrogate, who must not be an agent of the service provider,” could be inserted.

Response: We do not believe the commenter’s recommendation to add language regarding a surrogate is necessary. The HCBS regulations already address this in the definition of individual’s representative.

Comment: Several commenters supported giving individuals who receive HCBS in provider-owned or operated residential settings protections under landlord tenant law, and suggested adding protections afforded by the ADA to this section to ensure that individuals living in these settings whose health needs change are afforded appropriate accommodations (such as increased staff), in order to continue living in the setting.

Response: While we do not administer or enforce the ADA, we note that Medicaid regulations prohibit discrimination in State Medicaid programs (§ 430.2, § 435.901, § 435.905, and § 435.908). As these regulations apply in determining eligibility and administering the Medicaid program generally, it is not necessary to amend this regulation on this subject.

Comment: A few commenters recommended the word “unit” be replaced with “room” throughout the document.

Response: We do not agree with the recommendation to remove the term unit, but to provide additional clarification, we have revised the language to add the term “dwelling” since this is the common term used under prevailing state and local landlord/tenant laws.

Comment: Several commenters agreed with the list of requirements for provider owned and controlled

residential settings. One commenter added that preservation of the right to privacy, including having a lockable unit and the ability to control access to the unit, and self-control of the participant’s schedule, are also important indicators for basic human dignity. Another commenter noted that individuals with disabilities should be afforded the same rights as anyone else in the country.

Response: We agree and appreciate the commenter’s support.

Comment: One commenter indicated that “the freedom to furnish and decorate their sleeping or living unit” could use clarification noting that there are many landlords that have restrictions on water beds, or permission prior to painting. The commenter added that all rules relating to entrance locks, roommates, furniture preferences, daily schedules, food, visitors, etc., must include caveats as to feasibility and reasonableness.

Response: These requirements pertain to settings that are owned or controlled by a provider. Landlord tenant laws may allow landlords to set reasonable limits as long as the limits are not discriminatory or otherwise deny rights granted to tenants under the state law. Therefore, we have added additional language to this requirement to clarify that, in a provider-owned or controlled setting, the individual’s freedom to furnish and decorate sleeping or living units may contain limits within the scope of the lease or agreement.

Comment: One commenter expressed support of the criteria when an individual lives alone, but wanted to know in situations where an individual chooses to live with a roommate who is responsible for collaborating schedules and ensuring that one person’s right to have visitors does not infringe on the privacy of the other.

Response: While this is not specifically addressed through regulation, we note that there are many ways to address this concern, including through good roommate communication.

Comment: Several commenters recommended that “their” be changed to “the,” since “individual” is singular but “their” is plural.

Response: We agree with the commenter and have revised the regulation accordingly.

Comment: One commenter noted that individuals requiring care and services will have their privacy limited in some fashion while those care and services are being provided and suggested the following revision to § 441.530 and § 441.656(a)(1)(vi)(B): Each individual has privacy in their sleeping or living

unit, to the extent care and services are provided in accordance with the individual’s assessed needs.

Response: We do not believe the recommended revision is necessary as there is a general requirement that services are provided in accordance with an individual’s assessed needs. This requirement is expressed at § 441.530(a)(1) and § 441.710(a)(1) and also under person-centered planning provision of the regulations for sections 1915(c), 1915(i) and 1915(k) of the Act.

Comment: A few commenters disagreed with the proposed language requiring that units have lockable doors. The commenters believe that this requirement poses a safety risk in the event of an emergency and added that clarification is also needed on a unit owned by the resident who may not want to provide the appropriate staff with keys to his/her door. The commenters pointed out that in some apartment buildings the entrance door is the unit’s door and asked if the resident owns the unit whether he/she will be required to provide appropriate staff with keys.

Response: We disagree that the recommended change is necessary. However, the requirement for a lockable entrance door may be modified if supported by a specific assessed need and justified and agreed to in the person-centered service plan. Additionally, the state must ensure adherence to requirements set forth at § 441.530(a)(1)(vi)(F) and § 441.710(a)(1)(vi)(F).

We would like to clarify that this regulation does not require individuals to provide keys to anyone. The language is meant to curtail the issuing of resident keys to all employees or staff regardless of the employee’s responsibilities, thus granting employees unlimited access to an individual’s room. This provision indicates that only appropriate individuals should have access to an individual’s room. For example, it may be appropriate for the property manager to have keys, but it might not be appropriate for the individual working at a reception area.

Comment: One commenter recommended the additional phrase “if necessary” be added after “appropriate staff,” as there may be occasions when the particular setting will not have staff members holding keys to living units. Several commenters recommend adding the phrase “as appropriate” at the end of the provision since there may be times when a setting will not have staff members with keys to living units.

Response: We agree with the second commenter’s concern and have

modified the regulatory language accordingly to indicate “as needed.”

Comment: Other commenters advised that they support lockable entrance doors with appropriate staff having keys to doors, since there are also provisions under the individual modification of requirements discussed below that can be used for individuals with cognitive impairments for whom lockable doors and free egress may present safety and other issues. In such cases, alternative means for assuring meaningful individual privacy should be required (for example, knocking and waiting for a reply before entering a person’s private space, respecting private possessions, etc.).

Response: We appreciate the commenter’s support.

Comment: Two commenters expressed concern that the regulation does not specify a process to determine which staff will have keys, or that the individuals themselves must have keys. One of the commenters is aware of instances where people have been denied key access to their own homes without appropriate justification. The commenter recommended that CMS add language to require that (1) the staff that will have keys are included/identified in the person-centered service plan and chosen by the individual and (2) the individual must also have a key to the door. The commenter recommended the following language: “Staff holding keys will be named in the person-centered service plan and individuals must have keys to their own units” to § 441.530(1)(vi)(B)(1), § 441.656(1)(vi)(B)(1), and § 441.665(b)(3) for clarity across the regulations.

Response: We do not agree that the regulation should require that the person who has keys should be identified in the person centered plan, but we do agree that the individuals should have a say and agree with who that person is. We agree with the recommendation that individuals have keys to their door, and have clarified the language in the appropriate sections of the regulation so that this is unambiguous. As noted above, an individual’s use of the room key may be modified if supported by a specific assessed need and justified and agreed to in the person-centered service plan.

Comment: One of the commenters requested that CMS clarify whether the proposed rule requires the homes to be locked or the bedroom doors to be locked.

Response: We would like to clarify that the individual must be able to lock the door to their unit or dwelling, that

the individual has a key to the door, and that only appropriate staff have keys.

Comment: Several commenters offered support of the requirement that individuals share units only at the individual’s choice. One commenter does not believe that sharing units is faithful to the principles of HCBS. We also received comments opposing the requirement or requesting further clarification of the intent of the requirement. Several commenters believe this provision is inappropriate and recommended that the private room/living space requirement be deleted completely. Commenters noted that Medicaid does not cover room and board costs so they believe that the term “choice” could be misleading, as the determining factor for choosing double occupancy versus a single-occupancy unit may be whether a resident can afford to. Many individuals are not financially able to afford a private room in settings such as assisted living facilities. One commenter expressed concern that, as proposed, allowing individuals to choose to share units without also requiring states to provide (financially needy) individuals with adequate funding, such as increasing the maintenance needs allowance, will force those individuals into nursing facility settings. One commenter added that “individual choice” should be reflective of an individual’s resources and care needs. Another commenter believes that since beneficiaries typically pay for room and board out of their SSI benefit the proposed language would effectively exclude assisted living as an option for Medicaid individuals in many states since providers cannot afford to offer private rooms at the rate Medicaid beneficiaries pay. A few commenters added that sharing living units may be necessary to ensure a range of housing options the HCBS waiver program and at the same time manage resources to meet the cost-neutrality standard under the section 1915(c) of the Act waiver program. A few commenters interpreted the regulation to require separate bedrooms for all individuals receiving residential services unless the individual requests otherwise and stated that this requirement will result in a huge unfunded mandate that will double the cost of residential group home care. Commenters suggested the following regulatory changes related to this provision:

□ Revise the rule to say “Individuals in shared rooms will have a choice of roommate.”

□ Revise the rule to say “Individual roommate preferences are accommodated to the maximum extent

practical and documented in the individual’s person-centered service plan.”

□ Revise the rule to add a requirement that individuals should not have to share a unit unless it is with a spouse, partner, or other family member.

□ One commenter recommended that sharing a bedroom is clearly documented as the choice of the individual and that the room is shared only with a person of the individual’s choosing.

□ One commenter suggested that the rule needs to make it clear that a resident’s choice acknowledges his economic situation.

□ Other commenters noted that if the requirement is finalized, CMS needs to add an exception to the requirement for residential settings that do not meet the private room/living space requirement but are appropriate to meet the waiver client’s needs and preferences according to the individual, the client’s designated representative and the case manager.

□ Revise the rule to say “Individuals with disabilities receiving HCBS share units with other individuals with disabilities receiving HCBS, whether the unit is a single bedroom or a multi-room living space, only at the choice of the individual with disabilities receiving HCBS, at all times and under all circumstances. Individuals with disabilities receiving HCBS may share such units with a person who is present to provide services to the individual if necessary for safety reasons, if appropriately justified and documented.”

Response: We understand the concerns raised by the commenters. We have clarified that we are not requiring that every individual receiving HCBS have their own bedroom when receiving residential services. The rule is requiring that individuals be provided options of residential settings, including an option of a private room. This rule does not require every provider to have a private room option. Instead it requires the State to ensure that there are private room options available within a state’s HCBS program. We agree with the commenters that the financial resources available to an individual may impact the options available to a particular individual and we have changed the regulatory text to make that clear. We also agree with the commenters that if an individual chooses to share a room, that individual also must have a choice of their roommate. We have changed the regulatory text to clarify this. We plan to address these issues further through future guidance.

Comment: One commenter indicated that in their assisted living facility, all residents have a private room but share a ½ bath with the private room next door and believes that under the proposed regulation a resident in this kind of situation would never find the appropriate bath mate because the rule would require that they have their own ½ bath and the commenter believes this was not CMS' intent.

Response: We believe that the arrangement described by the commenter, that one bathroom is shared between two private rooms, will meet the requirement at § 441.530(a)(1)(vi)(B)(2) and § 441.710(a)(1)(vi)(B)(2) that individuals share units only at the individual's choice.

Comment: One commenter recommended that CMS form a work group of stakeholders to determine a method for ensuring that Medicaid waiver applications and renewals demonstrate how the state assisted living program ensures adequate reimbursement for private room occupancy (that is, the state assisted living program does not restrict room and board payments to less than the cost of providing a private room and provides housing assistance as required).

Response: States are required to provide opportunities for public input in the development of Medicaid service rate methodologies. During the SPA review process, we ensure that the state has met this requirement and that the state's proposed reimbursement methodologies comport with requirements at section 1902(a) of the Act. These include safeguards against unnecessary utilization of services, assurance that payments are consistent with efficiency, economy, and quality of care, and that payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such services are available to the general population in the geographic area.

Comment: One commenter suggested that the requirement that individuals have privacy in their sleeping or living unit should not be waived by the provider/state.

Response: We agree that an individual's privacy should always be respected. Where any modification of this condition occurs, we have included protections in the rule to ensure the individual's rights are respected.

Comment: Several commenters strongly urged CMS to require that a bathroom be in the unit for all settings with a capacity of six or more residents as the commenters believe that having

one's own bathroom is a fundamental characteristic of living in one's own home. The commenters noted that CMS proposed a similar requirement last year, and believes that such a requirement is no less important today and added that it would be difficult to consider a setting "community-based" if, for example, a building housed 10 or 20 residents who shared a bathroom or bathrooms located off a main hallway, and a resident at 2 a.m. had to walk down the facility hallway in order to use the bathroom. The commenters recommended the following provision be added to the requirements at (B): Units include at least one full bathroom (unless the setting is in a building with a capacity of six or fewer residents).

Response: We understand the commenters' concern; however, the standard for how many bathrooms a dwelling must have is governed by building code, and is beyond the scope of this regulation.

Comment: One commenter expressed the opinion that the bathroom is the most private part of their home, and inability to control functions performed in that room is a major source of feelings of loss of dignity and personal autonomy among people with disabilities. As such, the commenter believes that privacy in the bathroom should be maximized and assistance should be provided only when actually needed, limited to specific tasks and carried out one-on-one with the bathroom door closed.

Response: We agree with the commenter and believe that an individual's privacy should be respected in all activities of an individual's life.

Comment: Several commenters expressed strong support and appreciation for the inclusion of this provision and two noted that the inability to decorate or furnish a living unit would be a clear indicator of an institutional model.

Response: We appreciate the commenters' support.

Comment: A few commenters supported the proposed rule as written.

Response: We appreciate the commenter's support.

Comment: One commenter supports the regulation, but believes the rule should go further and require living units to have access to food storage and preparation space (with the caveat that stoves or microwaves could be removed if the assessment documented that it would be a danger because of the resident's cognitive impairment).

Response: We agree with the commenter and believe that this is reflected in this regulatory language.

Comment: Several commenters generally supported the proposal that individuals have the freedom and support to control their schedules and activities, but recommended that the word "control" be changed to "choose" noting that choice is a foundational element of HCBS and merely allowing individuals to control schedules and activities is inadequate. According to commenters, supporting an individual and providing the support necessary to participate in activities (for example, the transportation to attend a selected activity) allows for full community living.

Response: We believe that it is fundamental for individuals to have the control to make their own choices. Therefore, we do not believe it is necessary to change the word control.

Comment: While commenters agreed with the principle that a resident should be able to eat, socialize and come and go freely, several commenters expressed concern with the proposed language and suggested that (a)(1)(vi)(C) should not focus on "access" but rather on the individual's choice to select the foods they eat, to store food in their rooms, to bring back food from the facility's kitchen and to reschedule meal times. The commenters pointed out that because HCBS facilities most likely schedule meals at specific times, as required by regulation, a resident may not have access to all food in the building all the time, and a residential setting cannot reasonably accommodate each individual's preference on a 24-hour a day basis. One commenter requested clarification as to whether or not the proposed "access" requirement would result in a housing arrangement that includes a daily activity (such as meals) at pre-arranged time not being considered a home and community-based setting. A few commenters requested that the final regulation be stronger in its intent to ensure meaningful choice and provide for activities that will support integration with the community. The commenters noted that as written the language could be easily interpreted to maintain institution-like settings instead of true community living. The commenters are concerned about situations in which individual choice is not meaningful, for example, an individual being given access to food by having the choice of a snack bar or a pitcher of water and crackers.

Response: We disagree with the commenters' belief that a residential setting cannot reasonably accommodate an individual's preference on a 24-hour a day basis. The opportunity for individuals to select the foods they eat,

store food in their room, eat in their room, and decide when to eat are all ways in which the access to food requirement can be met. Under this provision, giving an individual the choice of a snack bar or a pitcher of water and crackers does not meet the access to food requirement. An individual should not be presented with narrow options, decided by someone else, without input from the individual.

Comment: One commenter believes the term “food” can be interpreted broadly and could lead participants to believe that there must be 24/7 access to full service dining. The commenter recommended that in order to eliminate the range in interpretation, CMS replace the word “food” with “snacks.”

Response: We disagree with the recommended change. We expect that the individual will have access to food. This requirement does not pertain to full dining services or to meal preparation, only access to food.

Comment: One commenter cautioned that the freedom and support of access to food at any time needs to be carefully monitored and offered the example that unrestricted access to food may be unrealistic for individuals with eating disorders or brain injury.

Response: Modification to this requirement may occur as long as it is done in compliance with § 441.530(a)(1)(vi)(F) and § 441.710(a)(1)(vi)(F).

Comment: One commenter noted that freedom to control schedules and activities with support to do so is a different issue from “access to food at any time” and requested if CMS intended the support to be available for food related activities as well?

Response: It is unclear what the commenter means by “food related activities.”

Comment: One commenter believes that the requirement that individuals have “freedom to control schedules and activities with support to do so” should not be permitted to be changed by the provider/state. The commenter explains that this is a particularly important point because many residential facilities have policies and procedures that say that residents have freedom to choose and participate in preferred activities, but as a matter of actual fact, the facilities do not provide the necessary support to make such freedom a reality. The commenter suggests that this subsection may be an appropriate place to state that “a person’s ability to receive any service from any provider described in his/her person-centered plan will not be infringed upon by any provider for any reason.”

Response: We agree that a person’s ability to receive services identified in the person-centered service plan should not be infringed upon by any provider for any reason. We believe that preventing an individual from receiving any service identified in the person-centered service plan is a direct violation of the person-centered plan requirements and the home and community based setting requirements specified in this regulation.

Additionally, any setting not adhering to the regulatory requirements will not be considered home and community-based. The supports necessary to achieve an individual’s goals must be reflected in the person-centered service plan as required under § 441.725(b)(5).

Comment: One commenter suggested that, to modify the condition pertaining to individuals having visitors of their choosing at any time, provider documentation should be required for a safety need to restrict access to a person’s desired visitors, the names of specific visitors whose access will be controlled, how access will be controlled, along with a description of the specific independently-verifiable threats of real harm that uncontrolled access by those visitors represent to the person. The commenter suggested that the plan should allow visits even by people on this controlled-access list if they can be conducted safely by providing a monitor or other means.

Response: We appreciate the commenter’s general support. The regulation has been modified at § 441.530(a)(1)(vi)(F) and § 441.710(a)(1)(vi)(F) to specify the requirements that must be met to modify the condition pertaining to individuals having visitors of their choosing at any time.

Comment: One commenter expressed concerns that some assisted living settings may have policies about visitation and that as a result they would be automatically eliminated from being considered community-based settings.

Response: Settings that do not comply with the requirements of this regulation will not be considered home and community-based settings.

Comment: Several commenters supported individuals’ rights to have visitors of their choosing at any time; however, the commenters noted that in a provider-based setting this right should be viewed in the context of shared living arrangements. Several commenters noted that the safety of other residents and their ability for quiet enjoyment of their living setting must be considered and suggested that the rule be revised to add language that allows

for reasonable rules for safety and the quiet enjoyment of the provider setting.

Response: We acknowledge that in certain living situations the preferences of others must also be respected. We expect that there will need to be communication and coordination between all parties affected.

Comment: A few commenters voiced concern that allowing some individuals to have any visitors of their choosing at any time in some cases could be a safety issue. Another commenter added that it is not reasonable that residents be allowed to have visitors to the extent that they can “visit” for extended and/or indefinite periods of time, noting under the proposed language, these visitors could actually live in the HCB setting.

Response: It would be reasonable for there to be limitations on the amount of time a visitor can stay as to avoid occupancy issues. Such limitations should be clearly stated in a lease, residency agreement, or other form of written agreement.

Comment: Several commenters supported the proposed language in general but one recommended that CMS add “including overnight” to allow for individuals to have visitors of their choosing at any time as this is a right that others have.

Response: We believe the language adequately addresses this issue, and allows for flexibility as appropriate.

Comment: Several commenters recommended that the proposed requirement on visitors have additional language and protections, which would allow for reasonable limitations on how and where visits are conducted for safety and the quiet enjoyment of the provider setting for all residents. One commenter suggested that the provision be changed to read: “individuals are able to have visitors of their choosing at any time that is reasonably and mutually agreeable with other members of the household and consistent with their support needs.” Two commenters recommended adding the phrase “provided such visitors are not disruptive to individuals in the residential setting” to the end of the proposed language. One commenter recommended the rule be revised to say “if the building rules are established and approved by the residents, they are allowable and residents can receive HCBS.” Another commenter believes CMS should add a provision that the provider can deny access of visitors if there is a reasonable belief that the visitor presents a danger.

Response: We believe the regulatory language adequately addresses the visitation requirement. We will take the

commenters' suggestions under consideration as we develop further guidance.

Comment: Several commenters strongly supported this provision as proposed and stressed that it is an essential provision. These commenters expressed concern that under current standards, some assisted living settings are not physically accessible and have nonetheless received HCBS waiver funding for setting services. One commenter supported this requirement and added that the modifications and justifications for physical accessibility are included in the service plan.

Response: We appreciate the commenters' support.

Comment: One commenter believes that the proposed language is too vague and noted that additional guidance is essential, especially given the limited availability of resources to upgrade existing facilities and the varying degrees of accessibility needed depending on the nature of any particular disability. Some commenters noted that settings must be physically accessible under the ADA and Section 504 of the Rehabilitation Act without reference to any specific characteristics of the individual and therefore, indicated that this provision isn't necessary. A commenter indicated that there are no possible legitimate safety reasons for not providing a physically accessible residential or program setting to any person with a disability, and that failure to do so may be a safety hazard. These commenters advised that this condition must not be modifiable for any reason.

Response: We agree and revised the regulations so that they do not include § 441.530(a)(1)(vi)(E) and § 441.710(a)(1)(vi)(E) as an additional condition that can be modified.

Comment: Two commenters indicated that to ensure the exclusion of segregated settings and promotion of integrated settings, CMS should revise this provision to specify that a provider-owned or controlled residential setting should not only be "physically accessible," in terms of architecture for persons with mobility disabilities, but should also be accessible for persons with sensory disabilities. This includes ensuring effective communication through the provision of auxiliary aids and services, such as but not limited to sign language interpreters, alternative formats, and adapted equipment and devices, such as smoke alarms and telephones.

Response: We do not agree with commenter's suggestion to revise the regulatory language. Items and services that are needed by individuals to live in

their homes and communities would need to be identified through the person-centered planning process and some of those items and services may be covered through a Medicaid service, such as 1915(i) HCBS, State plan home health or under a 1915(c) HCBS waiver.

Comment: One commenter supports the list of excluded settings.

Response: We appreciate the commenter's support. The excluded settings included in the regulation are consistent with the settings excluded in statute.

Comment: Many commenters noticed the difference between § 441.530(a)(2)(iv) and § 441.656(a)(2)(iv). The commenters wanted to know if the difference exists because the 1915(i) statute refers to "hospital" as institutionalized care, whereas 1915(k) does not. To the extent possible, the commenter encouraged CMS to be consistent across authorities if it intends to clarify this difference.

Response: Whereas section 1915(k)(1)(A)(ii) of the Act expressly prohibits a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded from being considered home and community based settings, the statute did not include a hospital among the list of excluded settings. In an effort to be consistent with other authorities providing HCBS, we proposed to exclude hospitals providing long-term care services from the definition of a home and community setting for the provision of the Community First Choice Option. We believe that it would be duplicative to provide CFC services, such as assistance with activities of daily living, in such settings. Additionally, 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 that services are provided in the most integrated setting appropriate to the individual's needs. However, we understand that individuals will likely have a continued need for certain types of assistance while experiencing a short-term stay in a general acute hospital setting. Under such circumstances, most services provided in a general acute care hospital are not CFC services, but individuals who have an assessed need for assistance with IADLs may continue to receive such services while an inpatient in such a setting.

Comment: Many commenters requested this section be revised to exclude "a hospital" without the proposed qualification that it must provide long-term care services. One

commenter also agreed with the recommended revision and expressed concern about duplication of services. The commenter believes that allowing an individual to receive IADL services during a short-term stay in a general acute hospital would be hard to administer without increased costs to the state. The commenters want the language to be consistent with § 441.656(a)(2)(iv), which excludes any section 1915(i) of the Act service from being provided in a hospital.

Response: As with payment for any Medicaid service, we expect states to have processes in place to safeguard against unnecessary utilization of such care and services and prevent the duplication of the payments of Medicaid services. We understand that individuals may have a continued need for assistance with certain IADLs 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, as long as those services do not duplicate services provided by the hospital setting while an inpatient in an acute hospital setting.

Comment: A few commenters agreed with the regulatory language stating that individuals in an acute care hospital who need assistance with IADLs, should not be prevented from receiving such services while they are in an acute hospital setting. The commenters further stated that the ability to receive these services, as needed, while in the hospital could enable a smoother transition after hospital discharge back to a home or community setting and help prevent institutionalization.

Response: We appreciate the commenters' support, and will include this provision into the final regulation.

Comment: Several commenters requested the regulation be revised to add "Board and Care homes" for people with disabilities to the list of excluded settings, because of the institutional manner in which they operate.

Response: We do not believe it is necessary to identify specific settings, beyond what is specified in statute. States define settings differently, and the way board and care operates in one state, may be very different from the way board and care settings operate in another state. Recognizing the lack of national standard-setting definitions, we believe defining the qualities that all settings must exhibit to be considered home and community-based is the best way to apply a national standard. We believe the most effective and consistent

way to assure that individuals receiving Medicaid HCBS, regardless of age or type of disability, are offered HCBS in the most integrated setting appropriate to their needs and preferences, is to focus on the qualities of “home” and “community” that assure independence and integration from the perspective of the individuals. We will provide additional guidance to states to identify any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS.

Comment: In response to the request in the preamble for comments on whether there are settings in addition to those currently enumerated that are, by their nature, location, or administration inherently non-community based, several commenters suggested § 441.530(a)(2)(v) and § 441.710(a)(2)(v) be revised to say “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 isolated from the larger community, does not allow individuals to choose whether or with whom they share a room, limits individual’s freedom of choice on daily living experiences such as meals, visitors, and activities or limits an individual’s opportunity to pursue community activities.” The commenters also stated that if CMS does not make the recommended revision, then the regulations in § 441.530(a)(2)(v) and § 441.710(a)(2)(v) should specify that such characteristics give rise to a rebuttable presumption that the setting is not home and community based.

Response: We appreciate the commenters’ suggestions, however we believe they are already addressed in § 441.530(a)(1) and § 441.710(a)(1). Therefore we will not revise § 441.530(a)(2)(v) and § 441.710(a)(2)(v) to include the commenters’ suggestions as we believe it would be duplicative.

Comment: One commenter indicated that it is difficult to imagine how settings located on or adjacent to the grounds of an institution could be considered home and community based. Another commenter further added that the regulation should be revised to add that the settings listed in § 441.530(a)(2)(v) to the list of excluded settings.

Response: In response to the many comments we received, we will not amend the regulation to explicitly prohibit settings listed in section § 441.530(a)(2)(v) from the definition of

home and community-based. However, such settings are presumed to be institutional. States wishing to identify such settings as home and community-based may, during the SPA and waiver submission and review process, provide evidence as to how such settings are not institutional in nature. We will determine if the setting is not an institution and meets the HCB setting requirements.

Comment: One commenter requests CMS reconsider its position with regard to the provision of HCBS on ICFs/MR campuses and planned residential communities for people with developmental disabilities.

Response: ICF/IIDs (formally known as ICF/MRs) are statutorily prohibited from being considered home and community-based under the authorities of sections 1915(c), (k) and (i) of the Act and services provided on the campuses of these facilities are presumed to not have the qualities of HCBS under this rule and subject to the heightened scrutiny provision of this rule.

Comment: A few commenters requested the rule clarify that the exclusion is intended for residential supports and not supported employment or other vocational activity that may find an individual choosing competitive employment in a setting that may be located in a building on the grounds of, or immediately adjacent to a public institution or disability-specific housing complex.

Conversely, another commenter expressed concern that people with disabilities are being served in segregated work and day settings that do not meet the “most integrated setting” definition and do not comply with guidance related to the ADA and the *Olmstead* decision issued by the US Department of Justice (DOJ).

Additionally, the commenter indicated that DOJ has made it clear that the ADA’s integration mandate includes day and employment services, and that unwarranted placement in segregated day programs is a violation of this mandate. Thus, this commenter recommends that CMS consider excluding segregated, congregate facilities and programs from the definition of HCBS. The commenter also recommends specifying the following settings are excluded (per DOJ guidance): (1) Congregate day and employment services populated exclusively or primarily with individuals with disabilities, (2) Congregate day and employment services settings characterized by regimentation in daily activities, lack of privacy or autonomy, policies limiting visitors, or limits on individuals’ ability

to engage freely in community activities and to manage their own activities of daily living; or (3) Day and employment services settings that provide for daytime activities primarily with other individuals with disabilities. The commenter recognizes that if these recommendations are adopted, a transition period is necessary to ensure sufficient time for services to meet these new requirements.

Response: CMS does not have the general authority to enforce the ADA independently of its oversight of the Medicaid program. To the extent that the services described are provided under 1915(i) or 1915(k) (for example, residential, day, or other), they must be delivered in settings that meet the HCB setting requirements as set forth in this rule. We will provide further guidance regarding applying the regulations to non-residential HCBS settings. In addition, since this authority provides states the opportunity to provide individuals HCBS and not institutional services, individuals receiving 1915(i) State plan HCBS or 1915(k) CFC services must be living in settings that comport with the HCB setting requirements as set forth in this rule regardless of whether they are receiving HCBS in that residence. This is consistent with CMS’ longstanding policy regarding 1915(c) HCBS.

Comment: One commenter recommends establishing a maximum limit to the number of individuals living in a provider-owned or controlled residential setting.

Response: We do not believe there is a maximum number beneath which we could determine with certainty that the setting would meet the requirements of HCB settings. The focus should be on the experience of the individual in the setting. In addition, we respect a state’s right to establish state laws to implement such a requirement regarding size. We intend to provide additional guidance to states to identify any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS. We plan to include in the guidance examples of specific settings that will require heightened scrutiny and may identify additional qualities, including the size of the facility, triggering such scrutiny. Our experience through our work with other federal Departments and current research indicates that size can play an important role in whether a setting has institutional qualities and may not be home and community-based.

Comment: One commenter added that an approach focused on characteristics,

rather than locations, provides a useful framework to define home and community-based settings, while allowing consumers of long-term services and supports choices regarding the services and supports they receive and from whom they receive them, rather than limiting the person's choices arbitrarily. However, several other commenters expressed opposition to this language and requested that it be removed completely. These commenters stated that, if a provider-based setting can meet all of the criteria in paragraph (1), it should not matter where the provider is located, and applying a rebuttable presumption is redundant. They also stated that the focus should be on the autonomy of the individuals receiving services. One from this group of commenters stated that the "rebuttable presumption" could create a standard that is difficult to meet and imposes obstacles that are unnecessary and unreasonable. This commenter also stated that each setting regardless of physical location should be evaluated in accordance with the same quality review criteria and that the rebuttable presumption is not good public policy and has the potential to be prejudicial. Another commenter stated that the focus should not be on the setting, but rather on an individual's choices and the person-centered service plan, and does not believe arbitrary geographic or location-specific criteria are appropriate. One expressed that this requirement will hinder current initiatives to rebalance state's long term care systems. Another expressed concern with the effect this language would have on settings financed by the Department of Housing and Urban Development (HUD) with millions of dollars to develop group homes, apartment complexes and other housing for individuals with developmental disabilities. Another stated that some individuals make the choice to live in disability-specific housing with proximity to friends that rent from the same provider, or that they choose housing in a convenient location with access to services such as transportation.

Response: We appreciate the comments provided about the challenges of the term rebuttable presumption. The proposed language provided a list of settings that, from our experience in approving and monitoring HCB programs, typically exhibit qualities of an institutional setting. However, we recognize that state innovations, creative and proactive efforts to promote community integration, and market changes could

result in the settings being located in a building that also provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to a public institution, that in some instances could be considered home and community-based. In response to public comments, we have revised the regulatory language to say "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 any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the state or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings." We believe the revised language more clearly reflects the intent of this provision.

Comment: One commenter expressed concern with the ultimate discretion granted the Secretary through this regulation; the commenter categorizes it as "authority with strings attached." The presumption, coupled with the requirement of heightened scrutiny for certain proposals, makes it very difficult for the Secretary to find in favor of innovative partnerships that provide immediate and consistent access to necessary health care, peer relationships, and legitimate "integration," including HCBS homes located on ICF/MR campuses and planned residential communities.

Response: We do not agree with the commenter. We believe the requirements set forth in this regulation will support innovative partnerships that support community integration and provide individuals with maximum control.

Comment: One commenter recommended the rule apply a presumption of "community-based" if an individual has lived in an assisted living facility for at least 12 months and is the only available alternative to the institutional settings.

Response: We do not believe that the amount of time spent in a setting should be used to classify the setting as home and community-based.

Comment: Several commenters stated that while the concept of a rebuttable presumption may be attractive in the

abstract, the commenters doubt that it can be operationalized effectively. The commenters expressed concern that this will be done as an individualized determination falling under "we-know-it-when-we-see-it." The commenters stated that providers need clear guidance ahead of time, before the individual moves in and/or before the provider develops property. A couple of commenters expressed concern about the lack of guidance regarding rebuttable presumption and what would constitute adequate rebuttal of the presumption. One stated that the proposed rule already creates a set of requirements specific to provider-owned and controlled residential settings receiving HCBS funding, which effectively create heightened scrutiny for such settings. The commenter also questioned what procedural safeguards will be in place to allow appeals of decisions, who will make the final determinations, what are the additional administrative burdens placed on states and providers to add this additional layer of heightened scrutiny, and if a setting meets an individual's needs and preferences and meets the other criteria for home and community-based settings, who should bear the burden of proof to demonstrate that a setting is not home and community-based. Some commenters believe that the settings to which the rebuttable presumption will apply should be explicitly excluded rather than subjected to "heightened scrutiny."

Response: The regulation has been revised to make it clear that states wishing to present evidence that such settings are home and community-based may do so. Under such circumstances, we will engage in heightened scrutiny in the course of the review of a SPA and/or the state's transition plan of supporting documentation of this evidence to make a determination that the settings do comply with the requirements set forth in § 441.530 and § 441.710. This review will also include assessment of how the settings allow for full integration into the broader community. In addition to information provided from the state, we also will accept information from stakeholders and other third parties regarding whether such settings have the qualities of being home and community-based and do not have the qualities of an institution. We stress, however, that lacking strong evidence to the contrary, we will presume the settings are not HCB.

Comment: One commenter indicated disagreement with the application of a rebuttable presumption. Specifically, the commenter does not agree with

housing arrangements that encourage spouses and family members to tie their own housing to the institutional housing of the family member who requires the most care, rather than encouraging the development of innovative solutions for how individuals with various chronic and high care needs may be housed in the most integrated settings. The commenter also indicated that while it is tempting to cleanly differentiate between the needs and wishes of senior constituents and the disability community regarding this regulation, it does not take into account the increasing numbers of people with disabilities who are aging, who must be assured that they will not have any weaker protections around gaining access to services and supports in a truly integrated community setting.

Response: We appreciate the commenter's opinion. We believe our HCB setting requirements are beneficial to everyone regardless of age, condition or level of disability.

Comment: Several commenters suggest that rather than creating a rebuttable presumption, CMS should state that the settings listed in § 441.530(a)(2)(v) and § 441.710(a)(2)(v) are not home and community-based even if these settings meet the requirements in paragraph § 441.530(a)(1) and § 441.710(a)(1). The commenters urged that one of the most important qualities of a home and community-based setting is its location; a setting that is literally on the grounds of, in, or synonymous with an institution cannot be home and community-based.

Response: We appreciate the commenter's perspective. Such settings are presumed to be institutional and not home and community-based. However, we recognize that it could be possible for some of these settings to operate in a manner that is consistent with the HCB requirements set forth in this rule. Therefore, we will engage in a formal review of such settings if the state would like to recognize them as home and community-based settings under the applicable Medicaid authorities.

Comment: One commenter suggests that if we retain the heightened scrutiny of settings described in this section, then we should modify the regulation to include an exception from the requirement if the client, the client's designated representative and client's case manager believe it is in the client's best interest to be allowed to live in such a setting.

Response: We believe that individuals must have the opportunity to receive services under 1915(i) in settings that support integration with the greater

community. Therefore, State plan HCBS must be delivered in a setting that meets the HCB setting requirements as set forth in this rule and since this authority provides states the opportunity to provide individuals HCBS and not institutional services, individuals must be living in settings that comport with the HCB setting requirements as set forth in this rule. For settings that do not meet these requirements, we note that there may be other Medicaid authorities under which such services may be covered.

Comment: One commenter expressed concern that the presumptive ineligibility of certain congregate settings and disability specific housing may have a chilling effect on the development of innovative service delivery approaches designed to meet the preferences of and provide a wider array of options to people with limited income and resources. For example, the commenter notes that continuing care retirement communities (CCRCs) and dementia-specific assisted living have been important options for older persons who want to plan for a future in which increased disability is likely. But most of such settings and services are very expensive—well out of the reach of people who are likely to need Medicaid assistance. In response, some innovative providers of subsidized housing are co-locating assisted living settings on the same location or converting parts of their buildings to assisted living. If such approaches would mean that these settings were presumptively ineligible to participate in Medicaid HCBS programs, it could have a chilling effect on developing such innovations—effectively restricting them to those consumers who have substantial resources. One potential solution would be to recognize what the Fair Housing Amendments Act of 1988 has recognized in civil rights law—namely that “housing for older persons” is desired by a substantial number of people age 55 and older and that it is not considered discriminatory. It is relevant to recall that assisted living and CCRCs emerged largely as private pay options, reflecting strong consumer demand for age-specific housing with services that enable older people to live more independently than they would in a nursing home. This history stands in contrast to state mental hospitals or institutions for those with intellectual or developmental disabilities, where state policies created segregated environments for people with such disabilities. The history of age-specific housing with service approaches also contrasts with the history of nursing

homes, which grew dramatically after the enactment of Medicaid with its institutional funding bias. In correcting the history of state and federal actions that have segregated people with disabilities, CMS should not prevent the ability of older persons with low incomes to access innovative approaches to housing and services that have demonstrated strong consumer demand and are permissible under civil rights law.

Response: It is not our intent to hinder innovative ideas for future development of HCBS. Rather, we believe that the requirements set forth in this regulation are a result of many comments we received from stakeholders, including individuals receiving services. Thus, we believe that developers and states should use this as a foundation as they look at developing plans to provide long-term care services and supports in their communities. We believe that this could be a tool to assist states with adhering to the *Olmstead* mandate and the requirements of ADA.

Comment: The commenters also requested that CMS clarify that it did not intend to include such group homes located in and fully integrated into typical neighborhoods or small community ICF/MR homes in the definition of a “facility that provides inpatient institutional treatment.”

Response: It is possible that the setting described by the commenter could be considered a home and community-based setting, if it meets the requirements set forth at § 441.530 and § 441.710. ICF/IIDs regardless of size are statutorily prohibited from being considered a home and community-based setting, because they are institutions under the statute.

Comment: Several commenters indicated that a setting should not be disqualified based solely on physical proximity to an institution. One commenter expressed concern this provision could force people into nursing homes as the only financially viable option. Providers have been encouraged to diversify and move into HCBS, including converting portions of what would be considered “institutional” settings to assisted living or other type of residential setting. Similarly, some commenters believe that if a converted nursing home space meets the requirements of § 441.530(a) and § 441.710(a) then there should not apply a rebuttable presumption that the setting is not a home and community-based setting.

Response: We appreciate the commenters' concerns. It is not our intent to have individuals move into long term care facilities, when their

needs could be met safely and adequately in a less restrictive environment. Our experience has shown that settings in close proximity to institutional settings, whether on the same campus, in the same building, sharing the same staff, and perhaps sharing some common areas are more likely to be operated in a manner similar to the institution. They are often also similarly segregated from the larger community of individuals not receiving Medicaid HCBS. Therefore, we strongly believe in applying a presumption that such settings are institutional in nature. However, we recognize that not all settings co-located, or closely located with an institutional setting, exhibit the same institutional characteristics. Therefore, through the applicable state plan amendment process, states will have the opportunity to describe how such settings meet the HCB setting requirements set forth in this final rule and do not have the qualities of an institutional setting.

Comment: One commenter indicates that there is a strong incentive for states, local government authorities, and providers to work together to use existing segregated institutional locations. The incentive falls toward keeping these properties fully utilized. These incentives will not be easily overcome, and may well require an outright prohibition on providing public funding to settings that share the buildings or grounds of an institution that provides in-patient care. A few commenters expressed concern with the effect this rule will have on the commenter's state plan to rebalance its long term care system. The state is currently seeking to "right size" the nursing home bed supply. The driving force behind this initiative is to rebalance the long term care system and provide an optimal level of choice for the consumer. It would only be natural for long-term care providers to participate in this right size initiative by utilizing the state's successful model of affordable assisted living to create campus settings that would provide a full continuum of long term care services. Many nursing home providers possess land and existing structures that could be used to develop managed residential communities, individual homes or cottages, or other independent living options where assisted living or home care services could be delivered in accordance with an individualized person-centered plan.

Response: We recognize that repurposing existing building structures is a tool used to control costs. However, we believe that such structures should not be a state's first option when looking

to increase the pool of community-based residential settings. Such structures were often built and operated in such a way that they inherently hinder individuals from participating in the broader community, and reduce individuals' control of how and where they receive services. However, there may be circumstances where such a setting could be repurposed in a way that it would meet the requirements for HCB settings and would no longer have the characteristics of an institution. The final rule allows a state to submit evidence for CMS' consideration in this circumstance.

Comment: Many commenters requested § 441.530(a)(2)(v) and § 441.710(a)(2)(v) be modified to also include settings on the grounds of or adjacent to a privately operated institution. These commenters noted that a private institution is no less institutional than a public one and should be treated the same for purposes of this provision.

Response: We appreciate the commenters' concern. It is expected that all settings, public and private, meet the HCB setting requirements of this regulation. We specifically make reference to a setting that is adjacent to a public institution in the regulation language due to public input. However, while we did not incorporate this suggestion into the regulation, we note that heightened scrutiny will be applied to any setting that hinders or discourages integration with the broader community.

Comment: One commenter agreed that it is important to have rules that circumvent practices such as building many group homes or apartments on the grounds of institutions or on the property where an institution once stood. However, the commenter believes the requirements proposed go too far, as the standards would preclude people from choosing to live in many neighborhoods that might be in proximity to an institution, such as the VA hospital where they worked, even if they live in proximity to other aspects of community living as well.

Response: The presumption will be applied to settings that discourage integration of individuals from the broader community. We will describe these settings in future guidance and will take into account the commenter's concerns about group homes on the grounds of an institution that are recently closed. Regarding the concerns about settings adjacent to VA hospitals, a residential setting that allows individuals to have full access to community services, and allows for active participation in neighborhood/

community events, resources and integrated activities, but is located in close proximity to a VA hospital might meet the qualities for a home and community-based setting and not the qualities of an institution.

Comment: A few commenters indicated that older persons often seek out settings in which they can stay as they grow older and develop service needs. A significant number of older persons prefer to live in a senior community or similar setting that includes a nursing facility, particularly when one spouse or partner needs nursing facility care and the other does not. The commenter recommends that being on the grounds of, or adjacent to an institution not be a disqualifying characteristic.

Response: We will engage in discussion with any state who proposes that such settings would meet the qualities for home and community-based and not the qualities for an institution.

Comment: One commenter indicated that the Fair Housing Act contains an exception that allows distinctions based on age, and believes this rule should do so also.

Response: The purpose of this section of the regulation is to define qualities for home and community-based settings. Since Medicaid services are available to individuals of all ages, we do not believe it is appropriate to create age-based distinctions.

Comment: One commenter believes that hospital-based providers should not be allowable HCBS providers. The commenter also believes that there should be two types of HCBS allowed for a non-hospital entity to offer, even if they are provided on the grounds of a hospital: (1) Services provided by an HCBS provider in the emergency room before the patient is admitted to the hospital, and (2) Discharge planning with a patient in a hospital or long term care setting in order to help facilitate a more rapid, seamless, and coordinated transition into community-based care.

Response: We recognize that while an individual is moving through a state's overall service delivery system, there may be certain circumstances in which services provided under various authorities may overlap. Services should be provided as appropriate to meet an individual's needs; however, it is incumbent upon the state to ensure that there is no duplication of payment for the same services. A provider of HCBS could provide services in the emergency room, as long as those services are necessary and do not duplicate the services being provided by the emergency room.

We believe it would be a best practice for there to be communication between those settings and the program that will assist the individual in the community. However, such communication should not supplant the discharge planning activities that hospitals and long-term care settings are required to perform for any individual leaving its setting.

Comment: A few commenters requested the regulation define public institution. One commenter requested clarification on the definition of a public institution. Specifically the commenter wanted to know if “public institution” means an ICF/MR, or whether it also includes a university, library or community care hospital. Another commenter wanted to know if this provision presumptively excludes HCBS in publicly funded housing for older persons if a nursing home happens to be located on the same campus.

Response: The term public institution is already defined in Medicaid regulations for purposes of determining the availability of Federal Financial Participation (FFP). Section 435.1010, specifies that the term public institution means an institution that is the responsibility of a governmental unit or over which a governmental unit exercises administrative control. Medical institutions, intermediate care facilities, child care institutions and publicly operated community residences are not included in the definition, nor does the term apply to universities, public libraries or other similar settings. We will apply this existing definition in implementing the provisions of this final rule. However, we note that any setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny that it has the qualities of home and community-based settings. Thus, settings that are located on the grounds of, or adjacent to, institutions that are not defined as public institutions under the existing regulation will still be subject to heightened scrutiny if such settings have the effect of isolating or segregating those receiving HCBS from the broader community.

Comment: One commenter expressed concern about the effect this regulation will have on individuals living in continuing care retirement communities (CCRC’s). Another commenter believes that co-location on a campus facilitates efficiency, reduces administrative and food service costs, and potentially

increases the quality of services provided in the nursing home since the independent living residents often visit their friends who reside in the CCRC’s nursing home. The commenter added that co-location facilitates seamless transition among the various levels of care on campus. One commenter expressed concern that the regulation would have a particularly negative impact on not-for-profit long term care providers that more often provide services in a multi-level campus setting because of their missions to meet the multiple needs of the community.

Response: In general, CCRC’s are a combination of residential settings and care options that include independent living, assisted living, and nursing home care. It is possible that currently the state considers the independent living units to be home and community-based. Nursing facilities are statutorily prohibited from being considered home and community-based and is considered an institutional setting. The independent living units and assisted living units would be presumed institutional and receive heightened scrutiny if they are (1) located in the same building as the nursing home or other facility providing inpatient treatment; or (2) if they are located on the grounds of, or immediately adjacent to, a public institution.

Comment: One commenter believes that excluding assisted living facilities that are on the same grounds of an institutional facility may be limiting the choices available to individuals. The commenter believes that offering a variety of locations for community based services better addresses the diverse population that receives these services.

Response: Assisted living facilities are not excluded from being considered home and community-based if they are structured and operate in a manner that adheres to the requirements set forth in this rule.

Comment: One commenter requested that CMS clarify what is “inpatient institutional treatment” and asked whether “provides” means direct provision of services by the facility, any provision of services in the facility, or facilitating the provision of such services.

Response: Inpatient institutional treatment means that services are provided 24 hours/7 days a week. Therefore, to avoid confusion, we have retained the language “inpatient institutional treatment.”

Comment: Many commenters believe the proposed regulations would eliminate or severely restrict the provision of HCBS in programs located

adjacent to a public institution even though the program is also adjacent to other buildings such as local community colleges and universities, stores and businesses, and residential communities. Other commenters indicated that proximity to an institutional setting should not alone be the basis to disqualify a setting as HCB and stated that many seniors choose to live in a community that offers a range of settings.

Response: We believe that if the setting meets the requirements set forth in § 441.530(a)(1) and § 441.710(a)(1), is not described as prohibited under § 441.530(a)(2) and § 441.710(a)(2), and does not exhibit qualities of an institutional setting, then the services could be provided in settings like those to which the commenters refer.

Comment: A few commenters expressed concern that the language in the proposed regulation could be construed to prohibit the use of HCBS to fund appropriate services on a campus that provides a variety of day habilitation services and employment opportunities for individuals with intellectual and related disabilities. For the commenters this would be an unacceptable and radical policy change from the perspective of these individuals and families who have relied on these services for years. The commenters believe the location allows individuals to be part of the community. The program is located adjacent to a residential neighborhood and shares a parking lot with a college. The commenters are concerned that if these longstanding programs are no longer permissible for these individuals, their alternative would be institutional placement. The commenters request the language “adjacent to” not be included in the final regulation or that the interpretative language accompanying the publication of the final regulation explicitly clarify that the circumstances described above do not make this type of program ineligible for HCBS funding.

Response: 1915(i) State plan HCBS and 1915(k) CFC services (for example, residential, day or other) must be delivered in a setting that meets the HCB setting requirements as set forth in this rule. We will provide further guidance regarding applying the regulations to non-residential HCBS settings. In addition, since this authority provides states the opportunity to provide individuals HCBS and not institutional services, individuals receiving 1915(i) State plan HCBS or 1915(k) CFC services must be living in settings that comport with the HCB setting requirements as set forth in this rule regardless of whether they are

receiving HCBS in that residence. This is consistent with CMS' longstanding policy regarding 1915(c) HCBS.

Comment: We received many comments both in support of and opposition to the requirement that would have resulted in heightened scrutiny over a disability-specific housing complex. The comments we received on this provision are reflected as follows:

Several commenters recommend the regulation be revised to remove "disability specific housing complex" as a setting in which HCBS may not be provided. The commenters believe that people with disabilities should be able to choose to live in disability specific housing if the housing addresses their needs. One commenter stated that being a disability focused apartment building does not warrant the need for extra scrutiny. There are significant differences between an institution and a housing development.

Many commenters requested the rule clarify that the reference to a "disability-specific housing complex" was intended to refer to settings located in a disability-specific housing complex—as well as on the grounds of, or immediately adjacent to, such a complex.

Many commenters expressed concern that the proposed regulations would eliminate or severely restrict HCB services to residents with disabilities in supported living arrangements authorized under and meeting the requirements of HUD Section 811 and Section 202 multi-family housing units, because the homes built under HUD Section 811 or 202 are specifically restricted to people with specific disabilities. They believe the proposed rule appears to conflict with HUD policies.

Several commenters believe that regulatory language will result in the elimination of longstanding services that meet the needs of a large number of individuals. The commenters recommended that CMS issue interpretive guidance accompanying the final regulation to explain that a program located in a building on the premises of a disability-specific housing complex may receive HCBS if the housing complex is in compliance with the underlying laws and implementing regulations, including Section 811 of the National Affordable Housing Act of 1990, as amended and implementing regulations (supported housing for persons with disabilities), the Fair Housing Act, and the ADA.

Many commenters expressed concern that the use of the term disability specific complex would eliminate or

severely restrict the provision of HCBS in group homes set around a courtyard where individuals with disabilities have many needed services and supports built into their day-to-day living and have transportation and other assistance to access the general community.

Many commenters requested the regulation provide a definition of the term "disability-specific housing complex." Many commenters believe that undefined, the term is unclear, and too broad.

Several commenters requested we clarify that "CMS did not intend to include group homes located in and fully integrated into typical neighborhoods within the meaning of "disability-specific housing complex."

A few commenters requested the rule clarify whether the presumption that a disability-specific complex is not a home and community based setting applies only if the setting does not meet the other criteria established in the regulation.

One commenter believes the potential elimination of disability-specific housing complexes as home and community-based settings will compromise viable housing alternatives in a housing market that is already in crisis, devastate the ability of providers to deliver services in settings that promote health and safety, and force individuals with developmental disabilities to move from their homes or lose their services and supports.

One commenter expressed opposition to the heightened scrutiny level of review, as proposed in the regulation. According to the commenter, families believe their loved ones benefit from these settings. Some planned residential communities are much like retirement communities where amenities such as bowling alleys, theatre, community centers, restaurants and shopping are readily available, along with necessary health care, support staff, vocational training. The commenter further stated that while the rule seems to embrace certain principles of community, such as individual choice and person-centered planning, there remains a bias that characterizes any sort of program-wide structure and safety measures as too "institutional" without any regard to the input of individuals, their families and their legal guardians. This commenter also stated that given that there is already a Medicaid definition of institution, it is improper for CMS to be proposing an expansion of current Medicaid law redefining the term. Another commenter believes that the proposed rule that considers a "disability-specific housing complex" an "institution" could be confusing and

a barrier to effective community housing options for those with intellectual disabilities.

Many commenters objected to the inclusion of disability specific housing as institutional in that many people choose, as a function of age, to live with others with similar needs. The commenters indicated that senior housing, assisted living, and other such options are freely chosen by seniors without disabilities and inquired why people with disabilities who are eligible for HCBS be denied the same array of options available to their peers without disabilities. The commenter noted that the key is that the person-centered plan should provide for individuals making free choices in where they live as long as they do not include nursing facilities, institutions for mental diseases, intermediate care facilities for mentally retarded, hospitals, or other locations that have the qualities of an institutional setting as determined by the Secretary. Other commenters suggested that seniors often choose to live together in a variety of settings and request that CMS respect this preference by establishing exemptions from the proposed setting requirements for continuing care campuses, assisted living settings, and other housing for older persons. The commenter stated that CMS should not preclude successful options for people with disabilities simply based on location or proximity. Alternatively, one commenter indicated that he does not have the same philosophy and asserted that this provision must remain in these regulations. This opinion is based on the commenter's experience with the deinstitutionalization of people with intellectual and developmental disabilities and the commenter's knowledge of recent efforts in certain states to try and use waivers to fund settings that do not promote full inclusion in community life. If CMS does decide to create an exception, the commenter urges we keep it very narrowly tailored to senior communities only, so that it cannot be used to limit the opportunities of people with intellectual and developmental disabilities to experience true integration.

A few commenters requested the regulation clarify if housing or units within general housing, designated for persons with dementia or other cognitive impairments would meet the definition of disability-specific housing complexes. Other commenters added that it is discriminatory to deny HCBS waivers to individuals residing in an Assisted Living Facility providing care specifically to those with Alzheimer's

and dementia just because of where they live.

Response: As a result of comments we received on the use of the term disability specific-complex, we have revised the rule to remove the term “disability-specific housing complex” and replace it with the following language: “any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS.” We note that we are not redefining the term “institution” but rather defining what characteristics we will see as institutional and not HCB in nature. We plan to issue future guidance to provide examples of the types of settings that will be subject to heightened scrutiny.

Comment: One commenter shared the opinion that disability-specific housing complexes are established for the convenience of service providers, or because the developer believes that people with disabilities should be segregated, or both. The commenter further explains that disability-specific housing complexes are not integrated at all, and therefore certainly not the most integrated setting appropriate to anyone’s needs. The commenter recommends that they must not be included as home and community based settings.

Response: We appreciate the commenter’s perspective. We do not believe that all settings should be excluded; however, we do believe a close review of such settings may be necessary.

Comment: Many commenters indicated that if the rule is finalized with application of a rebuttable presumption then it should only apply to disability-specific housing complexes. The commenters recommended that CMS should specify that the presumption may be rebutted only when (1) the setting meets all of the requirements for home and community-based settings in § 441.530(a)(1) and § 441.656(a)(1), and (2) the setting was selected by the individual following a meaningful opportunity to choose from among alternatives, including the most integrated setting for the individual as documented in the person-centered service plan.

Response: We do not agree with the commenter’s recommendations. Section 441.530(a)(2)(v) and § 441.710(a)(2)(v) have been revised to better articulate the settings that are presumed institutional in nature and will receive heightened scrutiny to determine if they can be considered home and community-based settings.

Comment: One commenter believes the rebuttable presumption language also applies to settings where there are specialized services for individuals with similar diagnoses. Many of these programs were designed, developed and chosen by consumers to reflect new standards of care and treatment. The commenter urges CMS to change the language in the rule to reflect this model of care and not limit these programs to only non-Medicaid persons.

Response: We recognize that there are many forms of settings and service delivery models serving individuals with a need for long term care services and supports. Due to this variability across the country, we do not believe it would be best to carve out certain models in this rule.

Comment: Many commenters were concerned about the effect the proposed rules would have on settings specifically designed for individuals with autism. The commenters stated that many of these individuals failed to thrive in both institutional and totally independent settings, but they do thrive in certain non-urban community based models. The commenters believe the proposed rule ignores the community based nature of these models and inaccurately and unreasonably categorizes these settings as institutions. One commenter believes the proposed regulations will cause downsizing and elimination of public and private specialized residential facilities for persons with severe and profound cognitive-developmental disabilities.

Response: We believe that settings that are designed to prevent an individual from having the opportunity to participate in the broader community are not home and community-based. We believe that individuals, regardless of service need, can benefit from having the opportunity to participate in the broader community. The goal of this regulation is not to take services from individuals, or make individuals move from a location where they have always lived, but to describe the qualities of settings in which services intended to provide an alternative to institutional care may be delivered. The goal of this regulation is to widen the door of opportunity for individuals receiving Medicaid HCBS to support the same choices to participate in community activities as are available to individuals not receiving Medicaid HCBS; to have a choice in how, when, and where they receive services; and to remove unnecessary barriers and controls. We believe that the Medicaid program provides many options for states to develop delivery systems that meet the

needs of individuals regardless of where they fall on the continuum of care.

Comment: A few commenters expressed the belief that individuals with severe cognitive impairments should be allowed to live together, because the commenters believe that this is not a population that can benefit by integration within the community at large. The commenter stated that special programming and physical plan improvements for this population have contributed to increased quality of life and quality of care for this population. The commenters request the rule be amended to allow individuals with cognitive impairments to live together and that this not be considered disability-related segregation.

Response: We disagree with the commenter in part. We agree that individuals benefit from services that are specialized and tailored to meet their specific needs. However, we firmly believe that all individuals regardless of type or degree of disability would benefit from opportunities for community integration if it is their choice to live in the community and not an institution. We note that Medicaid continues to provide other service options that can support individuals who choose to receive services in non-HCB settings.

Comment: One commenter believes the proposed changes to the rules would prevent an individual from making a choice to live in a rural agricultural community setting with several homes on the property. The commenter requested the rules be revised so that every person with every type of disability is given a choice that would meet the individual needs and unique characteristics of the person.

Response: Under the requirements of this regulation, for a setting to be home and community-based, it may not discourage an individual’s integration with the broader community. The determination would not be based on whether the setting was in a rural, urban, or suburban community, but on whether it has the qualities of home and community-based settings as specified in this rule.

Comment: One commenter indicated that in their state, there is the option for individuals to choose fully accessible individual apartments and accessible complexes that are disability-specific housing settings located in community neighborhoods that provide quick response and 24-hour onsite coverage. The commenter stated that the number of these settings has grown and consistently includes waiting lists, and to eliminate these settings for Medicaid

HCBS recipients unfairly limits their choice.

Other commenters expressed concern that many seniors living in age-specific communities will inadvertently be prohibited from receiving HCBS due to proximity to a hospital or nursing facility. The rule, they believe, will lead to more nursing home admissions among seniors and limit choices available to them to receive services in an assisted living facility (ALF). The commenters also stated the proposed language would likely reduce the number of individuals in nursing homes who are able to transition to a more integrated setting, because many individuals transition to ALFs. It should be considered desirable that those served by Medicaid would have the same array of choices as those not on Medicaid.

Response: We have removed the references to disability-specific housing in the text of the final regulation. However, if the settings have the effect of isolating individuals receiving Medicaid HCBS from the broader community, we will apply heightened scrutiny to these settings to determine if they meet the required qualities for a home and community-based setting as set forth in this rule. The State could present information to CMS to demonstrate that the settings have the qualities of community-based settings.

Comment: Several commenters supported the language as written, stating appreciation that CMS has clarified that the term “community” refers to the greater community and not solely a community of one’s peers and, that integration also means more than integration in a community of peers. They further stated that focusing on the purpose of HCBS helps define its characteristics. A few commenters agreed that a home and community setting should facilitate individuals’ full access to the greater community as they choose, including in the areas noted. However, the commenters noted that individuals may vary in their choices as they seek full access to and participation in the greater community, and a home and community-based setting should facilitate such full access consistent with an individual’s choices and preferences. The commenters recommended adding the following language related to access “based on the individual’s needs and preferences.” Another commenter stated the belief that the language is very broad and ambiguous and should be defined along with “the greater community.” Another commenter requested that we define “community” and suggested the language parallel the language used

under the section pertaining to person-centered service plan, stressing that individuals should be given the right to obtain services “from the provider and the community of his or her choice.”

Response: We support individual choice and agree that individuals may vary in their choices as they seek full access and participation in the greater community. However, in order to receive approval of a State plan under which it will receive Medicaid funding for HCBS, a state must ensure that the choices available to individuals meet the requirements for community integration at § 441.710 of the final rule.

Comment: Some commenters expressed concern with the requirement as proposed at § 441.530(a)(1)(i) that the setting must permit access to the greater community “in the same manner as individuals without disabilities.” One commenter stated that it would be more appropriate to require access “to the same extent” and that this language will give HCBS providers reasonable flexibility in regards to making accommodations for disabilities and to avoid disputes and possible litigation on the exact manner in which such accommodation must be provided. Other commenters indicated that this requirement is not measurable and may reduce choice for rural populations.

Response: After significant consideration, we have removed from § 441.530(a)(1)(i) “in the same manner as” from this requirement, and replaced it with “to the same degree of access as,” to best describe our intent to ensure access to the greater community that includes individuals with and without disabilities.

Comment: One commenter stated that licensed facilities may be located in both urban and rural settings resulting in variation with the amount of “integration” available. The settings are chosen with this in mind, and one that seems to be less integrated to CMS may be preferred by some over living where it appears participation in community activities is greater.

Response: We agree that there is a large degree of variance regarding the geographical settings where licensed homes are located. We agree that an individual should be able to exercise choice in regard to these settings. We do not express preference in regard to the proximity of activities to where an individual lives; the emphasis is on access to those chosen activities and whether the individual has the same degree of access to such activities as individuals not receiving Medicaid HCBS.

Comment: One commenter believes that CMS should not disqualify any

setting from receiving federal financial participation (FFP) solely based on the fact that it is a congregate setting.

Response: It is not our intention to exclude a state from receiving FFP for a setting solely based on the fact that it is a congregate setting. Our intention is to specify qualities necessary for a setting to be considered a HCB setting. Congregate settings may be included if they meet the HCB setting requirements set forth in this rule.

Comment: Several commenters stated that a service provider (for example, a job coach), not a setting, facilitates employment-seeking opportunities. Similarly, a service provider, not a setting, assists individuals in managing what few disposable resources are available to them. One commenter seeks clarification regarding what facilitating “full access to . . . employment opportunities” entails and what possibilities, if any, would be imposed on the housing provider. One commenter supports the concept of community integration, but believes CMS has blurred the distinction between the setting and the service provider. One commenter believes that CMS is wrong to assume that location will enforce the goals of integration, for example, social interaction, productivity and competitive employment. The commenter further notes that having the ability to access the general community is very different from being forced to live in a community “setting” that is not only unwilling, but unable to provide resources for safety, supports, interaction, social integration and employment in competitive settings. One commenter encourages CMS to ensure that the settings in which residents receive services are designed to facilitate the actual integration of the recipients into the surrounding community.

Response: We agree that it is the responsibility of the service provider rendering the services and therefore we have added language under person-centered service plan requirements to ensure a clear understanding of our expectation. We believe the section on person-centered planning clarifies CMS’ expectations with regard to services being delivered in a manner that promotes/supports community integration to the extent of the individual’s preferences and desired outcomes.

Comment: Several commenters expressed strong support for the setting integration provision, but recommended modifying § 441.530(a)(1)(i) to specify that the employment-related provision apply only to those individuals who are interested in being employed. They

recommended modifying § 441.530(a)(1)(i) by adding the following language “for those individuals interested in being employed” following the words “integrated settings.” Another commenter recommended the following revision to § 441.530(a)(1)(i): “For individuals seeking to enter the job market, the setting should include opportunities to seek employment and work in a competitive integrated setting. For all individuals, the setting should permit them to engage in. . . .”

Response: We believe that individuals should be supported in seeking employment when interested in being employed and that the statement “opportunities to seek employment” implies choice. In addition, we believe that adding the suggested language to the regulation text is unnecessary.

Comment: One commenter offered support of CMS’ general approach of identifying the characteristics of integrated care, but suggested that CMS will need to take an active monitoring role to ensure that all the individual quality requirements are enforceable.

Response: States are required to demonstrate at the time of approval that quality measures with a monitoring plan are in place. This information must be included in the SPA and at a frequency to be determined by us or upon request by us. The review and monitoring of quality requirements will be covered in future guidance.

Comment: One commenter stated that, it would be unpatriotic to curtail any services in a manner that would adversely affect humans with limited abilities.

Response: It is not our intention to negatively impact any individuals we serve. Rather the purpose of the rule is to ensure that states will be better able to design and tailor Medicaid services to accommodate individual’s needs and preferences.

Comment: Commenters stated that all people need meaningful choices about where and with whom they live, how they spend their time and their activities, friends, and services (including who provides them). Permitting individuals the freedom to make their own choices allows them to remain as independent as possible. One commenter applauded efforts that focus on the individual’s ability to choose his or her own life setting and one that promotes community rather than institutions. Several commenters noted that while providers may make different choices than the client and have a different perspective, the provider must respect and honor the choices and autonomy of people with disabilities.

One commenter supports the proposed language as long as it provides assurances that real alternatives exist. Additionally, another commenter recommends reinforcing the idea that states should provide unbiased and informed options counseling for individuals seeking HCBS so that individuals are able to choose the setting that best assists them in meeting their needs and life goals.

Response: We agree that meaningful choices that allow individuals to make decisions that best meet their needs are important. In addition, they should be addressed as part of the person-centered planning process and reflected in the individual’s person-centered service plan.

Comment: One commenter stated that the proposed regulation would eliminate or at least severely restrict client and family choice of program options and opportunities and that consumers and families need more options, not fewer during these difficult times. Several other commenters expressed serious concern that the proposed regulation will eliminate instead of enhance choice for individuals with significant disabilities.

Response: We disagree. We are not eliminating the choice of institutional options. We are specifying the qualities necessary for settings to be considered home and community-based settings.

Comment: Many commenters stated the proposed language in § 441.530(a)(1)(ii) and § 441.656(a)(1)(ii) should be modified to more closely reflect the tenets of the ADA and the *Olmstead* decision by including additional language that conveys the individual’s choice of setting must be an informed choice, based on more than verbal descriptions or pictures of alternatives. Modifications should include language that permits individuals a meaningful opportunity to choose from among all available alternatives. Commenters conclude that the level of specificity with which a particular setting must be identified in a service plan is not clear and the requirement could inappropriately prevent individuals from receiving services when their desired living setting is specifically identified in a service plan.

Response: We believe the final regulation language supports these principles. Within future guidance, we will reinforce the importance of complying with other federal requirements such as ADA and *Olmstead*.

Comment: One commenter recommends striking the word “available” from § 441.530(a)(1)(ii) and

§ 441.656(a)(1)(ii) of the proposed regulation. The commenter believes that this word could limit choices of HCBS settings offered to individuals and offers the example of long waiting lists for certain section 1915(c) HCBS waiver programs/settings not being considered and reflected in the person-centered plan due to lack of availability.

Response: We have revised § 441.530(a)(1)(ii) pertaining to CFC settings and the final regulation text at § 441.710(a)(1)(ii) and we have removed the term “available.”

Comment: One commenter was supportive of this language as written. Another commenter supported CMS’ proposed list of essential personal rights in this section. The commenter stated that, in addition to freedom from coercion and restraint, people with disabilities in a community setting should have the freedom to pursue their sexuality, voting, and worship. In addition, a community setting should not be permitted to restrict access to the community as a form of punishment.

Response: We are concerned that one of the commenters believes we have provided a comprehensive list of rights. The factors related to determining whether settings are home and community-based and the description of the rights that individuals must have in these settings are not intended to be an exhaustive list of all legal rights of the individual. Individuals have many other legal rights not addressed in this regulation. For example, civil rights against various forms of discrimination are protected under the ADA and elsewhere. We regularly work with the HHS Office for Civil Rights, Department of Justice (DOJ), and others to assure that we provide appropriate guidance and assistance to states related to civil rights issues that bear on Medicaid requirements.

Comment: Many commenters stated that the inclusion of “essential personal” may create confusion and suggest that the term be omitted from § 441.530(a)(1)(iii) to more clearly demonstrate intent to protect the individuals’ human rights. Several commenters indicated that they strongly agree that these important personal rights should be protected. However, as currently written the placement of “essential” may imply that other rights are not essential and thus do not need to be protected. These commenters recommended removing the term “essential” from this paragraph.

Response: We agree with the suggested revision to § 441.530(a)(1)(iii) and have finalized the provision at § 441.710(a)(1)(iii) by removing the words “essential personal.”

Comment: One commenter generally supports the proposed language, but recommends that CMS delete the reference to restraint and/or provide an exception when the individual has a documented history of risk of elopement or susceptibility to behavioral flare-ups that can only be controlled by temporary restraint.

Response: We disagree with the recommendation as this is an important protection.

Comment: Several commenters supported the protection of independence and the autonomy of individuals in making life choices. One commenter stated that the post-rulemaking implementation must ensure that the intent of the proposal is carried out in practice. Another commenter generally supported the proposed concept, but noted that the life choices principles are dictated by the service provider and not the setting.

Response: The State Medicaid Agency will be responsible for ensuring that the HCB setting requirements are met by providers who own or control settings where individuals reside and/or receive services.

Comment: Some commenters stated that the language may potentially result in limited choice, scattered living proposals, limiting staffing resources and increasing costs associated with some individuals choosing to live secluded from others with disabilities. The commenter stated that individuals make choices that increase their independence (within the resources that are provided through Medicaid) based on informed experiences to “live and play” with others who are developmentally disabled because they have much in common. Another commenter disagreed with this proposed requirement and believes that individuals should have the right to choose where they want to live. Commenters stated that one size does not fit all and that different populations have differing needs. Commenters supported an individual’s right to choose to reside in a living arrangement that best suits his/her needs. The commenter also stated that this proposed requirement would eliminate important options that now contribute to the array of settings available to adults with disabilities and the elderly and the move to a more restrictive setting would ignore the participant’s choice, diminish the participant’s quality of life and increase costs to Medicaid.

Response: We believe that individual choice is important and we have worked to promote choice in the final rule, though we also acknowledge the

challenge of doing so in a manner that addresses the interests of diverse populations with differing needs. We have revised the language in the final rule to be more flexible and less prescriptive. Instead of automatically excluding certain settings from qualifying as HCB, the language in the final rule includes a presumption that these settings are not HCB. In other words, we will assume that certain types of settings—specifically, those located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, on the grounds of or immediately adjacent to a public institution, or any other setting that has the effect of isolating individuals receiving HCBS from the broader community—are not HCB, but afford states the opportunity to refute this categorization by providing additional information about the characteristics of specific settings. We have also included language in the final rule that focuses on the critical role of person-centered planning and addresses fundamental protections regarding privacy, dignity, respect, and freedoms.

Comment: Several commenters recommended that CMS delete the phrase “and not regimented” from the proposed language. The commenters expressed concern that under the proposed language, group programming could be viewed as “regimented” because it is provided in a congregate setting. One commenter noted that structured activities and socialization opportunities could be deemed inappropriate under the proposed language since they may be provided in a uniform manner.

Response: We disagree with removing this language from the final rule. We do not intend to invalidate all activities in a congregate setting. Individuals must be afforded choice regarding the activities in which they wish to participate including whether to participate in a group activity or to engage in other activities which may not be pre-planned.

Comment: One commenter recommended adding the following language to this provision of the rule: “(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 to the greatest extent possible and not regimented.” One commenter recommended that CMS clarify that the term “optimized” refers to the individual’s autonomy and does not refer to optimizing the institution’s promotion of autonomy. Another

commenter requested that CMS clarify who will determine and how to determine whether the individual initiative, autonomy, and independence in making life choices were optimized.

Response: We do not believe that “to the greatest extent possible” adds significantly to the term “optimized.” We believe the commenter’s concern about referencing individual autonomy is addressed in the regulation language. There are a number of methods inherent in the flexibility of the HCBS benefits to determine who and how the individual’s initiative, autonomy, and independence are optimized.

Comment: Many commenters stated that an individual’s choice regarding services and supports and who provides them is a key element of HCBS and, thus, must be ensured. Some commenters suggested substituting the word “ensured” in place of “facilitated.” One commenter stated that the word “facilitated” establishes a weak standard and should be replaced with “maximized.” Another commenter suggested that individuals be given choices about when services are provided and recommended deleting “is facilitated” and replacing it with “is honored” for further assurance. One commenter stated that an individual’s choice must be ensured, meaning “made certain or safe” and stated that in a home and community-based setting, personal choice should not only be brought about, but is safe. Another commenter expressed concern that “is facilitated” is not used to water down individuals exercising choice over services, supports, and providers. The commenter stated that some individuals may need assistance in exercising choice and the commenter suggested revising this criterion to note that support should be provided, as needed, to facilitate such choices and to acknowledge that an individual’s chosen representative may be acting on behalf of the individual.

Response: After consideration of the commenters’ thoughtful suggested text changes, we believe the proposed text/language reflects the intent of the provision.

Comment: Several commenters indicated that provider owned or controlled settings licensed by state law have requirements that make them responsible for the well-being of the resident and restrictions on who (in addition to the licensed provider) can provide services in the setting. Commenters stated that residents’ rights allow for individuals to supplement existing services provided by the providers, but not replace them. Several commenters recommended revisions to

this section of the rule and some of the commenters suggested that language be included to reference state licensure laws and licensing entities.

Response: We disagree with the suggested changes. Some of these were too descriptive to include in regulation and could have the effect of excluding numerous populations served through HCBS programs. We will instead consider these suggestions in future guidance.

Comment: One commenter requested that the rule clarify how a person's choice about the type of services they want and who they want to provide them "is facilitated." The commenter suggests this can be done by clarifying the qualifications that the facilitator must possess—for example, the facilitator must be knowledgeable of all community-based options (not only those that are considered readily available) and must be able to present options in a way that is accessible and is sensitive to the person's disability-related communication needs.

Response: States are responsible for determining the provider qualifications of the entities who will conduct the assessments and person-centered planning process as long as the requirements in the final regulations have been met. It is expected that these entities would have adequate training to perform this function. We agree that additional guidance should be provided to states and we intend to issue future guidance regarding the person-centered process and how we intend to apply it across Medicaid HCBS programs.

Comment: Several commenters supported the additional conditions stating that they are critical to ensuring that provider-controlled settings designated as home and community-based operate in a way that promoted choice, autonomy and independence.

Response: We appreciate this comment of support regarding the importance of the additional conditions.

Comment: One commenter generally supported the provisions but suggested that the language include "health needs" in addition to "safety needs" and that the term "dementia" be changed to "cognitive impairment" to include individuals with severe mental illnesses, traumatic brain injuries, and developmental disabilities, as well as Alzheimer's and other forms of dementia.

Response: The reference to dementia was only included as an example and was not meant to convey all of the possible situations in which a modification of the conditions might be supported by a specific assessed and documented need. We have, therefore,

removed this example from regulation text as this is more appropriate for us to address in future guidance, and we will consider these comments in that context.

Comment: Several commenters strongly agreed with the proposed language requiring that should a provider choose to modify conditions, changes must be supported by documentation in the person's service plan. Another commenter expressed support of CMS' efforts to allow necessary flexibility to address individual circumstances in provider-based settings, but urged CMS to allow flexibility in interpretation of the language, "specific assessed" need. Two commenters also expressed concern over this language, noting that in some instances residents may require services based on overall condition rather than a specific assessed need and suggested revision to this subsection of the rule.

Response: We acknowledge and appreciate support of the requirement that any modification of the conditions for provider-owned or controlled residential settings must be supported by a specific assessed need and documented in the person-centered service plan. However, we disagree that such modification would be acceptable based on a condition that does not also result in a specific assessed need of an individual. Allowing for modifications based on a condition that is not also supported by a specific assessed need and documented in the person-centered service plan could result in decisions being made based on global assertions as opposed to individual need, and thus be contrary to the purpose of this section of the rule. Therefore, we have not made the requested revision to this requirement.

Comment: Several commenters stated that modifications must be related to a clearly established assessed need and recommended a change to the proposed rule so that the requirements must apply to all settings where services are provided, regardless of whether or not they are controlled by the service provider.

Response: We agree that any modification of additional conditions must be based on the specific assessed need of the individual. The regulation includes qualities that apply to all home and community-based settings, but we disagree that the additional requirements for provider-owned or controlled settings must be required of all settings where services are provided, regardless of whether or not they are provider-owned or operated. The additional conditions were designed to ensure that individuals who are living

in settings in which the individual does not have ownership or control, will be afforded the same opportunities and community access as individuals living in their own private or family homes.

Comment: One commenter recommended that States should be able to detail their own policies and practices to address rights and restrictions as part of their application for HCBS authority, an expectation currently embedded in the waiver application but not in regulation.

Response: We disagree that states should detail their own policies to address rights and restrictions. Based on our experience and on input received from the public, we believe we must set these minimum additional conditions to ensure individual rights are protected.

Comment: Several commenters stated that CMS should take into account the differences between different disabilities in determining when departure from the additional conditions may be permitted. These commenters stated that, if CMS allows for the modifications to provider requirements, CMS should require that the restrictions be directly proportionate to a specific safety need and be reviewed for effectiveness and continuing need.

Response: Any modifications of the conditions can only be considered on an individual basis in accordance with the person-centered planning process and documented in the person-centered service plan in accordance with section 441.725.

Comment: One commenter recommends adding a component whereby direct feedback is gathered from the beneficiary or the beneficiary's representative regarding initial and ongoing overall satisfaction with the modification of conditions.

Response: The rule has been modified to require that any modification to the additional conditions under § 441.710(a)(1)(vi)(A) through (D) must have the informed consent of the individual (or representative).

Comment: One commenter stated that a modification may be needed to reflect the involvement of an individual's representative, as appropriate, when individuals are unable to act on their own behalf.

Response: The regulation already specifies the involvement of an individual's representative in the evaluation of eligibility (§ 441.715), independent assessment (§ 441.720), and person-centered service plan (§ 441.725). The regulations also include a definition for individual's representative in section 441.735 of this subpart. Since any modifications of the

conditions would need to comply with the requirements for these processes, we do not believe that modification to the regulation text is needed.

Comment: We received some comments related to the difficulty of achieving compliance with the proposed requirements. A few commenters expressed concern that the conditions for provider-driven settings might exclude assisted living residences (ALRs), as it remains unclear whether they would meet the proposed criteria. Another commenter expressed great concern that privately-owned residential settings that have proven successful in their state would not qualify under the proposed guidelines since many would not provide separate kitchens or sleeping and living areas. Another commenter stated that this regulation severely restricts program options and opportunities because of the impact the regulation has on HUD financed housing owned by providers, and that this regulation would restrict the use of HCBS waiver funding for services provided in these settings.

Response: We believe there will be residential settings that meet the HCB requirements as outlined in this regulation. However, we recognize that there may be some residential facilities that may not currently meet all of the HCB setting requirements for provider-owned or controlled settings. We will allow states a transition/phase-in period for states to demonstrate compliance with the requirements. In an effort to balance those comments that were concerned with the loss of a residential setting and the subsequent displacement of the service recipient based on the settings requirements and those comments that urged us to draw an immediate and clear demarcation for HCBS, our expectation is that the transition plan would facilitate a brief transition period wherever possible. However, we will afford states the opportunity to propose a transition plan that encompasses a period up to five years after the effective date of the regulation if the state can support the need for such a period of time. States are expected to demonstrate substantial progress toward compliance throughout any transition period.

Comment: One commenter expressed concern that the proposed language requires full participant direction even when such direction may not be appropriate for certain populations.

Response: Self-direction is an optional service delivery method, not a federal home and community-based setting requirement in the proposed or the final rule.

Comment: Many commenters indicated that the proposed language provides an unchecked and overbroad right for a service provider to modify any of the requirements, as long as the modification is supported by an assessed need and documented in a service plan. The commenters stated that CMS should allow modifications of the “additional conditions” only in rare and extraordinary circumstances, and then only after a provider has documented that less intrusive measures have already been tried, data has been collected on the modification’s effectiveness, and the need for the modification has been reviewed at least quarterly. Many commenters stated that allowable modifications should be limited to the requirements pertaining to access to food and lockable doors. Several commenters stated that the only appropriate reason to modify any of the listed conditions would be to address safety needs, and several recommended a revision to this subsection of the rule. However, other commenters stated that there is no reason for an exception/modification under any circumstances for many of the requirements and have recommended revisions to the regulation.

Response: We agree with the commenters that the basis for modifications should be justified through the person-centered planning process. The service provider does not lead the person-centered service planning process; it is driven by the individual and includes people chosen by the individual. We have revised the rule to require that any modification to the additional conditions under § 441.710(a)(1)(vi)(A) through (D) must be supported by a specific assessed need and justified in the person-centered service plan. We also delineated specific requirements to support that justification as well as expectations for the intervention.

Comment: Several commenters asked how frequently the assessment must be made if the condition causing the modification of the “additional conditions” was not likely to improve. One commenter recommended that CMS amend the current language to clarify that the specific assessed need must be of the individual, and should indicate that a determination has been made regarding the timeframe that the modification of conditions will be in effect.

Response: Per the response to the previous comments, we have revised the rule to require that any modification to the additional conditions under § 441.710(a)(1)(vi)(A) through (D) must be supported by a specific assessed need

and justified in the person-centered service plan. We also state in the rule that reviews and any needed revision of the independent assessment and the person-centered service plan, must occur at least every 12 months, when the individual’s circumstances or needs change significantly, and at the request of the individual.

Comment: Several commenters stated that CMS should not allow any departures from or modifications to the conditions.

Response: We disagree as there may be reasons why a modification of the conditions may be necessary.

Comment: One commenter offered general support of the proposed language’s intent and believes that the “legally enforceable agreement” condition should never be limited, or modified.

Response: We appreciate the commenter’s support and concern. While the final rules maintain the ability for a provider to modify this condition, we have added that this must be supported by a specific assessed need and justified in the person-centered service plan and delineated specific requirements to support that justification.

Comment: Several commenters stated that CMS should clarify that all settings in which the individual does not have a regular lease or full ownership (including adult foster care settings) be considered provider-controlled.

Response: For the purposes of this rule, a setting is considered provider-owned or controlled, when the setting in which the individual resides is a specific physical place that is owned, co-owned, and/or operated by a provider of HCBS.

Comment: Several commenters suggest that CMS clarify that all settings that require individuals to automatically transfer their income to service providers for the purpose of SSI/SSDI or other disability payments are not HCB settings for purposes of the Medicaid program.

Response: Room and board is not covered under Medicaid state plan HCBS. This rule does not specify how payment for room and board should be made.

Comment: One commenter expressed that all requirements listed for provider-owned or controlled settings should be a part of the final rule. The commenter also indicated concern that the example given in the rule creates the impression that addressing safety needs of persons with dementia is only one of many possible examples of how conditions might be modified.

Response: This was only intended as one example of this provision and is not depicting a full range of possible situations. To avoid confusion, and to clarify that person-centered planning is based on the person and not on his/her diagnosis, we have deleted this example from the regulation text.

Comment: One commenter stated that, in addition to the provisions at § 441.530(a)(1)(vi) and § 441.530(a)(2)(v), other provisions can be used to ensure that the settings in which residents receive 1915(k) CFC services are designed to facilitate the actual integration of the residences that are provider-owned or controlled for providing residential support to recipients.

Response: We agree with the commenter. For a setting proposed under 1915(k) CFC to be determined home and community-based, the setting must meet all requirements set forth in § 441.530.

Comment: One commenter urged CMS to give serious consideration to striking the “conditions for provider-driven setting” provision. The commenter stated that though the rules attempt to create a homelike environment by proposing conditions, no reasonable person would accept these conditions as homelike. In addition, the commenter stated that regardless of the size of a provider controlled setting, the very nature of these environments isolates, congregates and segregates the individuals living there, and limits personal freedom.

Response: We disagree. We believe there are provider-owned or controlled settings that not only meet the overall HCB qualities but also meet the additional conditions and allow for full integration into the community; therefore, we will keep the conditions to ensure the standards for HCB settings are met. We believe the commenter’s request to delete the conditions for provider-controlled settings would not accomplish the suggested purpose.

Comment: Several commenters suggested that CMS consider giving human rights reviewing committees the added responsibility of reviewing modifications, and requiring a clear appeals process for any individual who does not agree to the conditions.

Response: We have amended the regulations to include a requirement for informed consent and we specified that any modification of the additional conditions must be supported by a specific assessed need and justified in the person-centered service plan. We will add further descriptions in future guidance.

Comment: Several commenters request that CMS specify the requirements for provider-controlled settings so that providers and developers get the message that facilities cannot be built or established that are not the most integrated settings.

Response: We believe that all home and community based settings should be integrated into and allow access to the greater community and our regulation already outlines additional criteria that must be met to qualify as a home and community-based setting where the setting is provider-controlled. Adding further criteria may be too prescriptive and could limit individual choice of settings.

Comment: A few commenters believe the proposed regulations would eliminate or severely restrict HCBS in group homes for people with disabilities in which providers have adopted reasonable policies governing their operation designed to respect the individual’s rights and at the same time respect the rights of other residents.

Response: Based on our experience and significant public input, we believe we must set minimum additional conditions for provider-owned or controlled settings to ensure that they are home and community-based. The commenters did not indicate which conditions would result in this impact, nor provide suggestions for minimum conditions to meet the intent of this provision of the rule. In an effort to address the concerns raised by commenters who feared loss of current residential options and the subsequent displacement of the individuals living in such settings who receive HCB services and the concerns raised by other commenters who urged us to draw an immediate and clear line of demarcation for HCBS, we will permit states to propose transition plans for existing approved HCBS under 1915(i) in accordance with section 441.710(a)(3). While our expectation is that states would transition to compliance with this final rule in as brief a period as possible, we will allow states to propose a transition plan that encompasses a period up to five years after the effective date of the regulation if the state can support the need for such a period of time. States are expected to demonstrate substantial progress toward compliance throughout any transition period.

Comment: One commenter believes the proposed regulations are biased against provider-owned or controlled residential settings through the proposed imposition of additional regulatory conditions on such settings. The commenter believes that many

provider-owned residential settings are developed to assist with improving the availability of accessible and affordable housing so that individuals with developmental disabilities have some choice in community housing options and can avoid the need for unnecessary institutionalization.

Response: We believe that it is appropriate to specify additional conditions for provider-owned or controlled settings to ensure that all individuals receiving HCBS are afforded the opportunities that are characteristic of living in the community.

Comment: A few commenters stated their belief that the focus should not be on the setting, but rather an individual’s choices and the person-centered service plan. The commenter stated that arbitrary geographic or location specific criteria are not appropriate, and if a provider-based setting can meet all of the criteria in § 441.530(a)(1) or § 441.710(a)(1), it should not matter where the provider is located.

Response: We agree with these comments and believe the regulatory language at § 441.530(a)(1) and § 441.710(a)(1) achieves this purpose.

Comment: One commenter applauds use of the more general term “provider-owned or controlled residential settings,” but since CMS is creating a new technical term defining a class of services, it would be prudent to offer clearer regulatory guidance regarding the reach of such a term. For example, would an elderly housing project that included service coordination and other services be subject to these provisions as a provider-owned residential setting? CMS may want to consider limiting this term to apply to state-licensed or certified settings to avoid confusion.

Response: We are not defining a class of services. We are describing the conditions that provider-owned or controlled settings must meet to be considered home and community-based settings. If the elderly housing project is provider-owned or controlled, it would have to meet these additional HCB setting conditions. We do not believe limiting the application of the term “provider-owned or controlled residential settings” to those licensed or certified by the state is in the best interests of the individuals served under the HCBS programs, nor would that approach be adequate to achieve the goal of defining the qualities and other requirements for settings that are home and community-based.

b. Target Population

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. We proposed that target population(s) may be based on diagnosis, disability, Medicaid eligibility groups, and/or age. States may target services only to eligible individuals in their chosen target groups, or provide different services within the 1915(i) benefit to different target 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 section 1915(i) benefit 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 is not targeted to a specific population and instead uses only the needs-based criteria to establish eligibility for the benefit. The 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) of the Act 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.

Comment: One commenter requested that CMS not limit people seeking mental health treatment.

Response: We believe this commenter has misunderstood the intent of this provision of the rule, which does not allow states to limit number of participants but allows states the option to target section 1915(i) of the Act to specific population types. So in this example, a state could target a section 1915(i) benefit to individuals with a

chronic mental illness, but would not be able to limit or cap the number of people meeting this target criterion. Anyone meeting this target criterion, and also meeting the other eligibility requirements under section 1915(i) of the Act, would be eligible to receive any needed services included in the state's benefit.

Comment: A couple of commenters pointed out that the reference to target criteria in § 441.656(b)(2) of this section was incorrect.

Response: We thank the commenters for noting this error and we have corrected this reference so that it now reads as “§ 441.710 (e)(2).”

Comment: Two commenters expressed concern that allowing multiple target groups within one 1915(i) state plan HCBS benefit might result in a net reduction of service availability, and lead to institutional care. One “fears that the blending of target audiences” will “leave the voiceless minority without access to adequate services.”

Response: As an optional approach available to states, this option is not intended to restrict or compromise service availability. States can choose which services they will offer under a 1915(i) State plan benefit, regardless of whether they take up the additional option to target a population(s). As with all state plan services, states must offer all needed services that they choose to include under their benefit to all who are eligible.

Comment: One commenter expressed concerns that allowing states to serve multiple target populations in one benefit will lead to states serving “incompatible populations in the same service setting.” They cited examples in states where individuals with one type of disability were harmed by others with a different disability, and requested CMS to expressly prohibit states from serving different populations in the same location.

Response: This section of the regulation does not speak to combining different target groups in the same living situations, but rather the inclusion of multiple target groups in the overall benefit design and operation. Including multiple target groups in one benefit will not alleviate responsibilities of States for quality assurance and detailing their quality improvement strategies for that benefit.

Comment: A few commenters indicated that we should explicitly state that “a state may propose more than one set of section 1915(i) of the Act benefits, with each benefit package targeted toward a specific population” and that the state may also target multiple

populations under one set of benefits or offer different services to each of the defined target groups within the benefit.

Response: Under § 441.710(e)(2)(ii) of the regulation text, we specify “The State may elect in the State plan amendment to limit the availability of specific services defined under the authority of § 440.182(c) or to vary the amount, duration, or scope of those services, to one or more of the group(s) described in this paragraph.” In the preamble to the proposed rule, we stated “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 non-application of comparability and instead uses only the needs-based criteria to establish eligibility for the benefit.” A change to the regulation text is not necessary but we will include this information in future guidance.

Comment: One commenter recognized the benefit of the targeting option as “many states will not consider the State Plan HCBS benefit if it does not include mechanisms to control costs, especially given this existing economic climate.” However, the commenter also noted that “generally systems should be designed to promote community access over institutional access, regardless of individuals’ presenting characteristics.”

Response: We agree with this commenter and note that the ability to target the benefit to specific populations is a state option afforded by section 1915(i) of the Act, and thus, not something being made available solely through this regulation.

Comment: A couple of commenters noted that § 441.656(e)(2)(ii) references “§ 440.182(b)” which should be referenced as § 440.182(c).

Response: We thank the commenters for noting this error and have corrected this reference at § 441.710(e)(2)(ii) so that it now references services defined under the authority of § 440.182(c).

Comment: A couple of commenters requested that the regulation explicitly state in § 441.656(e) that states may propose a section 1915(i) benefit that “does not choose non-application of comparability and instead uses only the needs-based criteria to establish eligibility for the benefit.”

Response: Revision to regulatory text is not needed as § 441.710(e)(2) already specifies that disregarding

comparability is a State option: “In the event that a State elects not to apply comparability requirements: * * *” And § 441.715 specifies the requirement that States establish needs-based criteria for determining an individual’s eligibility under the State plan for the HCBS benefit.

6. Needs-Based Criteria and Evaluation (§ 441.715) (Proposed § 441.659)

Section 1915(i)(1)(A) of the Act requires states to establish 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 needs-based criteria for each specific State plan home and community-based service that an individual would receive.

Comment: Some commenters supported the use of needs-based criteria in determining eligibility for State plan HCBS. Several also expressed appreciation of the statutory requirement that a state notify CMS and the public 60 days in advance of any proposed restriction on the needs-based eligibility criteria (adjustment authority), if the number of individuals enrolled in the benefit exceeds the projected number submitted annually to CMS. These commenters agreed that notification to CMS should take the form of a State plan amendment.

Response: We appreciate these comments supporting this provision of the rule.

Comment: A couple of commenters suggested that CMS clarify that a 60-day public notice be required for any changes in need-based criteria, as well as any related level of care changes, and to include notifying the individual and any authorized representative. They also requested that this notice include guidance for states on the individual’s appeals rights and stipulate that appeals information must be included in communications to individuals. A couple of commenters also recommended a formal comment period, to provide an established mechanism for public input on the state proposed modification prior to federal action.

Response: Section 441.715(c)(1) requires states to provide at least 60 days notice of a proposed modification of the needs-based criteria to the Secretary, the public, and each individual enrolled in the State plan HCBS benefit. In addition, § 441.715(c)(5) requires any changes in service due to the modification of needs-based criteria under the adjustment authority to be treated as

actions as defined in § 431.201 and these actions are subject to the fair hearing requirements of part 431 subpart E of this chapter. States are also required under § 431.12 to provide for a medical care advisory committee to advise the Medicaid agency director about health and medical care services, and the committee must have the opportunity for participation in policy development and program administration. We encourage states to seek effective public engagement in all of their Medicaid 1915(i) activities.

Comment: A couple of commenters recommended a formal comment period/participant notice be required when a state proposes to change its level-of-care criteria for institutional care.

Response: Criteria for institutional care (level of care) are set by states as a means to determine an individual’s medical necessity for a service. These criteria are state policy, not approved by us, and not articulated in the Medicaid State plan, so we do not have an opportunity to require notice or comment periods. States could adopt their own notice and comment requirements. We note that to the extent a change in level of care would affect access to Medicaid services, states are required to notify beneficiaries and provide an appeal process. We may review state institutional level of care criteria, for example, to determine if stringency requirements are met in considering a state plan amendment to establish the State Plan HCBS benefit under section 1915(i) of the Act. Such review is for approval of the proposed benefit, not approval of the level of care criteria, and our review does not reopen state level of care policy for public comment.

Comment: A couple of commenters recommended that we change “will” to “may” in the proposed regulatory language so that CMS will retain some discretion to adapt to unexpected circumstances.

Response: We agree with this recommendation from commenters. This sentence in the regulation at § 441.715(c) now reads “The Secretary may 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 . . .”

Comment: One commenter recommended that the 60 day written notice to the Secretary (for proposals to revise needs-based criteria) be provided at the same time as tribal notice is made, 60 days in advance of submission of the State plan amendment.

Response: We acknowledge the comment with the following reminders: § 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. Further, Section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Recovery Act), Public Law 111–5, codified at section 1902(a)(73), requires states to solicit advice from tribes and Indian Health Programs prior to the state’s submission of any Medicaid or CHIP State plan amendment likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations. The statutory requirement is that states must solicit this advice prior to submission of a SPA or waiver to CMS following the process described for soliciting advice from Indian Health Providers and Urban Indian Organizations in each state’s approved State Plan.

Comment: One commenter requested revision to § 441.659(b) to specify that there it is not a requirement that institutional or home and community-based waiver criteria be higher than their level prior to implementing the State plan HCBS benefit.

Response: We are unable to make this revision as it is would not comport with section 1915(i)(1)(B) of the Act, which requires needs-based criteria for receipt of services in nursing facilities, intermediate care facilities for individuals with intellectual disabilities, and hospitals, or waivers offering HCBS, to be more stringent than the needs-based criteria for the State plan HCBS benefit.

Comment: One commenter indicated that their state is attempting to further change the Medicaid institutional level of care criteria to restrict Medicaid eligibility to the lower need individuals in several categories of settings, including the HCBS setting, and expressed concern about how the federal proposal would intersect with this state proposal, and whether the criteria would align, be duplicative, or conflicting.

Response: In order to implement and maintain section 1915(i) State plan HCBS, the state’s institutional level of care criteria must be more stringent than the needs-based criteria for the State plan HCBS benefit.

We note that 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 beyond the scope of this regulation, for example, statutory requirements for maintenance of effort (MOE) in effect at the time of this final rule, requirements of the ADA and the *Olmstead* decision, and funding constraints. 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.

Comment: While several commenters expressed support for grandfathering of institutional and waiver participants when states increase stringency for institutional level of care, they also had concerns that the stringency requirements might be interpreted to allow a state to change the needs-based criteria between the institutional and waiver level of care and the state plan home and community-based level of care with the net effect that people would not be eligible for either. They recommended that CMS revise the regulation to require states to grandfather HCBS participants who would lose Medicaid eligibility due to "stringency" adjustments. Two other commenters also noted that CMS misinterpreted the statute where it specifies that FFP "shall" continue to be available, as a state option stating their belief that this indicates a state requirement and not an option.

Response: The statute at section 1915(i)(5) of the Act does not create a mandate for states to continue to provide assistance to such individuals and to claim FFP. The statute permits states the option to continue receiving FFP for individuals who are in an institution or HCBS waiver, if a state needs to modify section 1915(i) needs-based criteria after implementation of a section 1915(i) benefit, and also needs to modify institutional needs-based criteria in order to meet the 1915(i) stringency requirement. Therefore, we have not adopted this change as requested to regulation text language at § 441.715(b)(2). However, we note that other legal provisions, such as those

related to discharge planning, might require the continued provision of certain services to individuals.

Comment: One commenter recommended deletion of the provision at proposed § 441.659(c)(4)(ii). The commenter believes that the HCBS population has predictable fluctuations in status and therefore the grandfathering provision should be flexible enough to protect individuals who go through short-term transitions.

Response: We disagree with this recommendation and have not made this revision as requested. Section 441.715(c)(4)(ii) is an important provision that requires states, when they revise needs-based criteria after implementation of the benefit (adjustment authority), to continue providing State plan HCBS to individuals who were eligible prior to the change but no longer meet the state's new needs-based criteria until such time as they no longer meet Medicaid eligibility requirements or eligibility requirements to be served under the state's section 1915(i) benefit.

Comment: One commenter recommended that CMS define the term "independent" in the regulation.

Response: This is defined at § 441.730. Section 441.715 already indicates that an agent (who performs the evaluation) must be independent and qualified as defined in § 441.730.

Comment: A couple of commenters commended the inclusion of a requirement at § 441.659(d)(3) to consult with the individual, but recommend this be defined and strengthened to include a more central role for the individual, including for example consultation with providers, social service staff, or others identified by the individual. Another requested § 441.659(d)(3) be changed to reflect that the person-centered service plan should have the person "directing" the plan whenever possible and suggested that if the individual wishes, other people of the individual's choice be consulted.

Response: This section of the rule pertains to the independent evaluation to determine eligibility. Therefore, we do not believe it is necessary to include requirements about the person-centered service planning process, for which there are separate regulations at § 441.725(a) and which already reflect the recommendations of this commenter.

Comment: A couple of commenters noticed that § 441.659(b)(2) includes an incorrect reference to (c)(7).

Response: We have corrected the text in § 441.715(b)(2) of the final rule to change the reference from (c)(7) to (c)(6).

Comment: One commenter noticed that § 441.659(d) incorrectly references § 441.656(a)(1) through (5), and that § 441.659(d)(2) incorrectly references § 441.656(a)(1) through (3) and (b)(2).

Response: In § 441.715(d), we have corrected the reference so that it now reads as § 441.715. In § 441.715(d)(2), we have also revised the reference so that it now reads correctly as § 435.219 and § 436.219.

Comment: One commenter requested that we eliminate the word "eligibility" from § 441.659 and replace it with "services" to eliminate confusion so that eligibility would be centered on categorical eligibility while service criteria were used for needs-based criteria.

Response: We are unable to make this requested revision, since needs-based criteria are necessary for eligibility, in addition to the other eligibility requirements specified in § 435.219 and § 436.219.

Comment: A couple of commenters requested that the regulation include an individual's inability to perform 2 or more ADLs or IADLs as a requirement for eligibility under section 1915(i) of the Act.

Response: This is not an eligibility requirement under the statute and we are not able to make this requested revision. While 1915(i)(1)(F)(i) requires that the independent assessment include an objective evaluation of an individual's inability or need for assistance to perform 2 or more ADLs, this is only a suggested element at 1915(i)(1)(D)(i) and thus, not required for an individual to be determined eligible for 1915(i) State plan HCBS.

Comment: One commenter requested that we add a provision to § 441.659(d)(3) to include consultation with the parents of a child.

Response: We believe that the broader term "individual's authorized representative," used in 1915(i) of the Act and in this regulation, would include, in the case of a child, the child's parents or legal guardian, and does not need to be explicitly stated in regulation.

Comment: Another commenter recommended that when assessing the individual's support needs for purposes of evaluation of eligibility, that informal supports arranged by the individual not be considered unless the individual explicitly chooses to include them.

Response: This suggestion is already captured in § 441.720(a)(2) where the regulation requires the assessment to "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."

Comment: A couple of commenters stressed the importance that FFP be available for evaluations even when an individual is subsequently found ineligible for section 1915(i) of the Act services.

Response: As stated in section III.N.2. of the preamble to the proposed rule, FFP is 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 section 1915(i) of the Act 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.

Comment: Some commenters requested clarification regarding level of need, as defined by the state and provider, including whether a state may leverage existing and/or specific instruments that are used to determine HCBS waiver eligibility in order to determine whether a beneficiary meets the State plan HCBS needs assessment criteria for participation, understanding that the State plan HCBS benefit eligibility criteria must be less stringent than that used for HCBS waiver programs.

Response: The state's process for determining eligibility must meet the requirements at § 441.715(d). We do not require a specific instrument(s) that states must use in meeting these requirements.

Comment: One commenter indicated that if states establish needs-based criteria for each specific service that an individual receives, it would add to the complexity of the assessment service planning, the overall costs of program administration, and potential beneficiary and family caregiver confusion. They stressed that such variability in Medicaid across states could become extremely difficult to track and monitor.

Response: As specified in the regulation, this is optional for states. This option could be of benefit for states that wish to include services for individuals with specific needs within a section 1915(i) of the Act benefit that is not targeted to a specific population group(s) and is designed to provide a broad array of services.

Comment: One commenter requested CMS require states to make needs-based

criteria publicly available, including public Web site posting. Another inquired how CMS will maintain publicly available documents relating to the state's modification proposal, approval and denial letters, comments submitted and communications with the state.

Response: We agree that web posting is an ideal way to make state plans and amendments available to the public, and we are building a web-based information system for all of Medicaid and CHIP that will provide immediate access to state plan amendments. Section 1915(i) of the Act SPAs will be part of that system. Until then, SPAs are processed on paper and posted sometime after approval. We encourage states to provide for effective public engagement in all of their Medicaid program activities, and states are required to provide 60 day public notice when states change reimbursement methodology or revise CMS approved section 1915(i) needs-based criteria.

7. Independent Assessment (§ 441.720) (Proposed § 441.662)

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. We note that while section 1915(i)(1)(F)(i) of the Act requires that the independent assessment include an objective evaluation of an individual's inability or need for assistance to perform 2 or more ADLs, this is only a suggested element at section 1915(i)(1)(D)(i) of the Act and thus, not required for an individual to be determined eligible for 1915(i) State plan HCBS.

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 proposed specific requirements for independence of the assessor in accordance with section 1915(i)(1)(H)(ii) of the Act, and we will 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.

Comment: Many commenters expressed support of the independent assessment requirements in this section of the rule. One commenter who expressed agreement with § 441.662(a)(1), stated that individuals with disabilities have a right to choose their own lifestyle, just like their peers without disabilities.

Response: We appreciate these comments and support.

Comment: One commenter stated that clear assessment standards are necessary to ensure that individuals deemed eligible for section 1915(i) of the Act services receive the services that are most appropriate and effective.

Response: We agree and have specified these requirements in § 441.720.

Comment: A commenter requested that we ensure there are assessments of need for individuals residing in facility-based settings before the development of their person-centered service plans.

Response: The requirements of this regulation pertain to all section 1915(i) of the Act eligible and enrolled individuals residing in home and community-based settings, regardless of the setting.

Comment: One commenter stated concern that § 441.662(a)(1)(i)(A) refers to "health care professionals," given that often assessments of support needs—such as the Supports Intensity Scale and functional-behavioral needs assessments—are made by case

managers or social workers, rather than health care professionals.

Response: As enrolled Medicaid providers of Medicaid services or administrative activities, case managers and social workers are included in our regulation as “health care professionals.”

Comment: A couple of commenters requested that CMS add to paragraph (a)(2) “friends” as respondents that the individual may identify to participate in the assessment. They also commented that this paragraph should require that the assessor actually contact and involve individuals identified.

Response: We do not believe it is necessary to add an exhaustive list of all the examples of the persons that an individual participant may choose to include in this process. The requirement specifies a few examples but emphasizes that these are just examples and not a limitation.

Comment: A couple of commenters requested clarification in § 441.662 (a)(4) on the requirements for a caregiver assessment, including what it means, the process, and purpose. Another commenter suggested its removal, stating that it unnecessary since there is already an assurance elsewhere in the regulations that states must assure the enrollees’ health and welfare. However, many others expressed their support of this provision and stressed the importance of its inclusion in the regulation; some even urged CMS to include this under other Medicaid HCBS authorities. One of these commenters requested the addition that the caregiver assessment will assess the training, support and respite needs and identifying options for receiving these services. Another stated that the assessment should evaluate the caregiver’s well-being, needs, strengths and preferences, as well as the consequences of caregiving on the caregivers.

Response: We included this provision in the proposed rule as a result of comments received in response to the first proposed rule pertaining to section 1915(i) of the Act, which was not finalized. Those commenters stated that taking into account the capacity of primary caregivers to provide for the individual’s assessed needs is necessary, and some stated that natural supports often have declining capacity, and to fail to take this into account leads to unrealistic plans. We agree that when caregivers are being relied upon to implement the person-centered service plan, it is important that a caregiver assessment be required in order to acknowledge and support the needs of informal family caregivers. We agree

that caregivers provide critical care and support that enables individuals to live in their homes and communities. When there is a caregiver involved, an assessment of the caregiver’s needs is essential to facilitate the individual’s linkage to needed supports. We appreciate the comments regarding definition and process, which we will consider for future guidance.

Comment: Many commenters requested that CMS add language to the rule that specifically addresses assessment of needs related to cognitive impairment. A couple of commenters noted that this is needed to promote early diagnosis of memory problems and prevent the cycle of under-diagnosis and misdiagnosis of Alzheimer’s disease. They stated that many individuals with dementia need supervision and cueing or are unable to perform instrumental activities of daily living. Others expressed support of a more comprehensive approach to include social, medical, behavioral, emotional, physical and cognitive strengths and challenges, and also noted that on-going training and coaching in understanding cognitive and behavioral issues unique to brain injury in the planning process should be a part of the delivery system. They stated that CMS and states will need to work with program participants and community advocates to determine the appropriate depth of assessment, allowing for an informed planning process while also being respectful of some individuals’ desire for a non-intrusive approach. They also noted that a range of professionals may be suitable for assessing cognitive as well as behavioral issues, including neuropsychologists, psychologists trained in brain injury, educators, and speech and language therapists.

Response: We agree with these comments and have added “cognitive” to § 441.720(a)(4).

Comment: One commenter expressed support of the requirement for a person-centered assessment process.

Response: We agree that this is essential to the assessment and person-centered service planning process.

Comment: One commenter stated that it would be helpful for providers and practitioners to have a degree of flexibility in prioritization and to override recommendations for lower levels of care. They noted that this could be kept at a particular level (that is, no more than 5 percent of the time), but there are certain conditions and situations that can result in skewed assessment results.

Response: We do not agree with this comment. We do not believe it would be

consistent with the intent of this subsection, or with the person-centered process requirements at § 441.725, and would enhance the potential for conflict of interest.

Comment: A few commented on the statutory requirement regarding assessment of an individual’s inability to perform two or more ADLs. One suggested that the assessor also consider cueing as assistance, whether by someone, a device or service animal in addition to individual assistance or assistive technology. Another stated that the statute does not set any specific needs-based or ADL criteria as a standard for eligibility for any HCBS, and that CMS should clarify that states should not interpret the two ADLs evaluation criteria in the assessment to mean that two ADLs is the standard for eligibility for the state plan option or for any specific services under the state plan option. One commenter recommended that CMS clarify in the preamble that while ADL review is a required element of the assessment, the result of the ADL review cannot be a litmus test for access to services.

Response: An objective evaluation of the individual’s inability to perform two or more ADLs is, in statute, a required element of the independent assessment but it is only a permissible element of the independent eligibility evaluation. The statute does not specify that eligibility for state plan HCBS must be based on the evaluation of the individual’s inability to perform a minimum number of ADLs. We concluded that partial or complete inability to perform two or more ADLs is not a statutory prerequisite to eligibility for State plan HCBS. However, the evaluation of an individual’s inability to perform two or more ADLs, as required under section 1915(i)(1)(F)(i) of the Act, is related to the state’s responsibility under section 1915(i)(1)(E)(ii) of the Act to use the results of the assessment to determine a necessary level of services and supports, prevent the provision of unnecessary or inappropriate care, and establish an individualized care plan.

Comment: Some commenters recommended that in-person assessments be required or, alternatively, that telemedicine assessments be allowed only in very limited circumstances when in-person assessments cannot practically be performed. Other commenters agreed that it may be appropriate to use technology to conduct assessments in certain circumstances, such as for individuals in rural or underserved areas, but not for beneficiaries for whom such circumstances do not create

barriers to an in-person and in-home assessment. They suggested additional language to limit use of technology to conduct assessments to individuals in rural areas, or other special circumstances by requiring states to make an individualized determination of the need for substituting telemedicine for genuinely in-person assessments. One commenter stated that it should only be allowed if the state makes an individualized determination of the need for substituting telemedicine for genuinely in-person assessments. Another stated that assistive technology or other alternative or augmentative communication should be made available for those who would benefit from it. A few commenters stated that § 441.662(a)(1)(i)(B) should include, if the individual wishes, the presence of family, a peer/parent support provider, or other people of the individual's choice.

Response: In our preamble to the proposed rule, we indicated that we added this provision of the regulation in recognition 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. However, we are concerned that by limiting this technology to only these circumstances, the regulation may end up precluding instances where it may be useful, maybe even essential. Therefore, we are not adding this limitation to the regulation, but will include this example in future guidance and monitor its use by states. We also note that these requirements do not override the other requirements for the assessment in this section, including the person-centered process and consultation with persons that the individuals choose to include.

Comment: A couple of commenters stated that § 441.662(a)(7) regarding habilitation services specifies that only Section 110 of the Rehabilitation Act of 1973 and the Individuals with Disabilities Education Improvement Act of 2004 are primary payors and that (a)(8) should require documentation indicating that State plan HCBS also available through other Medicaid services or other federally funded programs, will not be provided:

“No State plan HCBS are provided which would otherwise be available in the same amount, scope, and duration to the individual through other Medicaid services or other federally funded programs available under Section 110 of the Rehabilitation Act of 1973 and the Individuals with Disabilities Education Improvement Act of 2004.”

Response: We do not agree with this suggested addition. The broader requirement of this provision ensures that if the same services are available through other sources, then State plan HCBS would not be provided. Adding the suggested clause would leave the possibility for a state to claim FFP for a service through section 1915(i) of the Act before or instead of claiming it through these other authorities/programs. Since the intent of this provision is to ensure that states only claim for State plan HCBS when they are unavailable through other sources, we are unable to incorporate the language requested.

Comment: A couple of commenters recommended adding a modification so that § 441.662(a)(8) would require that the services be “immediately” available to the individual.

Some commenters stated concern that a state might deny an individual's ability to choose to receive a service through the section 1915(i) of the Act benefit, if that service would be theoretically available under another federal program but the fact that the individual was not provided with assistance in applying for those services would result in delayed access to services or no access to services. They instead proposed a “no wrong door” policy in enrolling individuals in the section 1915(i) of the Act State plan benefit, so that regardless of their eligibility status for services under other programs the individual begins receiving the services they are determined to need through their individualized assessment without having to apply or complete additional eligibility determinations. They also stated that individuals should be able to utilize the program that best meets their needs and preferences, and provides for the greatest degree of service coordination and administrative simplification.

Response: We developed the requirements at § 441.720(a)(7) and (8) due to concern over duplication of habilitation services and other state-defined services. Additionally, since some individuals may be simultaneously receiving services through a HCBS waiver and the section 1915(i) benefit, we require in § 441.720(a)(9) documentation that the services provided through section 1915(c) and section 1915(i) of the Act authorities are not duplicative for the same individual. This will also include coordination of assessments, person-centered service plan development, and case-management to ensure that individuals receiving services under both authorities are not subject to

multiple assessments and person-centered service plans. We believe the term “available,” addresses the concern and revision is unnecessary.

Comment: A commenter asked whether individuals would be required to utilize the State plan HCBS benefit first, when those services are duplicative of services also offered under a HCBS waiver for which that individual is eligible, such as habilitation services.

Response: The determination of how such services would be provided must be made during the development of the person-centered service plan. Additionally, if the State plan HCBS will provide the same amount, duration, and scope of service as another covered Medicaid service, states must explain in their proposed SPA how they will ensure against duplication of service and payment.

Comment: Several commenters expressed support of the requirement for the assessment to be conducted “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.” However, one of these commenters stated this language stops short from stating that the participant has a role in deciding who participates in the assessment process, indicating that person-centered practices require that participants drive the assessment process, and this includes decisions pertaining to who is part of their team when identifying and addressing unmet need.

Response: We believe this concern is fully addressed in the section pertaining to the person-centered planning process at § 441.725(a), and we have added a cross reference to this section to § 441.720(a)(1).

Comment: A commenter asked whether states can set limits on amount/scope/duration of State plan HCBS benefits, as approved via the State plan amendment process.

Response: Yes. Section 441.700 specifies that states are to describe the services that they will cover under the State plan HCBS benefit, including any limitations of the services.

Comment: One commenter expressed that states should have flexibility in choosing the independent assessor to serve populations.

Response: States have the flexibility to determine the entity that can perform this function, consistent with the

requirements at § 441.730 regarding qualifications and § 441.720 regarding the independent assessment.

Comment: One commenter noted that they have seen great variability in assessment results for the same individual depending on what incentives staff have for scoring a child or adult into or out of particular specialty services. They expressed that it needs to be clear which care provider or entity is responsible for completion of assessment for a particular patient and, if there are competing assessment results, which provider's or entity's assessment is prioritized.

Response: We agree, which is why we emphasized the section 1915(i) of the Act requirement for conflict of interest standards at § 441.730(b). When a state proposes a SPA to add section 1915(i) of the Act HCBS, we require that the state specify the entity that will be responsible for the assessment, the qualifications of that entity, and how the state will meet the conflict of interest requirements at § 441.730(b). The commenter mentions the presence of multiple assessments with competing assessment results, so we further note that there should be one assessment that incorporates the findings of any other records or information needed to develop the person-centered service plan as required in § 441.725.

Comment: One commenter asked that § 441.662(a)(2) also require that the assessor actually contact and involve the individuals identified.

Response: Section 441.720 (a)(1) requires the assessment to be a face-to-face contact with the individual and to be a person-centered process.

Comment: One commenter stated that it will be important for CMS and states to incorporate core elements of assessment that inform the participant direction process and at minimum, are not in conflict with participant-directed processes. They also stated that assessment questions should not lead to premature assumptions pertaining to who is appropriate for participant-direction simply based on diagnosis, the availability of informal caregivers, the individual's functional need, or cognitive status. Instead, assessment questions should be built on an assumption that all individuals, with the appropriate level of support, can participate in some form of participant direction. Assessment questions should assist the participant and others involved in the assessment process to identify unmet needs and the type of support that may be beneficial to the individual to allow for successful participant direction. In addition to identifying unmet need (as defined by

the individual), this could include an assessment of strengths, abilities, individual goals, need for a representative, capacity to self-direct with an eye for developing a support system to ensure success in self-directing, and risks. For a participant direction assessment to be successfully integrated into a larger assessment process, those performing the assessment need to be well-informed of participant direction programs, benefits, and requirements. Those performing and overseeing assessment processes also need training on the difference between traditional and participant-directed paradigms of service delivery. State and local leaders need to be informed, as well as educate their program staff, of the core competencies required to effectively support people to self-direct.

Response: We appreciate these comments and will consider them in future guidance that we develop after final publication of this rule.

Comment: One commenter recommended that the requirement to use a "person-centered process" in § 441.662(a) cross reference § 441.665, and suggests the phrase ". . . and meeting the requirements of § 441.665" be added to the end of § 441.662(a).

Response: We agree with this recommendation and have added "that meets the requirements at § 441.725(a)" to § 441.720(a)(1).

Comment: A couple of commenters requested clarification of the relationship between the needs-based criteria that states must establish for determining eligibility for HCBS, and for each specific service. One of these commenters noted that § 441.662(a)(5) implies that need-based criteria must be in place for each service and suggested moving the term "(if any)" to after the word "criteria," and editing it to "(if any have been established)".

Response: We agree with this suggestion and have revised the first sentence of § 441.720(a)(5).

Comment: One commenter stated that clarification is needed regarding the independent assessment that is conducted by a qualified health care professional (suggesting a medical model approach), and a true person-centered planning process.

Response: We acknowledge that this term used in this paragraph is inconsistent with other language in this regulation, and have revised § 441.720(a)(1)(i)(A) accordingly.

Comment: A commenter recommended that in § 441.662(a)(6) CMS create a stronger regulation to promote self-direction of services, and recommended the term "any

information" be modified to "notice, all information, and any supports."

Response: We did not make the changes requested by this commenter. This paragraph pertains to what must be included in the assessment with regards to self-direction if the State offers this under the State plan HCBS benefit. Other requirements regarding self-direction of services are contained in § 441.740.

Comment: Several commenters had opinions on the frequency requirements of the assessment. One requested that CMS expand this to "at the request of the individual," as is similarly provided in the regulation at § 441.665(c). Another stated that the assessment should be required every 3 years if clients are stable and engaged in the community, to reduce stress on the case management system. A couple of others just stated that re-assessments should occur "frequently" and when an individual's support needs or circumstances change significantly. Some stressed that the assessment and re-assessment process should be based primarily on individual need, and not place burdensome processes on the individual. One stated that for individuals unable to communicate via spoken, signed, written, or alternative/augmentative communication, the regulations should include language that significant changes in behavior and/or temperament indicate a need for reassessment of services. And another stated that CMS should clarify that the requirement for reassessment should not be interpreted to mean that each individual requires a full-scale medical re-evaluation, but instead re-assessment of services currently being used and new services requested by the individual or those important to him or her. One commenter asked how frequently the assessment must be made if the individual's condition is one that is not likely to improve.

Response: The current regulation language states "the re-assessment of needs 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 person-centered service plan." We believe that this language captures some of the concerns noted by the commenters. For others, in order to accommodate the varying and sometimes opposing comments, we believe that we should not change this requirement as provided in the proposed rule. This minimum frequency is consistent with the minimum frequency requirement for the review of the person-centered service plan, which

is based on the statute at section 1915(i)(1)(G)(ii)(III) of the Act.

Comment: Several commenters noted language from the preamble of the proposed rule that indicates that an assessment of “needs and strengths” is more appropriate than needs and capabilities, as the words capability and ability are historically connected with a deficit oriented approach to assessment. They requested that CMS add the word “strengths” to § 441.662(a). Some also requested that the reference to needs in § 441.662(a) specifically include physical and mental health needs stating that it must be made clear in the opening paragraph of this sub-section that these must also be assessed in order to establish a service plan.

Response: While we agree that these are elements that must be included in the assessment process, we believe this is already captured sufficiently under § 441.720 (a)(4) of this section which states, “Include in the assessment the individual’s physical, cognitive, and behavioral health care and support needs, strengths and preferences. . . .” Therefore, we have not adopted this change as requested.

Comment: Several commenters stated the regulation text should also include the language from the preamble that indicates that services must be furnished to individuals with an assessed need, and must not be based on available funds.

Response: This was an explanatory statement of the requirement at § 441.677(a)(1)(ii) of the proposed rule, which is now at § 441.745 (a)(1)(ii) of the final rule, and is not necessary to specifically state in regulation.

Comment: Several expressed that the regulation should include language from the preamble that states the “role of the assessor is to facilitate free communication from persons relevant to the support needs of the individual.”

Response: This is an explanatory statement in the preamble of the requirement already included at § 441.720(a)(2) regarding consultation with the individual and if applicable, the individual’s authorized representative, and others that the individual would like to include. We will plan to include this explanation in future guidance.

8. Person-Centered Service Plan (§ 441.725) (Proposed § 441.665)

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. As explained in the May 3,

2012 proposed rule (77 FR 2012–10385), we have adopted the term “person-centered service plan” in this regulation. 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 proposed to require such a process be used in the development of the individualized person-centered service plan for all individuals to be served by section 1915(i) of the Act benefit. We proposed certain requirements for developing the person-centered service plan, but noted 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.

a. Person-Centered Planning Process § 441.725(a)

Comment: One commenter requested that CMS ensure that there is a plan in place and implemented for more than medication management for individuals residing in facility-based settings.

Response: The requirements of this regulation pertain to all section 1915(i) of the Act eligible and enrolled individuals residing in home and community-based settings, regardless of the setting.

Comment: One commenter states that the driver and focus of the person-centered planning process is the individual and this concept is presented in § 441.665. However, it is not referenced at all in the provisions of § 441.659 pertaining to needs-based criteria and evaluation, nor in the provisions of § 441.662 related to independent assessment.

Response: The needs-based criteria established by each state determine an individual’s eligibility through an independent assessment and evaluation, which by its nature, focuses on the person. The individual does not drive or control these processes; however, the individual is the center of this process. The regulation at § 441.720(a)(1), regarding independent assessment, references § 441.725, person-centered service plan.

Comment: One commenter supports the expectation that states support individuals in the planning process as well as monitor the person-centeredness of the process itself. The commenter requests further refinement of the rule to ensure that program participants and community stakeholders are actively engaged in the states’ design of the

program as well as its ongoing quality management structure so that person-centered processes can be designed and monitored with substantial involvement of stakeholders. The commenter is also pleased to see that as part of the service planning process, program participants (including those not self-directing) will be offered choices pertaining to the services and supports they receive. The commenter requests that specific examples or guidelines be offered to states to demonstrate what this choice may look like within traditional services.

Response: We agree with the commenter’s suggestion and will take it into consideration in developing future guidance.

Comment: Some commenters stated that it is important that the regulation include the statement in the preamble that indicates that the service plan “should be constructed in a manner that promotes service delivery and independent living in the most integrated setting possible.”

Response: It is our expectation that the person-centered process incorporate the ideals stated in the preamble and we believe that this expectation is expressed in the regulation text at § 441.725(b)(1).

Comment: A few commenters recommended the following revision to § 441.665(a)(1), “Includes people chosen by the individual, including a parent and a parent support provider in case of a child and a youth support provider when the individual is under the age of 25.” A few commenters recommended the person-centered planning process allow HCBS providers and other health care providers to participate in service plan development and/or be the service plan developer.

Response: We appreciate the commenters’ perspective and suggestions. We do not want to prescribe all people who may be included in the planning process since that action may unintentionally exclude someone who is chosen by the individual.

Comment: Several commenters recommended that § 441.665(a) address those individuals not able to indicate a choice of whom they would like to participate in the person-centered planning process and that in these instances, the process should allow inclusion of people who know and care about the individual. One commenter encourages CMS to note the potential role of family members, peers, providers, and others during the person-centered service planning for HCBS. One commenter recommended that individuals who require assistance in

making decisions due to profound cognitive limitations may need the protection of legally-appointed guardianship arrangements, preferably by a family member or another individual who is familiar with an individual's unique needs. In many instances, it will not be feasible for service planning for individuals with brain injury to be furnished by any other individual or entity. One commenter encourages the use of advance directives to assure that a person's wishes are clear in the event he/she needs assistance, but is unable to otherwise express himself/herself.

Response: We believe that the regulation text as proposed, and which we are finalizing at § 441.725(a)(1), encompasses the suggestions that the commenter proposes.

Comment: A few commenters recommended that § 441.665(a) of the proposed rule should also require that person-centered service plans include examples and language referring to positive strategies to minimize the use of all types of restraints (chemical, physical, and mechanical) and other restrictive procedures.

Response: We have strengthened the language of this section in the final rule at § 441.725(b)(13) by indicating that any modification of the additional conditions must be justified in the person-centered service plan and added specific requirements about what must be documented in the person-centered service plan in these instances.

Comment: Several commenters recommend the following revision to § 441.665(a)(2), "Provides necessary information, support and experiences, if needed, to ensure that the individual directs the process to the maximum extent possible, and is provided meaningful opportunity to make informed choices and decisions." One commenter requested that the regulation more clearly state that an individual must be given information about all available supports and services.

Response: We believe that the regulation text at § 441.725(a)(2) is complete and clear.

Comment: A commenter suggested that the regulation must more clearly state that an individual must be given information about all available supports and services. The commenter also states that the individual must be given complete and accurate information about his/her right to a fair hearing and the regulation should require that this information be provided at every person-centered planning meeting and that a simple easy to use form be provided to request a fair hearing.

Response: It is our expectation that during the person-centered planning process and development of the person-centered service plan, all services and support options available will be articulated and discussed with the individual. States must adhere to the fair hearing requirements at part 431, subpart E for all Medicaid programs.

Comment: A few commenters recommended modifying § 441.665(a)(3) to read, "Is timely, flexible, and occurs at times and locations of convenience to the individual." One commenter requested clarification regarding the standard against which a state's "person-centered" process will be reviewed or the timeline for development of those criteria.

Response: We believe that the requirement regarding scheduling the meeting at the convenience of the individual addresses the flexibility issue and are not incorporating the suggested language. The minimum standards for person centered planning are enumerated in the regulation.

Comment: Many commenters recommended that the language in the regulation text at § 441.665(a)(4) be revised to include physical, linguistic and cultural accessibility in the person-centered planning process. One commenter requested that cultural considerations be expanded to include "lifestyle" choices of the individual.

Response: We appreciate the commenters' suggestions and note that the regulation text at § 441.665(a)(4) addresses cultural considerations. We have added regulation text at § 441.725(a)(4) to specify that the person-centered planning process must be accessible to persons who are limited English proficient and persons with disabilities, consistent with the Medicaid programmatic accessibility provision at § 435.905(b). Policy guidance to promote compliance with Title VI's prohibition against national origin discrimination affecting persons with limited English proficiency is available on the Department of Health and Human Services Office for Civil Rights Web site at <http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html>.

Comment: Several commenters suggest inserting language at § 441.665(a)(2) such as meaningful choice, informed decision-making, provision of meaningful information about settings, including the most integrated setting alternatives appropriate for that individual.

Response: We appreciate the commenters' suggestions. While we have not made any revisions to § 441.725(a)(2), we have considered

these comments for other revisions made to the regulation.

Comment: Many commenters agreed with the provision at § 441.665(b)(1) that the person-centered plan should record the alternative home and community-based settings that were considered by the individual. Another commenter requested CMS add a requirement that "all residents have selected this setting from a meaningful choice of alternatives, including the most integrated setting appropriate for each resident." One commenter requests with respect to § 441.665(a)(8), that this provision should be modified to read, "Documents how the home and community-based settings, services and supports, including both residential and employment settings and supports, are in line with the USDOJ most integrated setting mandate under the ADA and *Olmstead* decision, and in cases where settings and services are not fully aligned with the 'most integrated setting' mandate, provides full documentation regarding why less integrated/congregate settings and services are being utilized."

Response: We appreciate the commenters' support. We have addressed the concern regarding meaningful choice and most integrated settings by clarifying that the individual's selection must include non-disability specific housing opportunities. We support the mandates of the ADA and the *Olmstead* decision and believe the final regulation reflects the spirit of these mandates.

Comment: A commenter supports the expectation that states support individuals in the planning process as well as monitoring the person-centeredness of the process itself. The commenter requests further refinement of the rule to ensure that program participants and community stakeholders are actively engaged in the states' design of the program as well as its ongoing quality management structure so that person-centered processes can be designed and monitored with substantial involvement of stakeholders. The commenter is also pleased to see that as part of the service planning process, program participants (including those not self-directing) will be offered choices pertaining to the services and supports they receive. The commenter requests that specific examples or guidelines be offered to states to demonstrate what this choice may look like within traditional services.

Response: We appreciate the support. States are provided the latitude to determine how they will operationalize

the regulation. We do not wish to be as prescriptive as suggested.

Comment: A few commenters recommended that CMS require any modifications to the conditions placed upon provider-controlled or owned residential settings be supported by a specific assessed need documented in the person's person-centered plan. One commenter stated that they did not support unnecessarily restrictive methods for providing person-centered services and supports even though they may be well-meaning.

Response: We agree with the commenters' statements and have strengthened the language of this section in the final rule by requiring at § 441.725(b)(13) that any modification of the additional conditions must be justified in the person-centered service plan. We also added specific requirements about what must be documented in the person-centered service plan in these instances.

Comment: One commenter suggested that CMS make the person-centered process the critical identification for what is determined to be community-based not where the site is located or what it looks like. Another commenter states that the person-centered planning meeting should be where the needs and preferences are matched with compatible and appropriate services/living arrangements and where modifications to existing services and acceptable compromises are determined. They state that maintaining a full continuum of services and settings is a better plan than limiting options or making them harder to access because some people might find them objectionable. One commenter states that specific restrictions on living arrangements should not supersede supports and services identified through the person-centered planning process.

Response: We believe that our regulations need to address the issue of what constitutes home and community-based settings. While the person-centered service plan can and does assist individuals with integration into the community, it is not the vehicle to determine whether a setting meets the requirements for being home and community-based.

Comment: One commenter requested deletion of the requirement that services be based on the needs of the individual as indicated in their person-centered service plan, stating that these plans are often limited by the experience of the individuals developing them and the most effective treatments/supports may not always be included. The commenter noted that service needs and ideas for how best to offer them evolve,

particularly as a person progresses and service plans often become stale before they are reviewed/updated.

Response: We do not agree with removing this requirement, and note that it is based on statute at section 1915(i)(1)(G) of the Act. States are responsible for determining that requirements related to the qualifications of the entities who will conduct the assessments and the person-centered planning process have been met. It is expected that the providers would have adequate training to perform the function consistent with the requirements set forth in the regulation. States must ensure the person-centered service plan process is timely and includes a method for the individual to request updates to the plan. Additionally, an assessment of need must be conducted when the individual's support needs or circumstances change significantly and revisions to the person centered services plan are necessary.

Comment: Many commenters recommend deletion of the language that says the requirements are "based on the needs of the individual as indicated in their person-centered service plan." The commenters believe that without deletion or modification of the proposed language, it would be too easy for a provider to insert certain language in a service plan.

Response: The person centered planning process includes provisions to protect a person-centered service plan from being changed without the individual's consent. We believe the inclusion of this language is a necessary beneficiary protection; therefore we did not revise the regulation to remove this requirement.

b. Person-Centered Service Plan § 441.725(b)

Comment: One commenter states that if CMS defines what a service plan should be, it may be in direct conflict with how states define their services and the commenter does not believe that this is the intent of CMS.

Response: We do not define specific services. However, we do define what should be included in the person-centered service plan, and by adopting the terminology and process of a person-centered service plan, the services and supports should reflect the individuals preferences based on their needs.

Comment: One commenter recommended, for high-need children and older adult beneficiaries, the option of further assessment and recommends that there be allowable reimbursement for these activities necessary for developing the service plan, including

communication with collateral treatment partners (that is, pediatrician, teacher, school representative, parent) as these partners and activities are critical for development of a service plan for vulnerable beneficiaries and are absolutely essential for proper care for children and for seniors.

Response: States may be able to claim reimbursement for assessment activity, as well as person-centered service plan development, as a Medicaid administrative activity that is in accordance with an approved cost allocation plan.

Comment: One commenter recommended enhancing regulation language to ensure that states have the flexibility to include services and supports that are appropriate and essential for child and youth development, but may not be Medicaid reimbursable, including education, housing, and transportation, as to encompass a comprehensive service provision supported by HCBS.

Response: We believe the language in § 441.725(b)(5) of the final rule supports this concept: "the plan must . . . 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."

Comment: Commenters supported § 441.665(b) and suggested that equal emphasis be placed on what is important for the individual and what is important to the individual. One commenter recommended the following, "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, and what is important to the individual with regard to preferences for the delivery of such services and supports, including, but not limited to, living arrangement, neighborhood, leisure activities, and relationships."

Response: We appreciate the commenters' support. As the language of the proposed rule supports this concept, we do not believe that the suggested revisions for the final rule at § 441.725(b) are necessary.

Comment: Many commenters stated their support of person-centered planning and expressed that when the individual welcomes the involvement of family or other informal caregivers, family members should be engaged as part of the care planning and care-giving teams. They stated that services to be provided by family caregivers should only be included in the person-and family-centered plan if they have agreed to provide these services and feel

prepared to carry out the actual tasks. One commenter agreed with preamble language that the service plan should neither duplicate, nor compel, natural supports, expressing that unpaid supports should be provided voluntarily. This commenter suggested that CMS include this specific language in the regulation text.

Response: We appreciate the support of the commenters. The language in § 441.725(b)(5) of this final rule states: "Natural supports are unpaid supports that are provided voluntarily to the individual in lieu of State plan HCBS."

Comment: One commenter supported requirements for the development of a person-centered plan but recommends that § 441.665(b)(9) should clarify that even though the service plan is "finalized and agreed to in writing by the individual" the individual retains the right to appeal a denial, reduction, suspension, or termination of a service described in part 431, subpart E.

Response: As the fair hearing requirements at part 431, subpart E, apply to all Medicaid services, it is not necessary to revise the text of the regulation at § 441.725.

Comment: Some commenters recommended that each person-centered service plan include the dollar figures of the budget allocations provided to each beneficiary, the starting date of services/supports, the scope and duration of service, and all other services that are not Medicaid reimbursable.

Response: We agree that the person centered service plan should be comprehensive and the language in the final rule supports this concept.

Comment: Two commenters were against requiring the signatures of all individuals and providers responsible for implementation of the service plan, stating that this is impractical and will make the process untenable. They also expressed that giving all providers the entire service plan would share personal health information of the member with providers who do not necessarily need to see that information. One commenter was concerned about liability and who is responsible if an individual has risky behavior.

Response: The regulation language at § 441.725(b) gives the flexibility for the individual to determine to whom the plan will be provided, in whole or in part, commensurate with the level of need of the individual and the scope of the services and supports available. Sharing of this information must be consistent with federal and state laws regarding privacy and confidentiality.

Comment: Several commenters recommended the following revisions for § 441.665(c): "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, an authorized representative, or healthcare or support providers." One of these commenters stated that while having a service plan required every 12 months may be minimally okay for some populations, it is insufficient (too lengthy) for those with chronic mental health and substance use disorders. Another commenter stated that, at a minimum, requiring service plan review every 6 months is adequate. Another commenter stated that the reassessment being done "at the request of the individual" could lead to inflated service hours and costs, both of which will add unnecessary costs to the provision of HCBS. This commenter believed the language at § 441.662(b) is better language. Another commenter was against requiring assessments before the meeting.

Response: We proposed 12 months as the minimum time period for an individual's person-centered service plan to be reviewed and revised. We agree and support reviews and revisions of an individual's person-centered service plan more frequently as needed. The person-centered service plan should be reviewed and revised when the individual's circumstances or needs change significantly and at the request of the individual, authorized representative or healthcare provider.

Comment: One commenter did not support standardized functional assessment. In addition, the commenter stated that when service providers use a functional assessment, it has been typically to establish funding levels, which should only be determined by a person-centered planning process and allowing such an instrument to overrule the person-centered plan completely negates the person-centered planning process.

Response: An individual's person-centered plan must be based on that individual's assessment of functional need. We have not specified the instruments or techniques that should be used to secure the information necessary to determine an individual's functional need, person-centered service plan, or service budget. States do have the ability to establish limits on amount, duration, and scope of services.

Comment: With respect to § 441.665(b)(6), one commenter stated that individual back-up plans have been a critical component of participant direction. A commenter suggested when refining the proposed language, it will

be important to reflect on the impact the traditional paradigm has on the role providers and participants play in defining, identifying, and addressing risk.

Response: We have strengthened the language in the final rule to ensure that reducing risk for individuals receiving Medicaid HCBS does not involve abridgement of their independence, freedom, and choice. Restricting independence or access to resources is appropriate only to reduce specific risks, and only when considered carefully and reflected in the person-centered service plan.

9. Provider Qualifications (§ 441.730) (Proposed § 441.668)

In the proposed rule, we proposed to require states to 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, and for those persons who conduct the independent evaluation of eligibility for State plan HCBS and independent assessment of need, and who are involved with developing the person-centered service plan. We noted that we will refer to the individuals and entities involved with determining access to care as "agents" to distinguish this role from providers of services. We also noted that the 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 believe that these qualifications are important safeguards for individuals enrolled in the State plan HCBS benefit and proposed 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 person-centered 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 proposed to require would 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 a financial interest in any of the entities that

provide care. Our experience with HCBS in waivers indicates that assessment and person-centered 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.

Comment: One commenter questioned the reason for defining persons responsible for the independent evaluation, independent assessment and the service plan as “agents” to distinguish them from “providers” of HCBS. Another commenter indicated that it is unclear whether one agent performs an assessment, or different agents with different expertise.

Response: In the preamble to the proposed rule, we discussed that we will refer to persons or entities responsible for the independent evaluation, independent assessment, and the person-centered service plan as “agents” to distinguish them from “providers” of home and community-based services. We also explain that this does not preclude the inclusion of input from other individuals with expertise in the provision of long-term services and supports, or the delivery of acute care medical services, as long as an independent agent retains the final responsibility for the evaluation, assessment, and person-centered service plan functions.

Comment: A commenter requested whether states would be permitted to allow a transition period for agents conducting the individualized independent evaluation, assessment and service plan development to attain any new qualifications, if necessary.

Response: We believe that it is important for individuals responsible for evaluation, assessment, and/or person-centered service plan development to fully meet the qualifications specified at § 441.730(c) prior to performing these activities.

Comment: Several commenters recommended adding a requirement to this section of the regulation that service providers not discriminate against recipients on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, marital status, source of payment, or mental or physical disability. Similar protections are contained in the regulations for the Program for All-Inclusive Care for the Elderly (PACE).

Response: There are already general provisions in other regulations that

pertain to the issues raised by the commenters and that prohibit discrimination in State Medicaid programs on the basis of race, color, national origin, disability, etc., (for example, see § 430.2, § 435.901, § 435.905, and § 435.908). As these regulations apply in determining eligibility and administering the Medicaid program generally, it is not necessary to add a regulation on this subject specific to section 1915(i) of the Act.

Comment: Several commenters requested further clarification pertaining to provider qualifications for the participant direction option and requested that provider qualifications for participant-directed workers not limit participants’ access to these providers but be defined by the program participant receiving services once s/he is trained on the program rules and expectations. One commenter recommended that CMS make provider qualifications “default rules” that could be waived through an informed and affirmative choice, with a signed statement, by consumers who are directing their own care. Another commenter requested that CMS add to the regulation “Such standards shall not be construed to limit the ability of self-directing individuals who have employer authority to hire, train, manage, or discharge providers pursuant to § 441.674.”

Response: As stated in the proposed rule, and retained in the final rule, individuals who choose to self-direct will be subject to the same requirements as other enrollees in the State plan HCBS benefit, including § 441.730 for provider qualifications. Section 441.730 requires states to define in writing standards for providers (both agencies and individuals) of HCBS, and for agents conducting individualized independent evaluation, independent assessment, and person-centered service plan development. As with section 1915(c) of the Act waivers, states have to define minimum service provider qualifications that apply across the service delivery models.

Comment: Many commenters expressed support of the conflict of interest provisions of the proposed rule. One such commenter stated support of standards that will result in service plans that have realistic expectations and payment for providers while adequately addressing the client’s individual needs, noting that too often costs are driving decisions about the appropriate services for the individual. One mentioned that it is difficult for a system to be completely free of conflict of interest, since any assessor that works

for the state has an interest in controlling costs, but stated their belief that acknowledging the conflicts helps to mitigate the effects. Another indicated that guidance should reflect administrative safeguards that consider each state individually and consider the unique characteristics and needs of each state, and include conflict free protections that address the development of the plan and choice of providers with an emphasis on individual preferences. Another requested that this be closely monitored.

Response: We appreciate the support and agree with the commenters. We will consider these additional comments as we develop future guidance.

Comment: Several commenters requested that § 441.668 exclude a managed care organization from conducting the independent evaluation of individuals. Another stated a managed care organization should not be permitted to conduct the independent assessment of individuals. And another requested this section also exclude “the state” from conducting the independent assessment of individuals.

Response: We do not believe it is necessary to list specific entities that would not meet these requirements in regulation. We believe the specific requirements of § 441.730 capture the purpose of these requirements to mitigate and prevent conflict of interest.

Comment: One commenter indicated that the requirements regarding an independent evaluator would not work in a capitation model, and that it adds another level of bureaucracy and impacts service systems already in place by some states that delegate or contract out this function to another agency. Another commenter stated that the requirements would limit states to the development or use of models that contradict decades of long term care policy and efforts to coordinate an otherwise fragmented system. They expressed that models that consolidate evaluation, assessment, care planning, case management and the provision of services into integrated, single entry systems enable beneficiaries to more seamlessly access services and receive coordinated, integrated plans of care (for example, long term home health care programs, managed long term care, PACE). Another commenter disagreed with the independent agent requirement, stating there may be cost implications if an independent contractor is used to develop the person-centered service plan and that this proposed requirement may work in a fee-for-service benefit, but would not work in a benefit that is capitated.

Response: We disagree and have experience with states where this does and is working in these models. While the evaluation to determine whether an individual is eligible for the benefit would need to be retained by an independent entity that is not the provider, providers can contribute information to the entity responsible for the final determination. Regarding the independent assessment of need and person-centered service plan, to summarize § 441.730(b)(5), states can allow providers of State plan HCBS, or those who have an interest in or are employed by a provider of State plan HCBS, to be the entity responsible for the assessment and person-centered service plan functions, when the state demonstrates that they are the only willing and qualified agent to perform these two functions in a geographic area, and the state devises conflict of interest protections including separation of agent and provider functions within provider entities, and a clear and accessible alternative dispute resolution process for individuals. In summary, the requirements at § 441.730, which are based on our experience as well as state and other public feedback, specify how states must comply with statutory requirements. Therefore, we are retaining the requirements from the proposed rule at § 441.730 regarding independent evaluation and conflict of interest standards, in this final regulation. We note that CMS stands ready to assist any State Medicaid agency in need of technical assistance with these requirements.

Comment: Several commenters requested that § 441.668(b)(5) be expanded to make it clear that when there is only one provider available, the provider may serve as the agent performing the assessment and the agent developing the plan of care, as long as the requirements in § 441.668(b)(5) are met. Another commenter proposed permitting providers in some cases to serve as both agent and provider of services, but with guarantees of independence of function within the provider entity.

Response: We believe that § 441.730(b)(5) already includes this requirement: "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."

Comment: A couple of commenters recommended deletion of § 441.668(b)(5), indicating that this provision to waive the conflict of interest standards minimizes safeguards to protect individual health, welfare, choice, and control. They indicate that states should be required to develop in all geographic areas sufficient systems of independent evaluators, independent assessors, and providers to develop service plans. They noted that since CMS's experience with HCBS waivers has shown that assessment and service plan development should not be performed by service providers, this should be carried over and applied to State plan HCBS as well.

Response: Section 441.730 (b)(5) requires that service providers not be permitted to be the agent responsible for these functions, but includes an exception to allow a state to permit a service provider to serve as the agent performing independent assessments and development of the person-centered service plan when that service provider is the only entity available in a certain area. This is only permitted to address this potential problem of not having any entity available that is not a provider to perform these essential functions of independent assessment and person-centered service plan development (under any circumstances, determination of eligibility for the State plan HCBS benefit cannot be performed by a HCBS provider or an entity with an interest in providers of HCBS). Without this exception, states would be unable to make State plan HCBS available to participants in these areas. If a state employs this exception it must guarantee the independence of this function(s) within the provider entity. In certain circumstances, we may require that states develop "firewall" policies, for example, separating staff that perform assessments and develop person-centered service plans 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 also will not permit states to circumvent these requirements by adopting state or local policies that suppress enrollment of any qualified and willing provider.

Comment: A couple of commenters expressed concerns that an independent agent may not have sufficient knowledge about the needs of an

individual, and that providers who have longer histories with the individuals are better qualified to conduct evaluations and assessments and develop care plans and would improve individuals' access to the benefit. One indicated that independent agents may not have the capacity to follow-up with individuals who are hard to reach, such as individuals experiencing homelessness. Another indicated that we should allow service providers within supportive housing to complete assessments or it might unintentionally limit the availability of supportive housing for HCBS beneficiaries. They suggest that CMS engage independent agents in oversight activities to ensure individuals are made aware of all available options and that providers do not inappropriately advantage themselves.

Response: We recognize the importance of ensuring that the agents responsible for the evaluations, assessment, and person-centered service plans are trained in assessment of individual needs for HCBS and knowledgeable about best practices. That is why we included requirements at § 441.730(a) for states to define in writing standards for agents, and at § 441.730(c), that these qualifications 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. We further note that we understand that the process of developing 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.

Comment: Another commenter stated that CMS's proposal to remove providers from participating in assessments, evaluations, and plans of care does not appear required by the DRA and requested that CMS remove this prohibition on providers' ability to carry out these critical functions and deliver the needed services to their beneficiaries.

Response: This rule does not prevent providers from participating in these functions, but requires that an independent agent retains the final responsibility for the evaluation, assessment, and person-centered service plan functions. We understand that the process of developing 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. In order to meet the intent of the statute for standards that safeguard against conflict of interest standards, we are retaining these requirements as proposed.

Comment: Several commenters recommended that minimum safeguards/standards be prescribed in the regulation, including standards related to training, skills, and competency, with state flexibility to develop additional standards and CMS reviewing the state standards for approval. One recommended giving service providers and agencies rate incentives to partner with training providers and community colleges to ensure that the qualifications of the workforce meet the needs of their clients. Others recommended adding that agents must have current knowledge/training in evidence-based practices for assessment and evidence-based best practices to improve health and quality of life outcomes, person-centered planning, and informed decision making. Another recommended that CMS identify broad competency areas and then identify the specific skills associated with each of these competency areas. Another noted that individuals performing assessments will need to be sufficiently trained to assess cognitive impairment.

Response: Section 441.730(a) of the proposed rule would require states to define in writing standards for agents, and at § 441.730(c), that these qualifications 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. We agree with the commenters' suggestions and have added "cognitive" to § 441.730(c).

Comment: One commenter encouraged the addition of language that focuses on the qualifications, training and outcomes "of the case manager in the areas of case management, the populations they are serving, funding and resources available in their community, the offering of free choice of providers and service options and training and expectations regarding conflict-free case management."

Response: We note that we are not restricting the individuals or entities who can perform these administrative activities to case managers. We also note that conflict of interest requirements are found at § 441.730(b). We agree that knowledge of available resources, service options, and providers is not an element specifically captured in the

proposed regulation language, so we have added language to § 441.730(c).

Comment: A couple of commenters requested that CMS revise the regulation to provide that the required training of agents must include person-centered and family driven services planning, as well as participant-directed practices.

Response: We believe that this idea is already reflected for purposes in the broader phrase "and current knowledge of best practices to improve health and quality of life outcomes."

Comment: One commenter pointed out that evaluators should also obtain proper training and should be reflected in § 441.668(c).

Response: The independent evaluators determine whether or not an individual meets the eligibility requirements for the benefit, but unless they are also the same entity responsible for the independent assessment and plan of care development, we do not believe it would be reasonable to require that they meet these minimum training requirements that are appropriate minimum qualifications for agents responsible for independent assessment and person-centered service plan development (assessment of individuals whose physical or mental conditions trigger a potential need for HCBS and supports, and current knowledge of available resources, service options, providers, and best practices to improve health and quality of life outcomes).

10. Definition of Individual's Representative (§ 441.735) (Proposed § 441.671)

In § 441.671, we proposed to define the term "individual's representative" to encompass any party who 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 did not propose to regulate the relationship between an individual enrolled in the State plan HCBS benefit and his or her authorized representative, but noted that states should have policies to assess for abuse or excessive control and ensure that representatives conform to applicable state requirements. We noted 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.

General Comments: All commenters for this section agreed with this provision, and some additionally suggested some revision to the language as described in the comments below.

Comment: A couple of commenters recommended changing "family member" to "a parent support provider."

Response: The language in this phrase is statutory, from section 1915(i)(2) of the Act. The commenter did not provide any definition of this term or explanation. For these reasons, we are unable to accept this change as requested, but note that this provision at § 441.735(b) is not an exhaustive list.

Comment: Another commenter expressed that an individual's representative may not necessarily be the individual's guardian, but some other representative freely chosen by the individual and important to him or her.

Response: We agree and believe the language in the regulation supports this as an option to the individual.

Comment: We received many comments about the term "best interest." Most of these commenters requested that CMS substitute the term "substituted judgment" instead of "best interest." One cautioned that "best interests" may be a highly subjective assessment, and stated their belief that substantial deference should be established for the stated interests of the individual and the decisions of their chosen representative. Others referenced guidelines established by the National Guardianship Association (NGA), which indicate that substituted judgment is a principle of decision-making that promotes the self-determination of the beneficiary and that substitutes, as the guiding force in any surrogate decision made by the guardian, the decision the beneficiary themselves would make based on their own preferences and wishes. This process involves consultation with the individual and those important to the individual. If a substituted judgment is not available, guardians can implement a "best interest" principle, which considers all options and alternatives and bases the decision on what a reasonable person would do in the given situation.

Response: We agree with these commenters and have revised this section of the regulation, § 441.735(c), so that it now reads as follows:

"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 uses substituted judgment on behalf of the individual. State policies must address exceptions to using substituted judgment when the individual's wishes cannot be ascertained or when the individual's wishes would result in substantial harm to the

individual. States may not refuse to recognize 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 accordance with these policies or cannot perform the required functions. States must continue to meet the requirements regarding the person centered planning process at § 441.725 of the rule.”

Comment: We received one comment about state laws regarding guardianship and the jurisdiction of the courts, in which they stated that guardians are appointed by the court, not chosen by the individual.

Response: We believe this concept is captured with the use of the term “legal” prior to “guardian” in the language of the final regulation at § 441.735(a) which pertains to a legal guardian authorized under State law to represent the individual. We note that the provision at § 441.735(c) only applies to individuals specified at § 441.735(b) who are authorized under the policy of the State Medicaid agency to represent the individual.

Comment: A couple of commenters confirmed the importance of participants’ access to a representative option. One requested that CMS add “States should ensure that representatives conform to good practice concerning free choice of the individual, and assess for abuse or excessive control.” Another stated that supports providers (for example, consultants, support brokers) need to be appropriately trained on the participant direction paradigm to be prepared to successfully identify when a representative may be using “excessive control” as well as to enforce “free choice” of representatives.

Response: If by “free choice of the individual” the commenter means the individual’s free choice of providers, this Medicaid requirement at section 1902(a)(23) of the Act is not waived or disregarded under section 1915(i) of the Act and is not a subject of this rule. We believe that the proposed language broadly covers the other elements of this comment, and we will consider addressing this issue further in future guidance.

Comment: One commenter requested that the word “should” be replaced with “must” or “implement policies to.”

Response: The proposed and final regulation language does not contain the word “should.”

Comment: One commenter expressed the need for a representative to be identified by the participant after s/he is well informed of the program and his/her responsibilities. They further

commented that effective practices for identifying and choosing representatives should be shared with the participants during program orientation and as needed.

Response: We believe this would be an example of a good state practice, which we will consider for inclusion in future guidance.

Comment: One commenter stated that based on the general principles of participant direction, states should not require that individuals have representatives without prior attempts to train and support the participant.

Response: The purpose of this provision is not to require an individual to have a representative but it is to require states to allow the option for an individual to choose a representative for the purpose of participating in decisions related to the person’s care or well-being when the individual requires assistance in making such decisions, and to have policies for the process for authorization, the extent of decision-making authorized, and safeguards. We note that where a legal guardian, conservator, or other person has the sole authority under state law to make decisions related to the individual’s care, the state must comply with the decisions of the legal surrogate.

Comment: One commenter requested that the following language from the preamble of the proposed rule, or something similar, be added to the actual regulation text: “. . . process should still be focused on the individual requiring services, and that supports should be provided to allow the individual to meaningfully participate and direct the process to the maximum extent possible.”

Response: We have added the following to § 441.735(c) of this rule: “States must continue to meet the requirements regarding the person-centered planning process at Section 441.725 of this rule.”

11. Self-Directed Services (§ 441.740) (Proposed § 441.674)

Section 1915(i)(1)(G)(iii)(I) and (II) of the Act provides that states may offer enrolled individuals the option to self-direct some or all of the State Plan HCBS that they require. 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) of the Act 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) of the Act waivers in implementing self-direction in the State plan HCBS benefit, we anticipate that states will make use of their experience with section 1915(c) of the Act waivers to offer a similar pattern of self-directed opportunities with meaningful supports and effective protections.

Comment: Several commenters recommended that CMS include training as one aspect of employer-authority activities that self-directing beneficiaries may be allowed to exercise. A couple of commenters urged CMS to require states to offer training for individuals on selecting, hiring, supervising and firing service providers, in addition to service provider training.

Response: We agree with this recommendation and have added the following to the § 441.740(e)(3):

“Voluntary training on how to select, manage, and dismiss providers of State plan HCBS.”

We note that many states currently have existing training programs available that could potentially be leveraged or modified to meet such a requirement. Training programs should be able to meet the needs of individuals at varying levels of need with regard to selecting, managing, and dismissing providers. Consistent with the philosophy of self-direction, this training must be voluntary, and may not be a mandatory requirement for the individual to receive services under this option.

Comment: One commenter requested training for agents conducting evaluations, assessments, and service planning.

Response: Training for agents conducting evaluations, assessments, and person-centered service planning is a requirement that was stipulated under the proposed rule at § 441.668, provider qualifications, and remains unchanged in this final rule at § 441.730.

Comment: One commenter recommended that CMS consider requiring states to provide joint trainings for both consumers and providers, as they have resulted in improved services, better

communication and a stronger relationship.

Response: We believe that this would be more suited as one option that a state could put into practice to meet training requirements.

Comment: One commenter indicated that states should be provided guidance on elements that are important for participant direction assessment (for example, strengths, abilities, individual goals, need for a representative, capacity to self-direct with an eye for developing a support system to ensure success in self-directing, and risks).

Response: These elements are already required under § 441.725(b), pertaining to the person-centered service plan.

Comment: One commenter applauded CMS for their inclusion of participant direction support functions, stating that they are well documented by research and that successful participant direction opportunities are dependent on the appropriate execution of each of these support functions. The commenter requests that CMS describe within the rule the elements of each of these functions (as seen with the financial management services function).

Response: We appreciate the support of the commenter. Experience with section 1915(c) of the Act and other Medicaid HCBS authorities have been instrumental in demonstrating the importance of the availability of information, assistance, and support to participants who self-direct their HCBS. Since the purpose of this regulation is to stipulate the minimum requirements that states must meet for the section 1915(i) of the Act authority, we believe the commenter's request will be best suited as future sub-regulatory guidance/policy.

Comment: One commenter expressed appreciation of well-structured definitions for both employer authority and budget authority, and recommended an edit to the "employer authority" definition to ensure its consistency with existing best practices: replace the "or" in "the ability to select, manage, or dismiss providers of State plan HCBS" with an "and" since the ability to do all three functions is critical to the model.

Response: Since each of these functions is optional, and we want to ensure that the protections at § 441.740(c) are provided with selection of any of these optional functions, we are unable to adopt the commenter's recommended revision.

Comment: Several commenters requested revising the provisions related to budget authority in § 441.674(d)(5) to make it clear that self-directing individuals with budget authority may

be allowed to pay providers directly. Another commenter requested revision to § 441.674(e)(2)(iii) of the proposed rule to clarify that employer-related financial transactions, such as paying worker wages and taxes, may also be made for individuals with employer authority.

Response: Section 1915(i) of the Act does not give states the authority to allow participants to perform transactions or convey cash to the individual or representative. It does allow for budget authority to grant individuals control of expenditures. In addition, with sufficient state Medicaid agency process and oversight, states may choose to employ alternate methods to maximize participant autonomy within the parameters of the section 1915(i) of the Act authority.

Comment: One commenter requested that we add a requirement to § 441.674(b)(4) that "there are state procedures to ensure the continuity of services during the transition from self-direction to other models of service."

Response: We agree with this comment and have added additional language to the rule at § 441.740(b)(4).

Comment: One commenter requested that § 441.674(d) regarding budget authority require that the service plan specify the authority to be assumed by the individual, any limits to the authority, and specify parties responsible for functions outside of the authority to be assumed.

Response: The commenter's request is already addressed in the requirement as included in the proposed rule under § 441.674(b)(2), which we are finalizing at § 441.740(b)(2).

Comment: Section § 441.674(e)(2) regarding financial management supports should clarify that federal financial participation (FFP) is available for this service.

Response: States have the option of providing this type of activity as a Medicaid administrative activity or as a Medicaid service, as long as the activity meets Medicaid requirements. It is not necessary for this to be specified in the text of the regulation. We will explain these options in future guidance.

Comment: One commenter requested clarification to indicate that a state may provide for employer functions itself, or through a fiscal/employer agent or other state-contracted entity under the state's direction and control. They stated that it should also be clear that states have the option to offer these supports to individuals directly or through a public entity.

Response: States have the option of providing this type of activity as a Medicaid administrative activity or as a

Medicaid service, as long as the activity meets Medicaid requirements. We do not believe that this degree of specificity would be appropriate as a requirement under regulation text, but will be considered in the development of any future guidance.

Comment: Two commenters requested CMS to revise the requirement that states offer individual supports so that it includes peer-to-peer support and family-driven care.

Response: While we agree that these are important supports that states should consider making available to individuals, we do not believe that this degree of specificity would be appropriate as a requirement under regulation text. We will however, consider this in the future development of additional guidance.

Comment: Two commenters indicated that it is unclear what is meant by, and stated concerns about, the statement that evaluation results will lead to the determination of "ability to self-direct [both with and without specific supports]." One of these commenters expressed support of any evaluation criteria that encourages an individual to personally assess his/her interests and abilities to self-direct while not leading to professional decisions made in isolation based solely on the individual's disability, personal characteristics, or experiences. The other commenter stated the belief that, with appropriate supports, essentially all individuals are able to self-direct, using Michael Weymeyer's concept of the individual as causal agent in their life, and that it is hard to understand the purpose of determining the ability of someone to self-direct without supports. Both agree that a person-centered system that includes participant direction should be able to support people to make informed decisions pertaining to their care while providing the individualized support s/he needs to successfully self-direct.

Response: The purpose of inclusion of "without supports" in this paragraph is to be inclusive of the individual's option to not avail him/herself of the opportunity to use the self-directed supports that states are required to offer under this option, while also preserving the responsibility of states to ensure that the individual receives the needed services in accordance with his/her person-centered service plan.

Comment: One commenter stated that self-directed service plans should be aligned with the most integrated setting definition under the ADA and *Olmstead* and recommended additional language be added under § 441.674(b).

Response: This recommendation is already captured under § 441.725(b)(1), which pertains to all person-centered service plans.

Comment: One commenter expressed an opinion about the requirement in the proposed rule that the service plan indicate not only the services that will be self-directed, but also the “methods by which the individual will plan, direct, or control these services.” The commenter expressed that this language is dangerously vague, and as a result, may lead to specificity within the service plan that is not sensitive to the flexible and dynamic processes required for successful participant direction.

Response: This language is referring to participant preferences with regards to how they choose to self-direct their services, including employer and/or budget authority if elected by the state. More detail and requirements regarding these two authorities is specified under § 441.740(c) and (d).

Comment: One commenter stated the importance of individualized contingency plans as being well stated, and appropriate in the proposed regulation. Another stated that risk management techniques should not interfere with the right to self-direct and other choices and rights unless there is a documented, clear, concrete danger present. Another commenter indicated that it is important that participant direction philosophy inform any risk management techniques, which are required in the proposed rule to be listed in the service plan, with the participant leading the process and creating back-up plans unique to his/her needs. The commenter also supports a transparent individual budget development and monitoring process, but at the same time recognizes the importance of providing participants with accessible information that is not too overwhelming and easy to digest. They recommend that any tools for this purpose be simple and straight forward, making them accessible to all program participants.

Response: We appreciate and agree with these comments and will consider them for inclusion in future guidance.

Comment: One commenter indicated that states are using the self-directed option to save money, and that self-directed services are often reimbursed at a lower rate than agency-directed services for no clear reason, causing wages for workers in self-directed programs to be substantially lower than wages for agency-controlled workers.

Response: Self-directed provision of services provides the states with the option to give individuals the flexibility to negotiate preferred rates for services,

frequently with individuals that have a pre-existing relationship with the consumer, for example, a friend or neighbor. This may result in costs for services that are lower than comparable services provided by an agency. The rates selected by individuals who are self-directing may or may not include the administrative overhead that occurs when an agency employs individual workers to provide services.

Comment: Several commenters stated that self-direction as a delivery method and supports to participants to self-direct, should be required and not state options. Another stated that agency-based services should be available only for those who cannot manage self-direction (with supports) and have no authorized representative.

Response: Section 1915(i)(G)(iii) of the Act allows states the option to offer individual election for self-directed services. The statute does not include the authority for the Secretary to require that the services that states offer under section 1915(i) of the Act must be self-directed. For states that choose to offer individual election to self-direct their HCBS, states must make information and assistance available to those individuals to support their direction of services.

Comment: One commenter applauded the ability for states to allow participants to direct any or all of the State plan HCBS benefit, and stated the potential for confusion, unnecessary complexity, and limited control when states decide to limit the ability to self-direct to one specific service. They strongly recommended that states receive technical assistance and guidance on the benefits of participant direction and how to implement participant direction opportunities to the furthest extent possible, including providing access to an individual budget model.

Response: We appreciate these comments. We are available to provide guidance and assistance to states and encourage states to contact us with any such requests.

Comment: One commenter stated that the following statement is extremely vague and requires clarification:

“According to the proposed rule, individuals who choose to self-direct will be subject to the ‘same requirements’ as other enrollees in the State plan HCBS benefit.” They stated that it is important that any requirements created be sensitive to the participant direction philosophy and informed by evidence-based participant direction practices.

Response: This statement in the preamble was only stating that the other

requirements of section 1915(i) of the Act, such as eligibility, adjustment authority, independent evaluation and assessment, person-centered service plan, etc., are still requirements that must be applied for individuals who choose to self-direct their services. Additional requirements specific to the self-direction option were included in the proposed rule, and were based on our experience with section 1915(c) of the Act waivers and other Medicaid authorities in order to include a similar pattern of self-directed opportunities with meaningful supports and effective protections.

Comment: One commenter stated the assumption that states have the option to provide program participants with employer authority or budget authority (as opposed to requiring both), but indicated that they find the language in the proposed rule pertaining to this point vague.

Response: Section 441.740(b)(2) already specifies “and/or” to indicate this option.

Comment: One commenter, with a reminder that the proposed rule allows states to enter into a “co-employer” relationship with participants, stated that it is important to recognize that there is no one standard definition for “Agency with Choice,” leading to inconsistent application and monitoring of this model. The commenter strongly encouraged CMS, in collaboration with the Department of Labor and informed by existing state labor laws and stakeholders, to set standards for the “Agency with Choice” model that are reflective of the participant direction paradigm and the liabilities specific to this model.

Response: We appreciate this comment and will take it under consideration in the development of future guidance.

Comment: One commenter recommended that § 441.674(b) include a reference to § 441.674(e) requiring self-direction supports to be included in the service plan, since paragraph (e) is cross-referenced in other paragraphs, at § 441.674(c)(2) and § 441.674(d)(4).

Response: After consideration of this comment, we believe the inclusion of this requirement under both § 441.740(c)(2) and (d)(4) is repetitive and would be better placed under § 441.740(b) as a new paragraph (5). Therefore, we made this addition to § 441.740.

Comment: One commenter recommended that § 441.674(e) should explicitly include the requirement suggested in the preamble (77 Fed. Reg. 26373, first column) for an “independent advocate.”

Response: We are not adding this as a requirement to this final rule. However, we believe the availability of an independent advocate to assist the individual with the access to and oversight of their waiver services, including self-direction, is an important component of a strong self-directed system.

Comment: One commenter recommended that CMS explain, in § 441.674(a), that individuals should be encouraged to retain authority over all functions (budgeting, staffing, etc.), but that individuals could choose only to retain authority over specific functions. They also recommended that CMS add the term “, but not limited to,” after the term “including.”

Response: The purpose of § 441.740(a) is to specify the state option to offer the election for self-directing HCBS. The language that the commenter has suggested would not be appropriate for this regulation since it would not stipulate a state requirement. Regarding the second comment, we do not agree with leaving this open-ended, and since it is unclear what else would be self-directed in addition to amount, duration, scope, provider, and location of the HCBS, we are unable to make the suggested revision.

Comment: One commenter urges CMS to promote matching service registries as robust models of information and assistance as a way to assist participants with identifying and accessing independent providers.

Response: We appreciate this comment and will consider it for inclusion in future guidance.

12. State Plan HCBS Administration: State Responsibilities and Quality Improvement (§ 441.745) (Proposed § 441.677)

a. State Responsibilities

States are required to provide CMS annually 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 section 1915(i) of the Act benefit, specific services within the benefit, or both. Under § 441.745(a)(1)(ii), we specify 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 the proposed rule, states have a number of permitted methods to control utilization. We proposed that once an individual is found eligible and enrolled in the benefit, access to covered services can be limited on the basis of the needs-based criteria as evaluated by the independent assessment and incorporated into the 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.

b. Administration

We proposed 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 proposed 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 section 1915(i) of the Act 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 proposed 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 proposed

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 needs 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 covered 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 covered 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 proposed 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 proposed 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 person-centered service plan. To the extent that the state Medicaid agency delegates these functions to other entities, we proposed 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. Delegation of responsibilities by the state Medicaid agency must comply with the single state agency requirements of section 1902(a)(5) of the Act and § 431.10.

In § 441.677(a)(2)(v), we included 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 added regulatory language reflective of our guidance that section 1915(i) of the Act 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 indicated 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.

c. Quality Improvement Strategy

We proposed in § 441.677(b) requirements for quality assurance which states are required to meet under section 1915(i)(1)(H)(i) of the Act. We proposed 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 proposed 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 proposed 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 proposed 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.

Comment: A commenter stated that the proposed regulations would result in cut backs, loss of jobs, and subsequent loss of care for people who cannot survive without assistance with all their basic needs.

Response: These regulations explain requirements for a new provision that provides states with the option to add additional HCBS to their state plan. Since these regulations allow for new additional services, we do not see how this would result in the impact that the commenter suggests.

Comment: One commenter requested revision to § 441.677(a)(1)(iii) to add to the requirements advance written notice and the right to appeal denials.

Response: This provision of this rule refers to requirements at part 431, subpart E, which is not a subject of this regulation. However, since advance notice is a topic in part 431, subpart E, we have added "advance notice" to this regulation at § 441.745(a)(1)(iii).

Comment: One commenter stated the belief that operating different parts of the state plan under different rules would be burdensome to states, and opposition to § 441.677(a)(2)(v), which would impose rules for effective dates of state plan amendments that differ from current state plan amendment policy.

Response: As explained in the preamble to the rule, and as required at § 441.745(a)(2)(v), state plan amendments which result in a reduction of eligibility or services to section 1915(i) of the Act participants must be submitted with a prospective, rather than retroactive, effective date. While this requirement differs from current SPA procedures, it is consistent with section 1915(c) of the Act submissions. And as section 1915(i) of the Act allows states to add services under section 1915(c)(4)(B) of the Act, we are requiring states submitting section 1915(i) of the Act SPAs to follow the same requirements for those section 1915(c) services outlined in CMS CMCS Bulletin dated April 16, 2012, regarding actions that result in reductions. If a state submits an amendment or renewal to an approved SPA that includes reductions, the reductions would be effective for the remainder of the approved period (once approved), but cannot be applied retroactively to the SPA action's approval date.

Comment: One commenter agreed that retroactive amendments should not be available for elimination or reductions in services, but does not consider changes to provider qualifications or rate methodologies to be substantive changes. The commenter stated that defining substantive change to include changes to rate methodology or provider

requirements prevents states from acting quickly and efficiently to address legislative direction or changing state needs.

Response: We disagree. Since changes to provider qualifications and/or rate methodologies could negatively impact provider availability and result in a reduction of services to a participant, we are requiring a state to submit such SPAs, and receive CMS approval, prior to implementing any changes of this nature.

Comment: One commenter stated disagreement with § 441.677(a)(2)(vi), limiting approval period for SPAs with targeting to 5 years and requiring submission of renewals 180 days in advance of expiration, and indicated that these provisions seem contrary to requirements for services under the state plan and are like the creation of a new waiver authority.

Response: Section 1915(i)(7)(B) of the Act specifies that when a state elects to target the provision of State plan HCBS to specific populations, that this election will be for a period of 5 years. Therefore, since the 5 year period of operation with the option to renew is a statutory requirement, we are unable to change this provision. Section 1915(i)(7)(C) of the Act permits states to renew for additional 5 year terms if we determine prior to the beginning of each renewal period that the state has adhered to section 1915(i) of the Act requirements and that the state has met its objectives with respect to quality improvement and individual participant outcomes. In order for us to determine that these requirements are met, states must submit renewal SPAs at least 180 days in advance of expiration in order to allow us sufficient time to review. The need for this review timeframe is consistent with our experience under section 1915(c) of the Act renewals.

Comment: A few commenters recommended that CMS add to the periods of approval requirement for states that elect to target specific populations at § 441.677(a)(2)(vi), so that it specifically includes the statutory renewal requirement at section 1915(i)(7)(c)(ii) to meet "the state's objectives with respect to quality improvement and beneficiary outcomes." They stressed the importance of quality improvement and good beneficiary outcomes, and indicated that a State plan HCBS benefit should not be renewed if it cannot meet such criteria.

Response: We agree with these commenters and have revised § 441.745(a)(2)(vi) accordingly.

Comment: We received many comments regarding the option for

presumptive payment at § 441.677(a)(2)(i), as noted below:

□ “CMS should clarify that home and community-based services furnished to individuals in the 3 months prior to a final determination of eligibility are also eligible for FFP once eligibility has been confirmed.”

□ “Presumptive Eligibility is confusing, and should not be limited to evaluations and assessment; however, if someone needed medical data to prove eligibility including disability determination, those services should be provided.”

□ “. . . encourages CMS to take this authority one step further to permit, on a time limited basis, federal financial participation for State plan HCBS furnished to consumers who are presumptively enrolled.”

□ “Please clarify that the availability of Federal financial participation for medically necessary State plan HCBS benefit payments under this option when the individual beneficiary has been found not to be eligible, allows states to hold the beneficiary harmless for the state financial portion.”

□ “We strongly encourage CMS to use its discretion, if possible, to include payment for the HCBS which a state believes the individual would be eligible to receive. This expanded authority is especially important in emergency situations, such as avoiding institutional care.”

□ “We support the creation of flexibility for states to provide HCBS based on presumed eligibility for assessment due to the fact that many disabilities occur rather suddenly, and because there is no guarantee as to when informal support networks may give out or end.”

□ “We commend the inclusion of authority in § 441.677(a)(2) to allow presumptive payment for HCBS evaluations and assessments, and the provision to allow FFP in the cases where presumptive payment was made based on good faith.”

Response: We appreciate these comments. Section 1915(i)(1)(f) 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. However, eligibility for services under section 1915(i) of the Act is not the same as an eligibility determination 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. Therefore, for clarity, we refer to this limited option as “presumptive

payment.” Since individuals not eligible for Medicaid may not receive State plan HCBS, 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. Payment for State plan HCBS is available once the individual is determined eligible, and not prior to that point. However, FFP would be available for both 1905(a) services and administrative costs incurred for evaluation and assessment activities for individuals who are already eligible for Medicaid. During any such 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.

Comment: One commenter requested clarification as to how states must ensure people are able to move from a needs-based criteria benefits package to benefits that require a level of care. They also requested guidance to states as to how they will monitor for unexpected changes in services and support needs, which might result in the need for services associated with an institutional level of care. They asked that we provide guidance on time lines and processes for conducting level of care assessments as well as for enrolling individuals in a program or benefit that requires a level of care that will best meet their needs.

Response: In order to receive approval of a section 1915(i) of the Act SPA, states must establish that the institutional level of care is based on needs-based criteria that are more stringent than the proposed section 1915(i) of the Act needs-based criteria. Although states are required to establish minimum needs-based criteria that an individual would have to meet in order to receive section 1915(i) benefits, the statute did not establish a maximum or ceiling. Therefore, states are permitted to allow access to those who meet institutional needs-based eligibility criteria. We also note that § 441.715(e) requires states to re-evaluate and re-assess individuals receiving the State plan HCBS benefit at least every 12 months, and when the individual’s circumstances or needs change significantly or at the request of the individual.

Comment: In § 441.677 (a)(1)(i), no details are provided about how states would “project” HCBS enrollment. This is a critical calculation because states might have an incentive to understate

projections to gain the discretion associated with over-enrollment.

Response: We do not believe it is necessary to include such details in the regulation. We note that this paragraph also requires states to report the actual numbers of unduplicated individuals enrolled in the State plan HCBS benefit on an annual basis.

Comment: One commenter commended CMS on the inclusion of § 441.677(a)(1)(ii)(C) prohibiting the state from limiting access to HCBS based on income, cost, or location.

Response: We appreciate the support of the commenter regarding the inclusion of this requirement which is now at § 441.745(a)(1)(ii)(C).

Comment: One commenter recommended that CMS require that states make publicly available targeting, phase-in, and quality improvement plans, including by posting on public Web sites.

Response: At this time, we do not post state plans on our Web site. We are working on a project to make approved state plans publicly available. We encourage states to provide for effective public engagement in all of their Medicaid program activities, and states are required to provide 60 day public notice when states change reimbursement methodology or revise CMS approved section 1915(i) of the Act needs-based criteria.

Comment: A couple of commenters noted that § 441.677(a)(1)(ii)(B) incorrectly cross-references § 441.656(b)(2), which should be changed to § 441.656(e)(2).

Response: We appreciate this comment and have made a revision to this final rule at § 441.745(a)(1)(ii)(B) with the corrected cross-reference to § 441.710(e)(2).

Comment: One commenter expressed that CMS should consider requiring states to report on quality measures related to home and community-based settings and community integration for HCBS provided under sections 1915(k), 1915(c), and 1915(i) of the Act.

Response: We agree. States are required to demonstrate at the time of approval that they have quality measures in place with a monitoring plan, must include them in the SPA or waiver, and will report to CMS at a frequency to be determined by CMS or upon request by CMS.

Comment: One commenter emphasized the important role that non-medical quality measures play in the meaningful evaluation of HCBS. The commenter stated that quality measures should reflect the ultimate mandate resulting from the *Olmstead* decision and the importance of quality of life,

independence, and community integration. The commenter further stated that for those who choose participant direction, measures sensitive to this mode of service delivery need to be implemented, including measures that recognize the role of participants as decision makers and evaluators of the quality of services and supports they receive.

Response: We recognize the importance of non-medical quality measures and will incorporate these areas (quality of life, community integration and factors specific to participant-directed services) in development of future guidance.

Comment: One commenter noted that due to reported abuses in some states, it must be clear that observation of actual conditions, through on-site monitoring and review and by interviews with service recipients and their advocates and family members, will be the method used to measure compliance; and not simply by reviewing policies, procedures, or assertions. The commenter further stated that it is crucial that the final rule contain the details so CMS has the legal authority to prevent creation of new loopholes or allow for misinterpretation.

Response: There may be multiple methods of monitoring health and welfare in a quality monitoring plan. States are required by the regulation to have a quality improvement strategy consisting of a continuous quality improvement process, and outcome measures for program performance, quality of care, and individual experience.

Comment: A commenter inquired about the applicability of the state assurances for HCBS waiver programs required by § 441.302, particularly § 441.302(a) Health and Welfare, noting that there is equivalent vulnerability potential for individual beneficiaries receiving HCBS under state plan authority as under section 1915(c) of the Act waiver authority.

Response: The regulations noted by this commenter specifically apply to section 1915(c) of the Act home and community-based waiver services and do not specifically apply to section 1915(i) of the Act State plan HCBS. The regulations that implement section 1915(i)(1)(H)(i) of the Act, which requires states to ensure that the provision of HCBS meets federal and state guidelines for quality assurance, can be found in § 441.745(b) and require that states have a quality improvement strategy consisting of a continuous quality improvement process, and outcome measures for program

performance, quality of care, and individual experience.

Comment: One commenter encouraged CMS to require states to submit their quality improvement strategy to CMS at a specific frequency and consider making such information public.

Response: We have required through these regulations that states make this information available to CMS at a frequency determined by CMS or upon the request of CMS. We will consider further specification of these requirements in the development of future guidance.

Comment: One commenter recommended revision to § 441.677(b)(1)(ii) to include the following language from the preamble in the text of the final rule: “Be evidence-based, and include outcome measures for program performance, quality of care, and individual experience as determined by the Secretary.”

Response: This recommendation has been adopted in this final rule at § 441.745(b)(1)(ii).

Comment: One commenter noted that in order to determine if there is a sufficient infrastructure to effectively implement HCBS, it is necessary for states to gather direct-care worker data such as numbers of direct service workers, gaps in services data, stability of workforce, and average compensation of workers.

Response: We agree that this would be useful data for states to consider in the development of a State plan HCBS benefit, but we have not required specific measures, such as the one recommended by the commenter.

Comment: One commenter further encouraged CMS to consider how quality principles/requirements would work within the management of long term services and supports and its impact on network adequacy.

Response: We appreciate the commenter’s recommendation and will take this under consideration as we develop future guidance.

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

Regarding the proposed provider payment reassignment provision, we received a total of 7 timely items of correspondence from home care provider representatives and other professional associations, state Medicaid directors, non-profit organizations, and other individuals. These comments ranged from general support for the proposed provision, to specific questions and detailed comments and recommendations regarding the proposed changes. A

summary of the public comments and our responses are set forth below.

The proposed rule included a provision, retained in this final rule, that will allow states to enter into third party payment arrangements on behalf of individual practitioners for health and welfare benefit contributions, training costs, and other costs customary for employees.

Comment: Several commenters expressed support for the proposed provision. Two state Medicaid agency directors appreciate the clarification that third party payments on behalf of certain providers are allowed for customary benefits. That ability, they recommend, is essential and cost-effective for a large group of individual providers of personal care.

Response: We appreciate the commenters’ support for the proposed provision. 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 personal care services, suffer from especially high rates of turnover and low levels of participation. We believe the proposed provider payment reassignment provision retained in the final rule will provide to states additional tools to help foster a stable and high performing workforce.

Comment: One commenter stated that authorizing 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 aligns with essential elements that they advocate for quality direct-care jobs. They stated their belief that this will support state efforts to expand and improve consumer employment and direction of in-home personal care workers. They further stated that workers need affordable health insurance, other family-supportive benefits, and excellent training that helps each worker develop and hone all skills—both technical and relational—necessary to support long-term care consumers in order to ensure that all direct-care workers are able to provide the highest-quality care to all long-term care consumers. They believe that for consumer-directed home care workers, it is even more vital that states assume some of the human resources functions of typical employers.

Response: We appreciate the commenter’s support for the proposed provision and agree with its potential to improve both the stability and the skills of the health care provider workforce.

The payment arrangements that we are permitting will enhance state options to provide practitioners with benefits that improve their ability to function as health care professionals. For the classes of practitioners for whom the state is the only or primary payer, these payment arrangements are an efficient and effective method for ensuring that the workforce has health and welfare benefits and adequate training for their functioning.

Comment: One commenter stated that it will be essential for CMS, states, advocates, program participants, and organizations to understand how this proposed rule is appropriately applied within a participant direction model. The proposed provision, they suggested, should by no means be interpreted to allow for restrictions on participants' decisions pertaining to what s/he feels is critical to the managing of workers. In their own training, program participants should be informed of the benefits for which workers are eligible to ensure informed decisions are made. They urged that any additional deductions should be paid for with increased funding for the program rather than be paid directly from individuals' budgets already allocated to needed services and supports.

Response: Direct payment of funds by states to third parties on behalf of practitioners, to ensure benefits that support those practitioners and provide skills training, may help ensure that beneficiaries have greater access to such practitioners and higher quality services. In addition, if a state elects to withhold certain payments from practitioners, as the proposed provision would allow, and forwards those amounts to a third party on behalf of that practitioner for health and welfare contributions, training programs, or in support of other employee benefits, there will not necessarily be any impact on program budgets. This rule will not require any change in state funding to the extent that practitioner rates already factored in the costs of benefits and skills training. This rule will simply provide flexibility for states to fund such costs directly and ensure uniform access to benefits and skills training for practitioners. Indeed, there may be cost savings resulting from the collective purchase of such benefits and greater workforce stability.

Comment: One commenter supports CMS' objective of clarifying the prohibition on reassignment in section 1902(a)(32) of the Act to ensure that it is limited to its intended application and that it does not have any unintended adverse impact on important state Medicaid operations.

They suggested that states have long sought this clarification primarily in the context of state efforts to expand and improve programs that maximize consumer choice and independence and allow individuals to receive long term care services and supports in their homes and communities. They stated that the health care providers who assist these individuals are considered independent service practitioners both due to their relationship to the state and the consumer, and as a result face barriers including a lack of access to benefits and training. It makes sense, therefore, for states to be able to make "employer-like payments from the Medicaid service fee to fulfill employer-like functions" that overcome these employment barriers.

Response: CMS appreciates the commenter's support for the proposed provision and agrees that for the classes of practitioners for whom the state is the sole or primary payer, and has many attributes of an employer, the state should be afforded flexibilities to help ensure a stable, high performing workforce.

Comment: One commenter indicated that as a future nurse practitioner, she believes the application of this proposed provision is timely and she believes it will support state efforts to claim "excess provider payments that are not directly going to the provider but could be used to advance statewide practice from a global perspective."

Response: We appreciate the commenter's support for the proposed provision. However, we would note that the proposed provider payment reassignment provision does not involve "excess provider payments". Rather, as in the proposed rule, the final rule will offer states flexibility in determining appropriate costs to consider in their development of payment rate methodologies to ensure adequate training, health and welfare benefits, and other benefits customary for employees within the development of that rate. States will be permitted to directly pay third parties for health and welfare benefits, training, and other employee benefit costs. These amounts would not be retained by the state, but would be paid on behalf of the practitioner for the stated purpose. In fact, we believe that direct payment of funds to third parties on behalf of the practitioner may be viewed as advantageous by the practitioner insofar as they have increased opportunities for training. 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.

Comment: One commenter noted that, using the proposed provision, Medicaid can leverage its dominant role and help stabilize the direct care workforce. Specifically, the commenter noted that by encouraging Medicaid to directly pay practitioners for health and welfare benefit costs, training, or other benefits customary for employees, job quality will improve leading to improving recruitment and retention of skilled direct-care workers and better quality care. The commenter also recommended that CMS provide states with the appropriate technical assistance in order to assist them in adequately conducting needs assessments of their own direct-care workforce.

Response: We agree that states that voluntarily elect to utilize the proposed provider payment reassignment provision may help improve their own health care provider workforce. We also agree with the need for states to receive adequate technical assistance from us in order to implement the provision. States with questions regarding the provision are encouraged to contact their Regional Office for further guidance.

Comment: One state asked if the third parties to whom withheld funds are provided would be subject to the provisions of part 455, subpart E, Provider Screening and Enrollment.

Response: No. If the state elects to reassign provider payments for health and welfare costs, training expenses, or other employee benefits, the third party to whom those payments are assigned would be the recipient of such funds, but not the provider of record and hence not subject to provider qualification requirements. The amounts paid to a third party would be on behalf of the individual practitioner.

Comment: One commenter seeks clarification as to what would constitute a health and welfare benefit contribution. Specifically, one state would like to know if this would include amounts for paid time off for personal care attendants.

Response: The proposed change, retained in the final rule, permits each state the option to elect such payment arrangements to the extent that the state determines that they are related to benefits such as health care, skills training and other benefits customary for employees. States will need to review their individual circumstances and workforce needs to determine if the measures are related to such benefits, and would help serve program objectives such as to ensure a stable, high performing workforce. We do not wish to prescribe the types of benefits

the state might wish to include in its definition of health and welfare benefits, such as paid time off for personal care attendants. As in the proposed rule, the final rule offers states flexibility in determining appropriate aspects to consider in their development of payment rate methodologies to ensure adequate training, health care, and other employee benefits for practitioners, as defined by the state.

Comment: One commenter requested a modification to the proposed regulatory text for the provider payment reassignment provision to avoid a possible misunderstanding as to its coverage. Specifically, the commenter recommended a change to clarify that it is applicable to providers for whom the main source of service revenue is the Medicaid program. As proposed, the language states that the provider payment reassignment exception is “[in] the case of practitioners for which the Medicaid program is the primary source of revenue . . .” Without such clarifying language, the commenter recommends, a state may not be able to make deductions for health care, training, and other benefits that it provides for individuals who operate adult foster care homes in their residences. Since the consumer pays the provider for room and board in that instance, the provider’s primary source of revenue may not be considered to be the Medicaid program.

Response: We have clarified the language in the final rule by specifying that the state must be the primary source of service revenue for the practitioner. The proposed regulatory text would permit states to make payment to third parties for provider benefits when the state is operating in the role of the provider’s employer (even if the state is not the employer for other purposes). As clarified, the text will provide flexibility for a state to look at revenue only related to services furnished by the practitioner, rather than revenue related to shelter and food costs. We believe the proposed regulatory text, which we are retaining, provides the necessary latitude for states to determine whether it is acting in the role of an employer for a particular class of practitioners.

III. Home and Community-Based Services (HCBS) Waivers (Section 1915(c) of the Act)

A. Background

Section 1915(c) of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to waive certain Medicaid statutory requirements so that a state may offer Home and

Community-Based Services (HCBS) to state-specified group(s) of Medicaid beneficiaries who otherwise would require services at an institutional level of care. This provision was added to the Act by the Omnibus Budget and Reconciliation Act of 1981 (Pub. L. 97–35, enacted August 13, 1981) (OBRA’81) (with a number of subsequent amendments). Regulations were published to effectuate this statutory provision, with final regulations issued on July 25, 1994 (59 FR 37719). In the June 22, 2009 *Federal Register* (74 FR 29453), we published the Medicaid Program; Home and Community-Based Services (HCBS) advance notice of proposed rulemaking (ANPRM) that proposed to initiate rulemaking on a number of areas within the section 1915(c) of the Act program. In the proposed rule published on April 15, 2011 (76 FR 21311–21317), we discussed the comments relating to questions posed by the ANPRM, which are addressed in this final rule. We included proposed language for settings in which HCBS could be provided to elicit further comments on this issue in the section 1915(c) of the Act proposed rule, in the section 1915(k) of the Act proposed rule published on February 25, 2011 and also in the section 1915(i) of the Act proposed rule published on May 3, 2012 as we recognize the need for a consistent definition of home and community-based settings. It is our goal to align the final rule language pertaining to home and community-based setting across the sections 1915(c), 1915(i) and 1915(k) of the Act Medicaid HCBS authorities. We further sought to use this opportunity to clarify requirements regarding timing of amendments and public input requirements when states propose modifications to HCBS waiver programs and service rates, and strategies available to CMS to ensure state compliance with the requirements of section 1915(c) of the Act.

We have earlier explained our purpose for proposing definitions regarding home and community-based settings (see discussion under section II.A. of this rule).

We believe that these final changes will have numerous benefits for individuals and states alike. In addition to addressing individual and stakeholder input, these changes will improve HCBS waiver programs and support beneficiaries by enabling services to be planned and delivered in a manner driven by individual needs rather than diagnosis. These changes will enable states to realize administrative and program design simplification, as well as improve

efficiency of operation. The changes related to clarification of HCBS settings will maximize the opportunities for waiver participants to have access to the benefits of community living and to receive services in the most integrated setting, and will effectuate the law’s intention for Medicaid home and community-based services to provide alternatives to services provided in institutions.

B. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

On April 15, 2011, we published a proposed rule (76 FR 21311) entitled, “Medicaid Program: Home and Community-Based Services (HCBS) Waivers” which proposed revising the regulations implementing Medicaid home and community-based services under section 1915(c) of the Act in several key policy areas. First, the proposed rule provides states the option to combine the existing three waiver targeting groups as identified in § 441.301. In addition, we proposed changes to the HCBS waiver provisions to convey requirements regarding person-centered service plans, characteristics of settings that are, as well as are not, home and community-based, to clarify the timing of amendments and public input requirements when states propose modifications to HCBS waiver programs and service rates, and to describe the additional strategies available to us to ensure state compliance with the statutory provisions of section 1915(c) of the Act.

We received a total of 1653 comments from State Medicaid agencies, advocacy groups, health care providers, employers, health insurers, and health care associations. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding the proposed changes.

Brief summaries of each proposed provision, a summary of the public comments we received (with the exception of specific comments on the paperwork burden or the economic impact analysis), and our responses to the comments are as follows.

The following summarizes a few general comments received regarding the notice of proposed rulemaking and also comments regarding issues not contained in specific provisions. We appreciate and thank the commenters for these various remarks. We realize these commenters raise important considerations in support of persons receiving Medicaid HCBS living in community settings, in integrated

settings, and working in jobs with meaningful wages. Since these important comments did not address any specific regulatory provisions in the proposed rule, there is no need to respond to them further in the final rule:

Comment: We received many comments supporting the proposed policies in the proposed rule, as well as some comments expressing concerns about the various aspects of the rule.

Response: We appreciate the feedback received on the proposed rule and have relied heavily on the insights provided by states, advocacy groups, consumers and health care providers. We appreciate the acknowledgement and support of the policies.

Comment: We received several comments expressing concern about stakeholder input with respect to these rules.

Response: We recognized the need for a diversity of stakeholder input. Thus, in the June 22, 2009 **Federal Register** (74 FR 29453), we released an advance notice of proposed rulemaking that proposed to initiate rulemaking on a number of areas within the section 1915(c) of the Act program and to solicit diverse comment. Additionally, after we published the proposed rule on April 15, 2011 (76 FR 21311), we continued to meet with stakeholders that included advocacy groups, states, other federal agencies, provider groups and assisted living groups as we developed this rule.

We plan to continue to communicate with states and build upon state experience as we work with states to implement new policies and program changes as a means of ensuring a successful partnership between states and federal government. In addition, we will provide technical assistance and support to states. We encourage states to share across states as implementation continues. The public comments we receive will inform the development of future operational guidance and tools that will be designed to support state implementation efforts.

1. Contents of Request for a Waiver (§ 441.301)

a. Person-Centered Planning Process § 441.301(c)(1) (Proposed § 441301(b)(1)(i)(A))

The provisions of this final rule will apply to all states offering Medicaid HCBS waivers under section 1915(c) of the Act. Comments were supportive of our interest in setting forth requirements regarding person-centered service and support plans that reflect what is important to the individual. The final revisions to § 441.301(c)(1) (proposed § 441.301(b)(1)(i)(A)) will require that a

written services and support plan be based on the person-centered approach. This provision includes minimum requirements for this approach.

At § 441.301(b)(1)(i)(A) we proposed that a state request for a waiver must include explanation of how the state will use a person-centered process to develop a written services and support plan, subject to approval by the Medicaid agency. We received 286 comments about person-centered planning, most indicating how important it is to individuals that HCBS are provided in a manner that supports their values and preferences, rather than to satisfy an impersonal or provider-centered plan of care. In the comments immediately below we outline the suggestions that do not directly affect the regulatory language, and indicate in some cases where we will consider these ideas in developing future guidance. Comments that pertain to the proposed regulation language will be considered in more detail, under the corresponding section of proposed text.

Comment: Many of the comments had to do with effective methods for conducting an individual person-centered planning meeting. While some commenters seemed to favor requiring certain features, a variety of commenters made the opposite general point, cautioning that too many or overly specific requirements would cause the process to become bureaucratic instead of personal. Comments that specific proposed provisions are too prescriptive are noted in those sections below. A few commenters agreed with the concept, but not the language of the proposed person-centered planning rule. They suggested replacing the entire person-centered planning section with the language “contemporary, promising practices that result in consumers having control over the services, resources, and planning of their lives.” Finally a few commenters believe that the proposed changes implement a “one size fits all” ideology.

Response: States administer Medicaid and have flexibility in how federal Medicaid requirements are implemented. Therefore, the language we are including in the final rule expresses what must occur rather than how. The federal regulations set the requirements and minimum standards for an activity. We may issue, as needed, additional guidance to states to assist in the interpretation and implementation of the rule.

Comment: Some commenters requested general clarification of terms and illustration by example. Specifically, commenters presented questions around how person-centered

planning is to be implemented and whether any substantive rights are established for the individual.

Response: Examples and other explanations are generally included in the preamble to a notice of proposed or final rulemaking rather than in the regulation text. The commenter is correct that beyond the requirements in subparagraph (A) we do not specify how the planning process is to be implemented, for the reasons given immediately above. The commenter did not specify the particular rights of concern, so we cannot respond specifically to that issue. We consider the requirements outlined here to confer to individuals the right to a person-centered service plan, and a planning process, that meets these requirements. Individuals also have other rights under different authorities, which do not rely on this regulation. For example, civil rights against various forms of discrimination are protected under the ADA and elsewhere. CMS regularly works with the HHS Office for Civil Rights, Department of Justice (DOJ), and others to assure that we address civil rights issues as they bear on Medicaid requirements.

Comment: Many and varied commenters suggested that CMS make person-centered planning requirements consistent across all the authorities in which HCBS may be offered, such as the new Community First Choice program and the State Plan HCBS benefit. Specific language from proposed rules for those authorities was recommended.

Response: We agree that person-centered planning, as well as other HCBS requirements, should be consistent across authorities. In response to comments, proposed rules for some HCBS authorities have been published in the last several years, reflecting development in the concept of person-centered planning. We are working to bring all rules into harmony. We do point out that rules reflect the nature of the service—for example, planning for Community First Choice involves the plan for that particular service, and may not involve some of the program elements of a section 1915(c) of the Act HCBS waiver. We will endeavor to make the requirements parallel across authorities; however, they may not be identical due to some statutory differences.

Comment: A variety of commenters requested that the planning process consider the needs of individuals more than satisfying regulations or “paper-completion.” Many asked that the regulation focus on outcomes, not process.

Response: We agree that the planning process should not be about filling out forms. The final rule requires actions and outcomes that result in a very active process and an individualized plan that is not focused on paper completion. We also 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.

Comment: A commenter believes that these requirements will be very expensive for states to implement because of added staff and IT system costs. The requirements should take into account states' current budget problems.

Response: States are currently required to develop a plan of care sufficient to meet HCBS waiver participants' assessed needs for health and welfare. We do not believe the provisions in these regulations will significantly increase burden and note that investment in effective information technology, with federal financial participation, will increase efficiency.

In § 441.301(b)(1)(i)(A)(1) through (7), we proposed requirements for the Person-Centered Planning Process. Following are general comments we received on these requirements.

Comment: Several commenters objected to the term "plan of care," which they believe dismisses active person controlled service planning, and would prefer something about outcomes.

Response: The regulatory text reads, ". . . a written person-centered service plan (also called plan of care) that is based on a person-centered approach. . . ." The term plan of care is widely used, and reflected in waiver application documents. We indicated parenthetically that we are not referring to another separate process, but to that function we have until now called plan of care. While we do not agree that either term necessarily implies lack of individual control, we agree that "person-centered service plan" is superior because it is less medical in connotation and conveys that it is a plan for long term services and supports and it is developed with a person-centered process. We will change the term "plan of care" to "person-centered service plan." Also, as noted in more specific comments below, many commenters wanted stronger language about the individual leading the process. We believe the phrase "led by the individual" clearly indicates that the individual is leading the process; however, we have further revised the language to read "led by the individual

receiving services and supports" instead of "led by the individual receiving services." Throughout the rest of the section, we will change any references to "services" or "supports" to "services and supports."

Comment: Some commenters objected to mandating person-centered planning on two grounds: some individuals may not want it, and some individuals may not be able to do it. They believe that CMS was assuming both interest and ability would be present in all HCBS participants. Some commenters listed specific disabilities they believe limit cognitive or expressive ability to such an extent that the individual could not lead the process.

Response: With regard to the issue of choice, the regulation language does not require individuals to be more involved than they choose to be in their own planning processes. Individuals may decline to participate in the process if they so choose. Regarding the issue of ability, we noted that commensurate with the level of need of the individual, the person-centered service plan must reflect the service and support needs as identified through a person-centered functional assessment. Individuals may select another person(s) to assist or represent them in the process. In addition, where state law confers decision-making authority to a legal representative, such as a guardian, that individual may direct the person-centered planning process on behalf of the individual.

Following are the comments we received on § 441.301(b)(1)(i)(A)(1) of the proposed rule, which is § 441.301(c)(1)(i) of the final rule.

Comment: Quite a few commenters urged that the individual be allowed to choose who attends the meeting. Many stated that a person-centered service plan should provide freedom from unwanted intrusion in preferences and choices which could be from family, providers and professionals, or others. In other words, the individuals should have "veto power."

Response: We believe the language in the final rule clearly indicates that individuals are allowed to choose who does or does not attend the meeting; we are therefore retaining the proposed language.

Comment: Most of the comments about assuring that certain persons could be present concerned the role of guardians and legal representatives or chosen surrogates. Some wanted these terms defined and roles specified, especially "legal" representative and attorneys. Others wanted to be sure that the rule allows for representatives who are not a legally designated

representative, but might be a family member, friend, advocate, or other trusted person chosen by the individual. Another asked for a statement that a public guardian may not act as the designated representative due to the inherent unavoidable conflict of interest. Several commenters believed that the participation of various surrogates would result in them, not the individual, leading the planning process. A few also asserted that parental and guardian authority prevents abuses by professionals in the person-centered planning (PCP) process. A few commenters believed that the proposed rule reduces the authority of a parent or guardian in the PCP process, as the Medicaid manual previously entitled them. Several other very specific suggestions were made for requirements applicable to representatives.

Response: Our omission of explicit mention of representatives and other surrogates was not intentional and did not signal any intention to exclude them from among those whom individuals may choose to include in planning. Any references in this rule to "individuals" include the role of the individual's representative. We are aware of the essential role that representatives, guardians, and family members play in the lives of some individuals with receiving Medicaid HCBS. We are also aware of the published literature on the problem and conflicts of interest that occur, particularly with publicly appointed guardians in some jurisdictions. We proposed in § 441.301(b)(1)(i)(A)(5) a process for identifying and resolving conflicts of interest. We do not agree with those who expressed the belief that guardians would lead the planning process, instead of the individual. Though we recognize that some individuals without receptive or expressive communication depend on others to determine and articulate their needs, we will continue to speak of the individual as being in the center. Therefore, we have revised the rule to clarify the expectation that the individual will lead the planning process where possible and that the legal representative should have a participatory role, as needed and as defined by the individual, unless state law confers decision-making authority to the legal representative. We note that the term "individual's representative" is also defined under 1915(i) State plan HCBS regulations at § 441.735 of this rule, and further note that this rule does not abridge the legal authority of a parent or legal guardian.

Comment: Two commenters stated that CMS appears to attempt to regulate

unpaid family members and friendly volunteers by including them in the rule. Another concern is that including lay persons could violate confidentiality protections for the individual.

Response: We do not agree that the rule inadvertently regulates unpaid participants in the planning process in a general or undesirable manner. Rather, we intend that individuals have a meaningful choice of who can assist them in the planning process. We also see no reason to believe that states will relax their responsibility to protect client confidentiality in this process. The individual chooses who participates in the planning process, and thus retains direct control over who has access to private information.

Following are the comments we received on § 441.301(b)(1)(i)(A)(2), which is now § 441.301(c)(1)(ii) of the final rule.

Comment: Commenters pointed out that the proposed language is ambiguous. Several commenters recognized the intent of the proposed regulation to strengthen the person-centered service plan development process, but were concerned that the language undermines the progress made to empower people with disabilities in their planning process. Commenters expressed concern that playing a “meaningful role” is not the same thing as authority for decision making. Several comments indicated a belief that at least some HCBS participants cannot lead or even contribute to the service plan; several specifically mentioned people with intellectual disabilities or dementia. A few suggested specific supports, such as decision making tools and communications support.

Response: We do not intend a shift from the individual directing the process. We agree that the language should be clarified. “Meaningful” is a subjective standard. We will clarify that the person-centered planning process 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. We believe the language “to the maximum extent possible” reflects the level at which the individual desires or is able to participate. We believe that with skillful facilitation, individuals can express themselves to their fullest extent.

Many commenters urged us to favor empowering the individual; others urged empowering those who believe they have the best insight into the individual’s needs and wishes. The regulation does not put these interests in competition. This final rule requires

a process that puts the individual in the center, driving the process to the extent feasible, and recognizes the other persons’ insights into the individual’s strengths, needs, and preferences. The supports help to identify and sort out differing views among those present. At § 441.301(c)(1)(v) we discuss further the role of the facilitation process in managing disagreements and the inherent differences in self-interest present in any diverse team.

We agree that some of the specific types of support commenters suggested will be valuable for some individuals, but we do not prescribe in regulation all the specific supports that can be offered. These vary according to many factors including the type of disability.

We have revised this final rule to read: “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.”

Comment: We received a few comments expressing opposite views on professionals participating in the planning. Two commenters did not believe that a planning process can include professionals and be person-centered because the individual will not direct the process. Others requested adding a provision to assure that the planning process is facilitated by a professional trained and skilled in person-centered planning techniques, possibly an independent facilitator.

Response: Person-centered service planning is a complex concept and requires both commitment and skill to implement. We agree that if professionals take control from individuals in the planning process, the requirements of this rule will not have been met. We do not agree that it is impossible for professionals to participate in the process appropriately. Indeed, as in many professional disciplines, the values, ethics, and the evolution of best practices in the profession offer the best means of consistently implementing a process that supports and serves the individual. We require that supports be available to assist all individuals in leading the planning process, and sometimes those supports include professionals skilled in facilitation. We believe the revised language is sufficiently clear in that it states an outcome—the individual directs the process, with supports if needed.

Following are the comments we received on § 441.301(b)(1)(i)(A)(3), which is now § 441.301(c)(1)(iii) of the final rule.

Comment: We received relatively few comments in response to this provision. Some commenters stated that the time and location preference only belonged to the individual, or that it should occur only in the individual’s home, while others pointed out that the logistics should be negotiated with all participants. Some wanted more specificity, including whether the process must always be face to face; others believe the rule to be too prescriptive. We also address here a comment that the rule lacks any requirement for timeliness.

Response: As proposed, the regulation text aims to address a problem significant numbers of waiver participants may have experienced: that the planning process is scheduled entirely at the convenience of the state and/or provider agency. This language is silent about the convenience or preference of other participants, and we do not agree that silence precludes taking these and other factors into account. We agree that timeliness is important. When individuals rely heavily on services and supports, waiting to update a plan in response to a changed need could be a significant hardship or even a danger. Because the need for planning can range from urgent to optional, we do not believe it is appropriate or helpful to specify time frames in regulation. However, we are revising this provision in the final rule at § 441.301(c)(1)(iii) as follows: “Is timely and occurs at times and locations of convenience to the individual.”

Following are the comments we received on § 441.301(b)(1)(i)(A)(4), which is now § 441.301(c)(1)(iv) of the final rule.

Comment: Several commenters suggested that the regulation be more specific and more clearly articulate and strengthen “cultural considerations,” include more detailed state responsibilities, and offer translation services in the individual’s first language. No comments objected to this provision specifically.

Response: We have added text to specify that a State’s waiver request include how the person centered planning process is accessible to persons who are LEP and persons with disabilities, consistent with the Medicaid programmatic accessibility provision at § 435.905(b).

Following are the comments we received on § 441.301(b)(1)(i)(A)(5), which is now § 441.301(c)(1)(v) of the final rule.

Comment: Several commenters asked that we clarify this statement, including how to implement it and the types of conflict anticipated. Many comments

suggested types of disagreement or conflicts of interest to address, including interpersonal disagreement, denial or reduction in service, failure to implement the plan or comply with regulations, and whether providers have an inherent conflict and should not be present.

Response: We do not think that additional clarification is appropriate in the regulation. Furthermore, states can exercise multiple strategies to comply with this requirement.

We note that some commenters confused a provider being in attendance with a provider being in charge of the process or the plan. The latter (a provider being in charge of the process or plan) is not appropriate; the former (the provider being in attendance) depends on the circumstance and is not a matter subject to blanket requirements. Individuals may choose, or not, to include a provider of service in the planning team. In some situations a direct care worker or a therapist has worked so long and closely with the individual that his or her perspective is very important. Also, some providers point out that they should be able to voice any limits in what they can provide, so that a plan for someone with intense need does not commit providers to services they are not able to provide. In other situations, for example, if the individual is anxious about repercussions from voicing problems, or has a tendency to defer to a provider, that provider's presence would be detrimental. Clearly some actions, such as intimidating the individual, are unacceptable.

We do not believe it is possible to define more specific conflict of interest requirements that would be meaningful in the variety of arrangements currently used to develop person-centered service and support plans. We have strengthened the language by requiring that the state devise clear conflict of interest guidelines addressed to all parties who participate in the planning process.

Comment: Several commenters asked to strengthen the provision by requiring case managers to be independent of any service provider, as an assurance that the individual's goals and services will be appropriate, and will reduce actual or potential conflicts of interest. Others indicated that we do not define conflict of interest.

Response: We agree that complete independence of the person(s) facilitating the planning process is important to promote the statutory objectives. In the final rule, we have added an additional requirement to the person-centered planning process at

§ 441.301(c)(1)(vi) to address conflict of interest.

Following are the comments we received on § 441.301(b)(1)(i)(A)(6), which is now § 441.301(c)(1)(vii) of the final rule.

Comment: One commenter stated that current overarching Medicaid regulations already require full freedom of choice of qualified providers and CMS requires that states document that individuals have been offered freedom of choice. This is duplicative.

Response: The regulations at § 431.51 describe the various statutory bases for the free choice of provider, and specify the requirements and exceptions to the principle. The phrase "full freedom of choice," however, is not from existing regulation. We assume the commenter's reference to a documentation requirement pertains to the section 1915(c) of the Act requirement that waiver participants be offered the choice of institutional alternatives to HCBS options in the waiver, which is unrelated to being informed of non-institutional service alternatives. Some persons with disabilities and their advocates have described the experience of "choice" in long term services and supports as being considerably different than that of a Medicaid beneficiary looking through a list of participating acute or general health care providers. We believe that a person-centered planning process should include providing the individual information about the services and supports relevant to their particular needs and goals.

Comment: Individuals receiving long term services and supports and their families discussed the experience of both being presented with options and not being given choices. Comments noted that individuals wish to be respected and offered choices, rather than others deciding what may be best for them. On the other hand, being presented with an exhaustive list of theoretical options and a directory of providers is overwhelming and not very useful, a familiar experience to many people negotiating a new health care need. One comment stated, "Ensure the person has the support he or she needs to understand all of the choices and options, their rights, and what they are agreeing to." Some commenters suggested adding the word "informed" before "choices," as this would be more consistent with the ADA.

Response: We agree that it is difficult to articulate a rule that ensures a perfect balance between too much and too little information. We believe that taken as a whole, the requirements in this final rule make clear that the process of planning services and supports puts the

person at the center of a highly individualized process. We agree with the suggestion to change "Offers choices" to "Offers informed choices." Individuals should be informed of all the possibilities from which they may choose, as well as the consequences of those choices, in a manner that is meaningful to the recipient and easily understood.

Comment: Several suggestions were made regarding specific issues or special circumstances regarding individual choice, including documentation of court orders or other legal issues, identification of rights, and linkage to entitlements or resources other than Medicaid.

Response: These suggestions appear to be good practices, but too detailed for regulation. We will consider them in the context of our ongoing efforts to provide information about best practices.

Following are the comments we received on § 441.301(b)(1)(i)(A)(7), which is now § 441.301(c)(1)(viii) of the final rule.

Comment: Two commenters pointed out that "as needed" may or may not include periodic scheduled updates, and does not address the timeframe within which a requested update be accomplished. They suggested changing the language to: "Include opportunities for periodic and ongoing plan updates as needed and/or requested by the individual and a time frame for reasonably scheduling meetings requested by the individual." One suggestion was to define timeliness in terms of the individual's goals. Another asked to make explicit that all individuals participating in the planning process be contacted so that they can be kept up to date.

Response: This section proposed a process requirement, having to do with informing the individual about what steps to take to schedule an update to the plan. We do not address timeliness regarding the response to request, as we are not able to set a single national standard that would be applicable across all HCBS waivers in the country. States must respond to urgent needs more quickly than to other types of requests, in order to meet the health and welfare requirements of the HCBS waiver program. States could accomplish this through an expedited process. Requiring that plan participants be notified when an update is scheduled has merit. However, given the requirements concerning who participates in the plan, who should sign the plan, and who should have copies of the plan, we cannot construct a notification policy that respects the various levels of confidentiality and

disclosure that may be required in some cases. At this time we believe that the individual or individual and representative should control notification about updates, consistent with the control they have under item (1) over who participates in the planning process.

b. Person-Centered Service Plan
§ 441.301(c)(2) (Proposed)
§ 441.301(b)(1)(i)(B))

At § 441.301(b)(1)(i)(B) we proposed that the Person-Centered Service Plan must include specific content. After further review, we believe the requirement at § 441.301(b)(1)(i)(A)(3) regarding timeliness and this requirement at § 441.301(b)(1)(i)(A)(7) regarding a method for individuals to request updates to the plan are sufficient and respectful of the individual's timeframe as reflected in the person-centered planning process. Therefore, we are removing the requirement at § 441.301(b)(1)(i)(A)(3) regarding a timeline for review because this will now be addressed through the requirements at § 441.301(c)(1)(iii) and (c)(1)(viii).

Following are the comments we received on § 441.301(b)(1)(i)(B)(2), which is now § 441.301(c)(2)(iii) of the final rule.

Comment: A commenter stated that a "person-centered functional assessment" is superior to a disability or diagnosis-based assessment. Another pointed out that "person-centered functional assessment" is not recognized terminology and suggested "individual assessment appropriate to the age and circumstances of the person" instead.

Response: We agree with parts of both comments. Applying "person-centered" to "functional assessment" is incorrect. Although in a general sense all long term service and support activities are to be centered on the person and not the provider, a functional assessment is objective. We also agree with the comment that "functional" assessment imparts an important distinction from other forms of evaluation such as diagnostic assessment. We therefore modify the proposed language to "through an assessment of functional need."

Following are the comments we received on § 441.301(b)(1)(i)(B)(3), which is now § 441.301(c)(2)(iv) of the final rule.

Comment: A commenter pointed out that there is no specific mention of mental health. Many comments in various sections mentioned that the rule should focus on outcomes.

Response: We agree with both observations. We recognize that we cannot provide an exhaustive list to reflect an individual's identified goals. Therefore, we are removing the examples and we are revising the final rule at § 441.301(c)(2)(iv) by adding "desired outcomes."

Comment: Related to the proposal to define home and community-based settings, we received many suggestions that the person-centered plan address the issue of housing and living arrangement in a definite manner. The proposed list of example goals included "community living" but this was not believed to sufficiently capture the complexity of housing and services issues.

Response: We appreciate the thoughtful comments and agree that this important subject warrants a separate item in the list of the plan content. We will add a new requirement at § 441.301(c)(2)(i) to read: "Reflect that the setting in which the individual resides is chosen by the individual. The state must ensure that the setting chosen by the individual is integrated in, supports full access of individuals receiving Medicaid HCBS 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 to the same degree of access as individuals not receiving Medicaid HCBS."

Following are the comments we received on § 441.301(b)(1)(i)(B)(4) which is now § 441.301(c)(2)(v) of the final rule.

Comment: We received few comments on this requirement. One commenter suggested replacing this language with "Respect and honor the choices made by the individual regarding supports." Another suggested adding the "full range" of services and supports. Others commented on or requested clarification about unpaid services, or urged us to clarify that unpaid services must not be required.

Response: We believe that natural supports and other unpaid services must be included in order to have a comprehensive plan reflecting all the services and supports required. The availability of unpaid supports may change from time to time and the plan must be written so as to be able to adjust the proportion of formal and informal supports without starting over at assessment. The planning process must not compel unpaid services. We have included the term "natural supports" in the regulation text at § 441.301(c)(2)(v) and have added the following sentence:

"Natural supports are unpaid supports that are provided voluntarily to the individual in lieu of section 1915(c) HCBS waiver services and supports." We do not believe other wording suggestions are required to achieve the intended meaning.

Following are the comments we received on § 441.301(b)(1)(i)(B)(5), which is now § 441.301(c)(2)(vi) of the final rule.

Comment: Comments supported the proposed language. We choose to address here similar comments on several sections of the proposed rule. Some commenters were concerned that in taking care to protect freedoms, the regulation did not provide for reducing risk due to certain kinds of disabilities. Dementia was mentioned most often, with many examples of why some believe individual freedoms may need to be curtailed to prevent wandering, injury with cooking equipment and so on.

Response: Based on the comments received, we conclude that additional language is needed to ensure that reducing risk for individuals receiving Medicaid HCBS does not involve abridgement of their independence, freedom, and choice either generally or at the spontaneous decision of persons providing services and supports. Restricting independence or access to resources is appropriate only to reduce specific risks, and only when considered carefully in the person-centered service plan. The person-centered planning process required in this regulation will engage the individual and others involved in the planning process as fully as possible in making these difficult but necessary decisions. As comments indicated, there may be a need for immediate action in emergent or changing circumstances—that is the purpose of backup strategies. In thinking through risk, the planning team will identify temporary measures to be used if needed, and then update the plan when needs have stabilized. Back-up strategies are to be individualized to the unique mix of risks, strengths, and supports represented by each waiver participant. We will articulate this in the final rule by amending the language at § 441.301(c)(2)(vi) to read: "Reflect risk factors and measures in place to minimize them, including individualized backup plans and strategies when needed." We have also added at § 441.301(c)(2)(xiii) that any modification of the additional conditions must be supported by a specific assessed need and justified in the person-centered service plan, and specified what must be documented in

the person-centered service plan in these instances.

Following are the comments we received on § 441.301(b)(1)(i)(B)(6), which is now § 441.301(c)(2)(ix) of the final rule.

Comment: Many comments on this requirement addressed the variety of persons who may be involved in formulating the plan and in carrying it out, any of whom may have complex relationships with the individual and each other. Some comments were primarily concerned with being inclusive, and in clearly communicating the plan for services to all involved; they noted that a person-centered plan is only effective if the people providing supports know what is included in the plan. Other comments were primarily concerned with privacy and control over personal information, noting that it is inappropriate to have an individual commit intimate details to paper (such as goals, hopes for personal relationships, etc.) and then require everyone involved in that person's care—no matter their role—to read, sign, and keep a copy. Many comments dealt with both signing and distributing the plan, but we address these comments separately.

Response: In response to the commenters' concerns about privacy and control over personal information, we have clarified in the final rule who will sign the plan and who will receive copies of the plan by revising § 441.301(c)(2)(ix) as follows: "Be finalized and agreed to, with the informed consent of the individual in writing, and signed by all individuals and providers responsible for its implementation."

Following are the comments we received on § 441.301(b)(1)(i)(B)(7), which is now at § 441.301(c)(2)(vii) of the final rule.

Comment: The few comments received supported the proposed language and went on to suggest specific examples, including making use of interpretation and translation, customized communication supports, in a format that is easily understood by the individual (Braille, ASL video, diagram/pictures, etc.), and taking enough time for decision making.

Response: As with some other requirements in this rule, we appreciate the examples given, but we do not think that CMS can list in regulation all the possible specific methods and tools to accomplish the desired outcome. For clarity purposes, we have added the term "supports" to this requirement.

Following are the comments we received on § 441.301(b)(1)(i)(B)(8).

Most of the comments we received on this proposed requirement were more applicable to other requirements and are summarized under those headings. The requirements at § 441.301(c)(1)(iii) regarding timeliness and the requirements at § 441.301(c)(1)(viii) regarding a method for individuals to request updates to the plan are sufficient and respectful of the individual's timeframe as reflected in the person-centered planning process. Therefore, we are removing this proposed requirement from the final rule. We did not receive comments on the proposed requirement at § 441.301(b)(1)(i)(B)(9), and adopt it in the final rule at § 441.301(c)(2)(viii).

Following are the comments we received on § 441.301(b)(1)(i)(B)(10), which is now § 441.301(c)(2)(x) of the final rule.

Comment: Many of the comments on this proposed requirement are also related to § 441.301(b)(1)(i)(B)(6), regarding who must sign the plan. Comments offered unique to the issue of distribution include suggestions of specific parties who should get copies of the plan and suggestions for case recordkeeping, including court or legal documents. Commenters also inquired whether distribution meant to every entity (for example, a company providing long term services and supports to the individual), or also given to every individual from that entity (for example, every direct service worker).

If the latter, concerns were expressed that parts of a true person-centered plan include very personal information, as required in § 441.301(c)(2)(iv) above—such as the individual's needs, aspirations, and even complaints—making it inappropriate to distribute the plan to everyone (that is, a housekeeper does not need to know about an individual's relationship goals).

Response: We appreciate the comments on this section of the rule. The language in the final rule specifies that the person-centered service plan will be distributed to the individual and other people involved in the plan. We have also revised the language in the final rule at the § 441.301(c)(2)(iv) to remove the examples and added the term "desired outcomes."

Following are the comments we received on § 441.301(b)(1)(i)(B)(11), which is now § 441.301(c)(2)(xi) of the final rule.

Comment: Some comments discussed "self direction" or "participant direction," which while they sound similar to "person-centered" are terms of art for a different concept, a method of managing long term services and

supports in which the individual assumes employer authority and/or manages a budget for the services and supports. A few comments discussed the distinction, while a few were confused by these concepts.

Response: Amendments to this regulation do not specifically address the issue of self direction. We issued extensive sub-regulatory guidance and technical assistance on self direction of services, to which we refer these commenters. We agree with commenters who pointed out the importance of a person-centered planning process in implementing self direction of services, and believe that the requirements in this rule will facilitate self direction and other complexities in planning long term services and supports.

Comment: Several commenters stated that this requirement is unclear. One commenter thought the proposed regulation would require self direction for all participants.

Response: We have clarified that the person-centered service plan covers all aspects of services and supports, including self direction where applicable, by rewording the text as follows: "Include those services, the purpose or control of which the individual elects to self-direct."

Following are the comments we received on § 441.301(b)(1)(i)(B)(12), which is now § 441.301(c)(2)(xii) of the final rule.

Comment: One commenter stated that the funding for identified supports needs to be in place for the plan to be implemented. Two other commenters asked us to clarify that the full range of services authorized by statute and included in the state's waiver proposal be made available to program participants.

Response: These observations about providing all needed care are the logical complement to the proposed language about unnecessary care. Taken together they address proper utilization of services. We agree that states must provide needed services to an eligible individual enrolled in the waiver. We believe the current language appropriately indicates that needed services must be provided, while unnecessary or inappropriate services should not; however, we have changed the term "care" to "services and supports."

Comment: One commenter found this language to be ambiguous because "prevent" is imprecise. Services should not be unnecessary or inappropriate.

Response: This requirement does not imply that the waiver offers services that are inherently inappropriate or unnecessary. It refers to the possibility

that particular services, or that the scope or frequency of them, may be inherently inappropriate or unnecessary for a given individual, especially as the individual's situation changes. One of the purposes of any service plan for health or long term care services is to specify the services a particular individual requires. There is no legitimate advantage to the individual or to Medicaid in providing unneeded services. However, some states or particular programs have historically had difficulty controlling utilization; individuals may all be given the maximum scope or frequency of service. We think that with the addition noted in the response above, the existing language adequately conveys the concept of appropriate utilization.

Comment: Some commenters asked that the rule include a reference to the "most integrated setting appropriate" standard. Two commenters consider this the most important aspect of the person-centered service plan. Many commenters of all types stated that person-centered planning should promote choice. However, regarding settings there was less agreement on what choices should be offered. Many who were concerned about preserving their present setting suggested they should be allowed to choose to live wherever they wish, and not have their current choice removed by a government policy.

Other commenters addressed the process of choice. They agreed with the planning process as proposed and stated that setting should be addressed, in terms of the individual's needs and goals. They asked that in the planning process no types of residential provider or housing options being offered to section 1915(c) of the Act HCBS waiver participants be omitted from the discussion. They and some others also suggested that this subject could be raised at regular intervals when appropriate, as the person centered service plan is updated. Their position was that competition among providers of residential settings for waiver participants is a good thing and will promote growth of the types of settings CMS seems to want to encourage, but will only work if it is a fair competition with all approved settings presented neutrally to the individual.

Some comments about settings in person-centered planning had more to do with the definition of setting than with the planning process.

Response: We agree that the setting options in which an individual resides should be an element in the person-centered service plan. We have included it as a separate item under the list of

"Person-Centered Planning Process" requirements at § 441.301(c)(1)(ix). It reads: "Records the alternative home and community-based settings that were considered by the individual." We respond to all of the setting issues, such as landlord/tenant relationship, in our discussion of that section of the rule. As all the comments on this subject make clear, the process of choosing among the housing and service options actually available to a particular waiver participant is an extraordinarily multifaceted issue. A truly person-centered planning process as required in this rule is the best venue for facilitating this important choice.

We also agree that part of meaningful choice is to be presented with all available options. A person-centered planning process is not about promoting certain options deemed to be more "person-centered" or otherwise desirable, than other options. A person-centered process is one that puts the individual in the center, facilitated to make choices that may be agreeable or disagreeable to some participating in the process.

Therefore, we will require that the process of informed choice be documented. Best practices that develop will inform future policy. A new provision has been added at § 441.301(c)(2)(i) to read: "Reflect that the setting in which the individual resides is chosen by the individual. The state must ensure that the setting chosen by the individual is integrated in, and supports full access of individuals receiving Medicaid HCBS 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 to the same degree of access as individuals not receiving Medicaid HCBS."

Comment: One commenter stated that CMS should use the person-centered plan to ensure community integration.

Response: We agree that one of the essential purposes of the person-centered service plan is to ensure community integration. In the regulation at § 441.301(c)(4)(i) we have clarified that home and community-based settings must be integrated in, and that individuals have full access to the greater community.

Comment: Other commenters offered specific additions to the proposed rule that we considered but found to be either too prescriptive or too detailed to require in regulation. For example, one commenter urged CMS to establish benchmarks in the rule, as a

requirement for states to receive FFP for person-centered HCBS waivers.

Response: Many of these comments reflect good practice in administering services. We believe that states have both sufficient incentive and practical experience to be following such practices. Where they are not, we offer a variety of technical assistance services to state agencies, at no charge, to assist with these sorts of practical strategies. We find this approach more productive and flexible than specifying detailed regulations for operating the program. In addition, some of these suggestions we have addressed in sub-regulatory guidance such as instructions for the section 1915(c) waiver application, letters or bulletins to State Medicaid directors, and other vehicles.

Comment: One commenter recommended that CMS include specific language in the final rule that updates to person-centered service plans must be completed within a sufficient timeframe to meet the individual's goals.

Response: Person-centered service plans must be reassessed at least annually, and more frequently if the condition of the individual changes, as indicated in § 441.365(e).

2. HCBS Settings § 441.301(b)(1)(iv) (final § 441.301(c)(4))

Through the proposed rule, we proposed to clarify and sought public input on how to define the characteristics of home and community-based (HCB) settings where waiver participants may receive services. In new paragraph, § 441.301(b)(1)(iv), we proposed clarifying language regarding settings that will not be considered home and community-based under section 1915(c) of the Act. We clarified that HCBS settings are integrated in the community and may not include: facilities located in a building that is also a publicly or privately-operated facility that provides inpatient institutional treatment or custodial care; or in a building on the grounds of, or immediately adjacent to, a public or private institution; or a disability-specific housing complex designed expressly around an individual's diagnosis, that is segregated from the larger community, as determined by the Secretary.

We noted that this rule change does not exclude living settings on tribal lands that reflect cultural norms or ALS for persons who are older regardless of disability, when the conditions noted above in the background section are met.

The clarification and request for input was partially in response to instances in

which states or other stakeholders expressed interest in using HCBS waivers to serve individuals in segregated settings or settings with a strong institutional nature, for example, some proposed settings on campuses of institutional facilities, segregated from the larger community. These settings often 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, activities; and limit individuals' opportunities to pursue community activities.

CMS' definition of HCBS setting characteristics has evolved over the past four years, based on experience and learning from throughout the country and feedback about the best way to differentiate between institutional and community-based care. For example, in our April 4, 2008, proposed rule, Medicaid Program; Home and Community-Based State Plan Services, (73 FR 18676), we used the number of unrelated people living together in a facility to define whether or not a setting was HCB. Our April 15, 2011, proposed rule, Medicaid Program; Home and Community-Based Services (HCBS) Waivers, (76 FR 21432), no longer included the number of residents as an HCB characteristic, but did include a detailed list of the types of settings that do not qualify for HCBS waivers because they are not integrated into the community. Based on further public comment on these proposed regulations and on the comments we received on the 1915(i) and 1915(k) proposed rule, we are moving away from defining HCB settings by what they are not, and towards defining them by the nature and quality of beneficiaries' experiences. These final regulations establish a more outcome-oriented definition of HCB settings, rather than one based solely on a setting's location, geography, or physical characteristics.

Comment: Many commenters believe quite passionately that public funds should only be used to support persons in "home and community-based" settings—not institution-like or congregate facilities. A commenter wrote, "Please protect the interests of the disabled people of the world and stand your ground and allow HCBS funds to be used for their intended purposes." Another commenter stated, "HCBS funds are limited and designed to serve specific purposes, not to be available to any and all settings which operate under the name 'community'."

Response: We agree with the general statement that waiver funds should only be used for their intended purpose of supporting individuals in the

community. HCBS must be delivered in a setting that meets the HCB setting requirements as set forth in this rule (except for HCBS that is permitted to be delivered in an institutional setting, such as institutional respite), and since the purpose of this authority is to provide individuals with HCB alternatives to institutional settings, individuals must be living in settings that comport with the HCB setting requirements as set forth in this rule. We believe the criteria set forth in the final rule will enable CMS to differentiate between HCBS settings and non-HCBS settings for funding purposes.

Comment: Several commenters shared the sentiment that true community integration is more than being in the community, but rather truly participating in that community through working side by side with others without disabilities in community activities, such as jobs, clubs and other civic activities.

Response: We agree with this comment and believe that the changes in the text of the final rule address tenets of community integration. A home and community-based setting must be integrated in, and supports full access of individuals receiving Medicaid HCBS 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, to the same degree of access as individuals not receiving Medicaid HCBS.

Comment: A number of individual commenters shared personal stories expressing satisfaction with their current living arrangements and displeasure that new regulations might force them to move or dictate where they should live. One person wrote, "Please allow Medicaid waivers to continue to pay for services in planned communities similar to retirement communities. I want to live in a community with my friends." Another noted, "I believe this proposed rule would . . . deny access to residential care and assisted living for those who need it most." Many commenters talked about the importance of retaining freedom of choice. One commenter stated, ". . . what I am advocating is CHOICE. We should be expanding options rather than narrowing possibilities and options, and we should ask those with disabilities and their families what they want, not what others think they want." Finally, quite a few commenters echoed a warning to stay away from a "one size fits all"

approach in defining HCBS and to embrace more flexibility: "The needs and circumstances of each individual are too diverse to warrant an outright ban on HCBS funding for individuals who might need specialized care." They further challenged CMS that housing and setting options should not be arbitrarily limited by defining HCBS through physical and geographic structures, but rather through the person-centered plan, personal outcomes and satisfaction.

Response: We very much appreciate hearing personal stories as they help us better understand how our proposed actions will affect individuals receiving services under the HCBS waiver program. We believe that individual choice is important and have worked to promote choice in the final rule. In addition, it is important to note that HCBS waiver funding is only one way in which federal Medicaid finances long term services and supports; a setting that may not meet the HCB definition may still qualify for Medicaid financing, but not as a home and community based service.

We agree that the definition we included in the proposed rule for HCBS settings may have had the result of restricting the settings in which HCB waiver services can be provided in a way that we did not intend and in narrowing choices for participants. The final rule is more flexible and less prescriptive in that it does not preclude certain settings per se but rather establishes affirmative, outcome-based criteria for defining whether a setting is or is not home and community-based. The language in the final rule specifies that any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS, will be presumed to be a setting that has the qualities of an institution unless the Secretary determines, through heightened scrutiny, based on information presented by the state or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings. Therefore, states and others have the opportunity to refute this categorization by providing sufficient evidence that the individuals in the facility are, in fact, integrated in the community in a manner that overcomes any institutional appearance of the setting. This means

that we will continue to be discerning about what types of settings qualify for waiver funds. We are including language in the final rule that focuses on the critical role of person-centered planning and addresses fundamental protections regarding freedom, dignity, control, daily routines, privacy and community integration.

Comment: A number of commenters cautioned that restricting living situations reduces access to long term care in the community and may force people back into nursing facilities. They advised that CMS not include any specific restrictions on settings.

Response: We have made significant changes to this section of the rule, but still define general tenets and characteristics of HCBS that will preclude institutional settings from qualifying as HCB, although they might qualify for Medicaid financing under other authorities. We specifically noted that home and community-based settings do not include: “a nursing facility; an institution for mental diseases, an intermediate care facility for individuals with intellectual disabilities; a hospital, or any other locations that have qualities of an institutional setting, as determined by the Secretary.” Statutory requirements specify that an individual be offered a choice between services in an institutional setting or in a HCBS setting, therefore making it necessary for us to define the difference. We recognize that there are limited long-term care options in many communities and may be few alternatives beyond institutional care. However, states need to understand what qualifies as a home and community-based setting, and also understand that this might trigger change and even dislocation. To mitigate, we have developed specific provisions to allow for a transition period, for existing approved HCBS waivers under 1915(c) in accordance with section 441.301(c)(6). We will afford states the opportunity to propose a transition plan that encompasses a period up to five years after the effective date of the regulation if the state can support the need for such a period of time. States are expected to demonstrate substantial progress toward compliance throughout any transition period. For states that are submitting renewals early in the first year after this final regulation takes effect, states may submit a request for a temporary extension to allow time to fully develop the transition plan for that HCBS waiver program.

Comment: A couple of commenters expressed concern about negative financial impact on providers.

Response: We appreciate the concerns regarding service providers and wish to point out that states will have tremendous flexibility in how they design 1915(c) waivers, including how they define services, provider qualifications and service rate methodologies in their programs. The purpose of this regulation is to ensure that beneficiaries in Medicaid HCBS waivers receive services in home and community-based settings that are true alternatives to institutional settings and that states and providers have a clear understanding of how applicable definitions will be applied by us.

Comment: One commenter thought that privacy is already protected in administrative rules, so it is not necessary to address in this rule.

Response: We disagree with this comment and have included a statement in the final rule about qualities that must be included in HCBS, including the right to privacy.

Comment: A significant number of commenters recommended that CMS remove the entire section on HCBS settings in the proposed rule from the final rule.

Response: CMS has made significant changes to this section of the rule, but has not eliminated it. We have listened to the many concerns expressed by commenters regarding the description of HCBS settings and have chosen a different, more person-centered and outcome-driven approach for defining settings than what was described in the proposed rule.

Comment: Commenters generally liked the CMS prohibition against using HCBS waiver funds to provide services to individuals living in a setting in which they are required to receive and participate in services as a condition of continued tenancy. Further, some commenters wanted CMS to require providers to promote aging in place. They stated the need for additional qualified services and supports should not be justification for asking a person to leave a setting; however, should the person's needs exceed what legally can be provided in the setting, appropriate transfer processes and protections must be in place.

Response: There is nothing in this rule that negates or waives compliance with other Medicaid requirements, not specifically waived by section 1915(c) authority, such as an individual's right to obtain services from any willing and qualified provider of a service. In the final rule, we have revised § 441.301(c)(4) by replacing the language with new requirements for HCBS settings, and at § 441.301(c)(4)(v) we have included the following

requirement that the setting, “facilitates individual choice regarding services and supports, and who provides them.” This requirement applies to all settings including provider-owned or controlled residential settings.

Comment: A commenter asked if people currently living in settings that do not meet the new criteria will have a grandfathering period to move out or disenroll from the waiver. Many commenters strongly encouraged CMS to allow sufficient time for states, providers, and individual waiver participants and their families to make the transition away from historic legacy settings that may not comport with the proposed rule language, in order to minimize adverse impacts on individuals and systems of services and supports. Some commenters suggested that if we consider grandfathering non-compliant programs, we should not make the grandfathered period permanent, but should only allow grandfathering of existing homes located on the periphery of a campus, but not separated by fencing or barriers.

Response: We understand that time is required to adjust to the new requirements set forth in the final rule. The revised language in the final rule includes the requirements for states to submit transition plans for coming into compliance for existing programs and HCBS waivers.

Comment: One commenter emphasized the need to involve stakeholders in dialogue as CMS moves forward on working with states to implement final regulations. Another commenter recommended that the Department of Defense have the opportunity to provide recommendations that will enhance military families' access to the waiver as they move from state to state.

Response: We engaged in a public input process on the 1915(c) regulation, which included both an Advanced Notice of Proposed Rulemaking (ANPRM) and the Notice of Proposed Rulemaking (NPRM), producing well over 2500 separate comments. We have taken the time to thoroughly analyze comments from a wide range of stakeholders and incorporate stakeholder suggestions in crafting the final rule. We have also reviewed comments from the proposed rules for the 1915(i) and 1915(k) programs and have incorporated suggestions into this final rule so that all three HCBS authorities are aligned. CMS is committed to working with states and providing technical assistance, as needed, with implementation of the final rule.

Comment: Many commenters suggested CMS clearly outline the qualities of an institutional setting in the regulatory text and not just in the preamble. One commenter proposed including a list of 12 qualities of an institution in the regulatory text.

Response: Rather than explicitly outlining the qualities of an institution, we have chosen to more clearly outline the qualities of home and community-based settings in the regulatory text. The final language provides a specific list of five qualities that must be present in order for a setting to be classified as home and community-based, as well as additional criteria that must be met by provider-owned or controlled settings. The final rule also notes that home and community-based settings do not include nursing facilities, institutions for mental diseases, intermediate care facilities for individuals with intellectual disabilities, or hospitals.

Comment: Several commenters wanted more detail in the rule defining HCBS “settings.” One commenter proposed that the following language be added to the description of appropriate HCBS “settings” in the rule: “support exercising full rights and responsibilities as community citizens” and “individualized services and supports.” Another commenter proposed a list of nine person-centered attributes that it believes should be found in all HCBS settings. The nine attributes are: core values and philosophy, relationships and sense of community, governance/ownership, leadership, workforce practices, meaningful life and engagement, services, environment, and accountability. Other commenters also provided differing views on whether sheltered workshops, adult day care services, and other congregate settings and non-residential facilities solely for persons with disabilities should be considered HCB. Some believed that the rule should exclude these settings from the HCBS definition as they still have the qualities of an institution. Others, however, believed these settings should qualify for waiver funding, stating that HCBS characteristics should not apply only to residential services.

Response: 1915(c) HCBS must be delivered in a setting that meets the HCB setting requirements as set forth in this rule. In addition, since the purpose of this authority is to provide individuals with HCB alternatives to institutional settings, individuals receiving 1915(c) HCBS must be living in settings that comport with the HCB setting requirements as set forth in this rule regardless of whether they are receiving HCBS in that residence. This

is consistent with CMS’ longstanding policy regarding 1915(c) HCBS.

Comment: Many commenters stated that they thought the regulation should specify that an HCBS setting must not be located on the grounds of, or immediately adjacent to, a private as well as a public institution.

Response: We appreciate the commenters’ concerns. It is expected that all settings, public and private, meet the HCB setting requirements of this regulation. These final rules specifically make reference to a setting that is adjacent to a public institution in the regulation language due to public input that stressed how such settings inherently discourage integration with the broader community. We will apply heightened scrutiny to such settings because of the likelihood that they do not offer the characteristics of a home and community-based setting and hinder or discourage integration with the broader community.

Comment: Many commenters thought some terms in the proposed rule were vague and/or needed further defining. For example, many commenters wanted the rule to include clearer definitions for terms such as “immediately adjacent to a public institution” and “housing complex designed expressly around an individual’s diagnosis or disability.” At least one commenter stated that terms like “meaningful access” and “choice” were too subjective to have a place in regulation.

Response: We appreciate some commenters’ desires for more specific and clear definitions in the final rule, but believe that highly specific, close-ended parameters are limiting and often prove ineffective. We are instead moving towards evaluating outcomes and characteristics to determine whether or not a particular setting produces desirable outcomes—while attempting to be as clear and precise as possible in describing those outcomes and characteristics. Where appropriate, CMS has added additional specificity to the final rule.

Comment: Some commenters believe that “immediately adjacent to a public institution” was unnecessarily restrictive. In contrast, another commenter believed that use of the term “immediately adjacent” was not restrictive enough, as “it could allow HCBS housing at an institution separated by a nature trail, parking lot or tree line.” One comment included the recommendation that we add the phrase: “or sharing common employees or management with a public institution” after the phrase “immediately adjacent to a public institution.”

Response: We believe that the process for heightened scrutiny, as described in the final rule, allows us to appropriately determine whether such settings meet the HCBS requirements. We believe this approach will allow us to take into account the kinds of issues the commenters described.

Comment: Several commenters believed CMS should strike the term “custodial care” from the rule. Another commenter wanted us to clarify whether “custodial care” prohibits care in foster care settings.

Response: We agree that the term “custodial care” is unclear and confusing and should not be included in the final rule. We have deleted it from the regulatory text.

Comment: We received many comments that certain settings—such as group homes, adult foster care, and assisted living facilities—should qualify as home and community-based because many individuals consider them to be their homes and to be a part of the community. On the other hand, we also received comments from others that these types of facilities are never appropriate as HCBS settings.

Response: Given the variability within and between types of housing arrangements, CMS cannot determine simply by the type of group housing, whether it complies with HCBS characteristics. As a result, particular settings, beyond those specifically excluded in the regulation text, will not automatically be included or excluded, but rather will be evaluated using the heightened scrutiny approach described in the regulation.

Comment: Commenters stated that the regulation should specify that a “housing complex designed expressly around an individual’s diagnosis or disability” includes complexes that serve individuals with different diagnoses or disabilities, as opposed to just individuals with a particular diagnosis or disability. Another commenter requested a definition of a housing complex that is designed expressly around an individual’s diagnosis or disability.

Response: We appreciated these comments, which indicated to us that the language means different things to different populations and programs. As a result of the comments we received, we have revised the rule to remove the language, “housing complex designed expressly around an individual’s diagnosis or disability.” In the final rule, we have removed this language. The regulatory text now includes the following language: “any other setting that has the effect of isolating individuals receiving Medicaid HCBS

from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the state or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.” We intend to issue additional guidance to provide examples of the types of settings that will be subject to heightened scrutiny. The guidance will also specify the process we will use to determine if a setting meets the home and community-based criteria.

Comment: Commenters disagreed with proposed language that would exclude “housing designed expressly around an individual’s diagnosis or disability” from the definition of an HCBS setting. They noted that certain disabled populations (such as those with brain injury and spinal cord injuries or Alzheimer’s disease) require specialized facilities and care designed to meet their specific needs. Commenters stated that complexes designed around an individual’s diagnosis or disability serve as alternatives to institutionalized care and allow residents to function with greater independence. We received a significant number of comments from diverse groups of individuals commenting that there are good reasons to live in residential settings specific to individuals’ needs.

Response: As noted above, the final rule no longer includes the term “housing designed expressly around an individual’s diagnosis or disability.” The new regulatory language is restated above. We agree that certain kinds of specialized settings may prove highly beneficial to particular populations and may be well integrated into the community. These factors will be taken into account when deciding whether or not a setting should qualify for HCBS waiver funding.

Comment: Some commenters asked CMS to look into HCBS settings’ implications for intersection with HUD 811 and 202 projects and whether this will result in people losing housing. They encouraged CMS to look at potential conflicts with Fair Housing rules and work collaboratively with HUD and the Department of Agriculture so that we better coordinate available federally subsidized housing options with delivery of waiver services. One commenter who believed that HUD-funded independent housing should qualify stated, “We would urge the Secretary to use her discretion to

recognize that even those Section 811 housing developments that are designed ‘expressly around an individual’s diagnosis or disability’ are often the most community-based and inclusive housing model available, and it would be illogical to deny HCBS waiver funds to support services to an individual living in such a setting.”

Response: We have worked closely with HUD and other federal agencies on the impact of this regulation on federally supported housing options. We believe the changes to the final rule allow for the appropriate designation of HCBS settings and for sufficient transition time for states to comply.

Comment: One commenter suggested that a “home” should not be considered “in the community” if more than four unrelated people live in the home.

Response: In the 2008 1915(i) Notice of Proposed Rulemaking, we did propose defining institutional care based on the number of residents living in the facility. However, we were persuaded by public comments that this was not a useful or appropriate way to differentiate between institutional and home and community-based care. As a result, we have now determined not to include or exclude specific kinds of facilities from qualifying as HCBS settings based on the number of residents in that facility. We have, however, established a list of specific conditions that must be met in provider-owned or controlled residential settings in order to qualify as HCBS.

Comment: A commenter thought CMS should not allow clusters of homes in gated communities to qualify as an HCBS setting. Others objected to classifying facilities on campus settings or farms as HCBS. On the other hand, many people supported categorizing these facilities as HCBS, noting that cluster or campus living may promote health and welfare in emergencies because of physical proximity. Many commenters expressed concern that the proposed rule would exclude rural farmsteads and farm communities for individuals with autism from receiving waiver funds. These commenters noted that rural, agricultural settings are desirable for people with autism, as they provide safe, calm environments—whereas urban settings can prove dangerous and disorienting.

Response: The Secretary will determine through heightened scrutiny, based on information presented by the state or other parties, whether such complexes do or do not have the qualities of an institution and whether these complexes have or do not have the qualities of home and community-based settings. We will evaluate both rural and

urban settings based on whether they have the characteristics required under the regulation.

Comment: Several commenters suggested that CMS needed to be careful of the unintended consequences of the prescriptive language about settings in the proposed rule that would force people to move from their long term homes in the community and lose services. Some commenters stated that CMS must also be open to unique situations and different types of living situations that may be designed for people in rural areas.

Response: We have considered the many concerns expressed by commenters regarding the description of HCBS settings in the proposed rule. Through the final rule we have chosen a different, more person-centered, outcomes-based approach than what was described in the proposed rule in part to address concerns about unintended consequences of specific language that was used in the proposed rule about settings.

Comment: There were several themes that emerged amongst the many commenters who agreed with the proposed language in the rule regarding home and community-based settings. Some commended CMS for taking a stand on what comprises home and community qualities. Others appreciated that we were using characteristics that will help people truly be included in their communities and not just focusing on size or location of settings. Other commenters specifically mentioned that institutions and other congregate settings should not be a part of a waiver and should not be allowed to call themselves HCBS. Commenters agreed that use of person centered planning, flexibility regarding meals and availability of food, control over daily activities, free access to visitors and privacy are all hallmarks of community living. Individual commenters and the general public focused on the importance of using waiver funding for people with disabilities to live in the community like everyone else and not be shut away from other people.

Response: We concur with much of the content from these commenters. Through the final rule we have chosen to take a somewhat different approach from what was described in the proposed rule in order to address the different commenters with divergent views on this issue. Specifically, we have chosen to be somewhat less prescriptive regarding physical and geographical characteristics of settings and to focus instead on the critical role of person-centered service planning

and on characteristics that are associated with independence, control, daily routines, privacy and community integration. Further, with respect to certain types of settings, the final rule specifies that the Secretary will determine through heightened scrutiny, based on information presented by the state or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

Comment: One commenter suggested that the proposed language runs counter to consumer choice, would restrict important specialized programming, and is counter to the entire course and direction of the waiver program recommending that CMS delete the proposed section in its entirety and begin anew by convening stakeholders to discuss this critical definition. The commenter added that these conditions are a first attempt to regulate federally the assisted living environment which could and should remain at the state level.

Response: This rule applies to all settings where individuals are receiving HCBS and does not single out assisted living environments. It is intended to assure, consistent with the statute, that Medicaid financing provided through HCBS waivers is available to participants who are receiving services in settings that are true alternatives to institutional care.

3. Target Groups § 441.301(b)(6)

Under section 1915(c) of the Act, the Secretary is authorized to waive section 1902(a)(10)(B) of the Act, allowing states not to apply requirements that the medical assistance available to categorically-eligible Medicaid individuals must not be less in amount, duration or scope than the medical assistance made available to any other such individual, or the medical assistance available to medically needy individuals. We have interpreted this authority to permit States to target an HCBS waiver program to a specified group of individuals who would otherwise require institutional care. A single section 1915(c) waiver may, under current regulation, serve one of the three target groups identified in § 441.301(b)(6). As provided in the rule, these target groups are: "Aged or disabled, or both; Individuals with intellectual or developmental disabilities, or both; and Mentally ill." States must currently develop separate section 1915(c) waivers in order to serve more than one of the specified target groups. A federal regulatory change that permits combining targeted groups

within one waiver will remove a barrier for states that wish to design a waiver that meets the needs of more than one target population.

This regulatory change will enable states to design programs to meet the needs of Medicaid-eligible individuals and potentially achieve administrative efficiencies. For example, a growing number of Medicaid-eligible individuals with intellectual disabilities reside with aging caregivers who are also eligible for Medicaid. The proposed change will enable the state to design a coordinated section 1915(c) waiver structure that meets the needs of the entire family that, in this example, includes both an aging parent and a person with intellectual disabilities. In this illustration, the family currently would be served in two different waivers, but with the proposed change, both could now be served under the same waiver program.

The revisions to § 441.301(b)(6) will allow states, but not require them, to combine target groups. Under this rule, states must still determine that without the waiver, participants will require institutional level of care, in accordance with section 1915(c) of the Act. The regulation will not affect the cost neutrality requirement for section 1915(c) waivers, which requires the state to assure that the average per capita expenditure under the waiver for each waiver year not exceed 100 percent of the average per capita expenditures that will have been made during the same year for the level of care provided in a hospital, nursing facility, or ICF/IID under the state plan had the waiver not been granted. We will provide states with guidance on how to demonstrate cost neutrality for a waiver serving multiple target groups.

The comments provided on this provision were largely positive, advising CMS to carefully consider quality elements and protections needed to ensure that all target groups are protected sufficiently in such a structure. Through this final rule, we include the requirements that each individual within the waiver, regardless of target group, has equal access to the services necessary to meet their unique needs.

Comment: A theme expressed by the majority of commenters who disagreed with this provision in the rule centered around potential negative impact on consumers. These included using the combining of target groups to limit service packages, serve less people overall, limit choices and create infighting among different disability groups. Several commenters were concerned that states would make

decisions based on service/cost, which may lead to less adequate services for people with disabilities.

Response: Challenges regarding limited resources at the state level already exist and will continue to exist whether or not a state chooses to pursue combining target populations in one waiver. This change to the regulation is not intended to have any impact on payment rates for services. To ensure transparency and input, we strongly encourage states interested in this option to consult with affected stakeholders in advance of implementation.

Comment: Several commenters expressed concern that combining of target groups will lead to frustration for states and cause barriers to timely innovations.

Response: The intention in the rule is to provide options to states that foster creativity and better integration of services across populations, which may lead to administrative efficiencies in state Medicaid agencies. The intent is not to prevent or inhibit innovation and the decision to combine target groups is optional for the state.

Comment: A few commenters noted that people with various disabilities, for example people with developmental disabilities, people with mental illness and frail elders, have different needs from each other and should not be residing together in housing situations. Further, they described how this can lead to dangerous situations that may threaten the well-being of more vulnerable individuals, such as frail elders when they reside with younger people with disabilities, particularly if there is any potential that such disabilities would make a person more likely to engage in any dangerous or aggressive behavior.

Response: The changes to this section of the regulation do not speak to combining different target groups in the same living situations, but rather to the inclusion of multiple target groups in the overall waiver design and operation. Including multiple target groups in one waiver will not alleviate responsibilities of states for ensuring the health and welfare of all participants and detailing their quality improvement strategies for that waiver. The final rule at § 441.302(a)(4) specifies that, if a state chooses the option to serve more than one target group under a single waiver, the state must assure that it is able to meet the unique service needs that each individual may have regardless of the target group.

Comment: A commenter recommended that if states are permitted to combine target populations

in a single waiver, CMS must expressly require a right of beneficiary choice.

Response: Including multiple target populations in one waiver does not change freedom of choice requirements that exist in Medicaid generally and in 1915(c) waivers specifically. Regardless of whether a state includes multiple target populations, all included services must be made available to those enrolled in the waiver who demonstrate a need for the services (as indicated in the person-centered assessment and service plan).

Comment: A number of commenters who disagreed with this provision responded to perceived changes that were not contemplated in the proposed rule. One commenter thought this rule would cause cost-neutrality issues between populations. Interestingly, some commenters thought the proposed rule would mandate states to combine target populations and believed it should be a state choice.

Response: The concern that cost neutrality would become problematic in waivers with combined target groups should not be a factor, as cost neutrality is calculated based on the relevant level of care group in the waiver, not by target population. For example, people with physical disabilities who meet nursing facility level of care would need to meet that cost neutrality level and people with intellectual disabilities would still need to meet the cost neutrality for ICF/IID level of care. In fact, multiple levels of care are an option currently in waivers where a particular target population may include multiple levels of care within the same waiver. As this choice is optional, the state will have the opportunity to submit two separate waivers if cost neutrality was not initially met with one waiver. Neither the proposed rule nor the final rule mandates states to combine target populations, but rather provides this option for states.

Comment: Several commenters were concerned that people who are currently receiving waiver services would lose their services if the state combined population specific waivers into one waiver that included multiple target groups. They suggested that CMS require appropriate safeguards to protect current participants.

Response: In an effort to ensure that safeguards are in place to protect the health and welfare of each waiver participant, the requirement in the final rule at § 441.302(a)(4) specifies that states must assure us that they are able to meet the unique service needs that particular target groups may present when the state elects to serve more than one target group under a single waiver.

In the Instructions and Technical Guide for section 1915(c) HCBS waiver applications, we currently require a transition plan for waiver participants who may be adversely affected when a change through amendment, renewal consolidation, or the termination of a waiver occurs.

Comment: Several commenters asked for clearer expectations around quality measurement and related documentation.

Response: Combining waiver target groups will not alleviate responsibilities of states for ensuring the health and welfare of all participants and detailing their quality improvement strategies for that waiver. Further guidance on waiver quality improvement strategies is addressed in the Instructions and Technical Guide for section 1915(c) HCBS waiver applications. We believe there may be potential for efficiencies by having a uniform quality system in one waiver that serves multiple target populations.

Comment: Several commenters would like to see CMS allow states to define different services packages for subgroups within combined waivers. Other commenters asked CMS to clarify that equal access does not mean that each individual receives the same type, amount, duration or scope of service. In addition, one commenter recommended that waivers serving multiple target groups should not be required to cover the array of services specifically needed by each of the covered groups as well as generic services that will benefit all. Another commenter suggested that CMS require a common service menu for all target populations.

Response: States may continue to design and keep 1915(c) waivers by individual target group and not choose to combine target groups. If they combine target groups in one waiver, equal access means that all included services must be made available to those who need them (as indicated in the person-centered assessment and service plan). This does not mean that individuals with differing needs would receive the same array, amount, duration or scope of services. Nothing in the proposed or final rule changes state flexibility in choosing services to meet the needs of people in waivers.

Comment: Several commenters raised the issue of waiting lists and the potential to crowd out one population group due to pent up demand with long wait lists for another group; this was specifically mentioned in relation to older adults not having timely access to services.

Response: One of the options available to states to ensure the

continuation of services to incoming multiple target groups under one waiver is to reserve capacity. Reserving capacity is only a means to hold waiver openings for the entrance of specific sets of individuals to the waiver. Capacity cannot be reserved to limit access to a specific waiver service. All individuals who enter the waiver must have comparable access to the services offered under the waiver. For example, capacity may not be reserved to limit the number of waiver participants who may direct some or all of their waiver services.

Comment: Several commenters pointed out that due to Medicaid's historic institutional bias, home and community-based services are still generally under-resourced relative to facility-based care. One commenter suggested that CMS not allow states to use newly combined waivers to cut back on HCBS services overall, as such a move would be inconsistent with a state's obligations under *Olmstead*.

Response: We intend to offer more opportunities to states to facilitate their participation in HCBS options, not to reduce states' participation in 1915(c) waivers or limit HCBS services. Further, this regulation change does not alleviate states' independent obligations under the Americans with Disabilities Act or the Supreme Court's *Olmstead* decision.

Comment: One commenter recommended that states be allowed the flexibility to create waivers that include hybrid care arrangements that have some institutional components.

Response: Since the waivers are statutorily designed for the purpose of providing HCBS as an alternative to institutional care, we disagree with this comment.

Comment: Several commenters agreed with this section of the rule but recommended that cost neutrality calculations be based either on combined calculations or on the target group with the higher estimated cost—not calculated separately for each population group. It was also recommended that we provide more detail on cost neutrality calculations in the regulation text, including whether states would have the option to combine populations with different institutional levels of need into one waiver. Several other commenters thought that states should be able to limit the number of waiver participants in each target group to maintain fiscal neutrality.

Response: Combining target groups allows states to combine people with different levels of care, for example, people with ICF/IID level of care and NF level of care, in the same waiver. Cost neutrality is calculated by level of care,

not target group. The Instructions and Technical Guide for section 1915(c) HCBS waivers provide guidance on calculating cost neutrality with multiple levels of care in one waiver. The current waiver application already prompts the user to enter costs for each level of care and then aggregates them for one combined cost neutrality test. States can choose to combine multiple target groups in a single waiver or continue to use separate waivers for each target group.

Comment: Several commenters shared concerns about cost limits negatively impacting particular populations by either being set too low or too high. CMS was also asked to calculate and monitor the baseline combined funding for individual populations.

Response: We do not believe that this change to regulation will have any impact on a state's choice to select or not select individual cost limits. We currently require states to report on funding for waiver services to ensure cost neutrality by waiver. At § 441.302(a)(4)(i), we have also included a requirement for states to report annually in the quality section of the CMS-372, data that indicates the state continues to serve multiple target groups in a single waiver and that a single target group is not being prioritized to the detriment of other groups.

Comment: A few commenters recommended that CMS require states to apply savings from newly combined waivers proportionately and equitably to target groups affected for the purpose of addressing waiting lists and expansion of access to waiver services.

Response: This comment goes beyond the statutory scope of what we can require in the context of section 1915(c) waivers.

Comment: A commenter asked CMS to clarify which state agency(s) will be authorized to implement the waiver (for example, state agency on aging or state agency dealing with ID/DD issues) when a state chooses to submit a combined waiver.

Response: In accordance with § 431.10, the Medicaid Agency is responsible for ensuring that a waiver is operated in accordance with applicable federal regulations and the provisions of the waiver itself. However, it may delegate operational activities and functions to another state agency (operating agency) to perform under the supervision and oversight of the State Medicaid Agency. Decisions around the design of waiver administrative structures rest with the state, subject to CMS requirements that the Medicaid Agency retains ultimate authority and

responsibility for the operation of the waiver. Greater detail on waiver administrative structures is provided in the Instructions and Technical Guide for section 1915(c) waivers.

Comment: Several commenters indicated that CMS should employ the lessons learned through the Aging and Disability Resource Center (ADRC) model.

Response: We agree that allowing states, at their discretion, to combine target groups in one waiver is consistent with one of the principles of the ADRC model to allow a cross disability population approach, as appropriate. Further, and as some other commenters noted, it is critical that if states choose to combine target populations in one waiver, they must assure CMS that they are able to meet the unique service needs that each individual may have regardless of target group, and that each individual in the waiver has equal access to all needed services.

Comment: Several commenters raised clarifying questions about combining of target groups. One commenter asked how waitlists would be handled—by population group, services or in some other manner. Several other commenters requested further clarification around wait lists.

Response: Through current guidance in the Instructions and Technical Guide for section 1915(c) waivers, CMS allows states to prioritize selection of entrants into a waiver, so a state has the flexibility to structure prioritization for waiver entry. However, once a person has entered the waiver all included services must be made available to those who need them (as indicated in the person-centered assessment and service plan).

Comment: One commenter asked CMS to clarify what “equal access” means. “Can there be different sets of services within a combined waiver targeted to specific groups?”

Response: Equal access means that once individuals have enrolled in the waiver all services in the waiver must be made available to them, if needed (as indicated in the person-centered assessment and service plan).

Comment: Commenters raised several concerns related to case management. One commenter stated that the case management entity should not be able to also be the agency that is administering the self-directed hours as the payroll agent. Another commenter expressed concern about combining disability populations in terms of quality of case management provided, the number of people for whom states can provide case management and how states can differentiate populations and services.

Response: We continue to appreciate the critical role of case management in the lives of waiver participants. How states set up their case management system for a waiver with combined target groups will be an important consideration. Through appropriate provider qualifications, we believe that states will be able to ensure that waiver case management services meet the needs of populations served.

Comment: There were several themes amongst the many commenters who agreed with the proposed language in the rule. These themes included supporting flexibility to allow a family-based approach to service design and delivery, improving access, reducing inequities and fragmentation between disability groups and improving administrative efficiencies at both the provider and state levels. Several commenters spoke favorably about how combining target groups would allow both an aging parent and a person with intellectual disabilities to be served in the same waiver. Other commenters commended CMS for breaking down “silos” between populations of people with different disabilities by allowing states to combine target groups in waivers. A few commenters expressed particular support related to the rule change's potential impact on expanding opportunities for people with mental illness to be served in waivers, as they have historically been underserved in section 1915(c) of the Act waivers.

Response: We appreciate these comments and are retaining the proposed language in this section of the rule.

4. State Assurances (§ 441.302)

In an effort to ensure that safeguards are in place to protect the health and welfare of each waiver participant, we proposed in a new paragraph § 441.302(a)(4) that to choose the option of more than one target group under a single waiver, states must assure CMS that they are able to meet the unique service needs that each individual may have regardless of target group, and that each individual in the waiver has equal access to all needed services.

Comment: Many commenters who agreed with the proposed changes in targeting stated that a comprehensive service array that “meets the unique service needs” of each individual in each target group is critical and that regulation language needs to be strengthened. Additionally, they believe that the provider expertise for specialty populations needs to be maintained. Multiple commenters singled out people with ID/DD in this vein as being at risk without appropriate safeguards to tailor

service packages and provider qualifications to meet their needs.

Response: We agree with this comment and strengthened the language included in § 441.302(a)(4) that directs states to ensure that the unique service needs are met. For participants enrolled in the same waiver, states cannot restrict services to certain target groups or choose to provide some services only to people with particular diagnoses. The language in the final rule at § 441.302(a)(4) will now read, “Assurance that the state is able to meet the unique service needs of the individuals when the state elects to serve more than one target group under a single waiver, as specified in § 441.301(b)(6).”

Comment: One commenter noted that “selects to serve” should be changed to “elects to serve” in regard to state choice about combining target populations in proposed § 441.302(a)(4).

Response: We agree and will change the regulation text to read “elects to serve” instead of “selects to serve” at § 441.302(a)(4).

In addition, to ensure that services are provided in settings that are home and community-based, we proposed in a new paragraph § 441.302(a)(5) that states provide assurance that the settings where services are provided are home and community based, and comport with new paragraph § 441.301(c)(4). While we are not changing the existing quality assurances through this rule, we clarified that states must continue to assure health and welfare of all participants when target groups are combined under one waiver, and assure that they have the mechanisms in place to demonstrate compliance with that assurance.

We received no comments on § 441.302(a)(5) and we will adopt the proposed language.

5. Duration, Extension, and Amendment of a Waiver (§ 441.304)

At § 441.304, we made minor revisions to the heading to indicate the rules addressed under this section. We revised § 441.304(d) and redesignated current § 441.304(d) as new § 441.304(g).

a. Waiver Amendments With Substantive Changes (§ 441.304(d))

The new § 441.304(d) will codify and clarify our guidance (*Application for a section 1915(c) Home and Community-Based Waiver, V. 3.5, Instructions, Technical Guide and Review Criteria, January 2008*) regarding the effective dates of waiver amendments with substantive changes, as determined by CMS. Substantive changes 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 added regulatory language reflective of our guidance that waiver amendments with changes that we determine 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.

CMS received 43 comments regarding § 441.304(d), which will clarify and codify existing technical guidance governing the effective dates of waiver amendments that make substantive changes.

Comment: Several commenters expressed concern that this requirement could be problematic if a state is directed by its legislature to make a change to a waiver program prior to CMS approval of an amendment implementing that change. CMS should consider this possibility as it finalizes this rule. There is no allowance for emergency situations or changes that might benefit clients or providers in the broad definition of “substantive.”

Response: The intention in the rule is to codify our current practice regarding what types of amendments must be implemented prospectively.

Comment: A commenter thought that retroactive approvals of waiver amendments should never be allowed.

Response: We believe there are situations when a retroactive approval is permissible. For example, codifying the continuation of the current practice for states of being able to increase the number of waiver participants served retroactively allows states to serve more people, while continuing to plan and manage waiver growth within their budgets.

Comment: A number of commenters wanted CMS to further clarify what constitutes a substantive change; however, the commenters varied in what they believe a substantive change should include. Several suggested that only changes to eligibility standards, procedures, or methodologies should be considered substantive; others recommended that elimination or reduction in services, and changes in the scope, amount and duration of services, as well as changes in provider rates, would always constitute “substantive changes.”

Response: Given the range of comments on what a list of substantive changes should include, we believe it prudent to maintain most of the

language in the proposed rule around the types of examples of substantive changes, while leaving flexibility to the Secretary to determine other types of proposed changes that may also be considered substantive. We have, however, changed the phrase “change in the eligible population” to “constriction in the eligible population” in the final rule to be more specific about the kind of change that would constitute a “substantive change.” We have also rewritten the phrase “changes in the scope, amount, and durations of the services” to read “reduction in the scope, amount, or duration of any service” to further clarify what constitutes a substantive change. We also believe that a listing of only changes to eligibility standards, procedures, or methodologies is too broad regarding what constitutes a substantive amendment. We do, however, make clear that a state must submit amendments for prospective review and approval by CMS that may have a potentially negative impact on waiver participants, as well as that the amendment must be accompanied by information on how the state has assured smooth transitions and minimal adverse impact on individuals affected by the change.

Comment: Several commenters wanted CMS to be more precise with language in this section of the rule. One asked that the list of examples of substantive items not be defined as exhaustive and several other commenters thought the use of “may include” in regard to substantive changes, was too permissive. Another commenter recommended that CMS state that the elimination or reduction in services and changes in the scope, amount, and duration of services will always constitute “substantive changes.”

Response: We agree that the term “may include” is not sufficiently precise to be helpful. We have deleted the word “may” from § 441.304(d)(1) and have rewritten this section of the rule as follows: “Substantive changes include, but are not limited to, revisions to services available under the waiver including elimination or reduction of services, or reduction in the scope, amount, and duration of any service, a change in the qualifications of service providers, changes in rate methodology or a constriction in the eligible population.” We believe the current language noting that the list of substantive examples is not limited to just the changes listed is sufficiently clear.

Comment: A few commenters wanted CMS to allow states to gain retroactive

approval to the date of the submission of the amendment, as opposed to the date CMS approved the amendment. The commenters noted that using the date of CMS approval can present significant challenges to a state when it is under legislative mandate to make a change or implement a budget initiative.

Response: While we are sympathetic to the budgetary challenges faced by states, we believe it would not be in the best interest of waiver participants to allow approval retroactive to the date of substantive amendment submissions. The rule reflects and maintains our current waiver amendment review procedures.

Comment: Commenters agreed with several aspects of the proposed language in the rule regarding substantive changes to amendments. Some liked that CMS is not allowing substantive changes in an already existing waiver to take effect until the waiver has been approved by CMS, as this will help ensure that waivers fulfill the mandate of the HCBS waiver program. A commenter agreed with CMS's definition of substantive changes. Another commenter noted that he liked that a state will need to demonstrate how it will ensure smooth transition and minimal disruption to service or adverse impact of a change on beneficiaries.

Response: We concur with these comments. We agree that the rule is being changed to achieve the purposes outlined by these commenters.

b. Public Notice and Input (§ 441.304(e) and (f))

Given the important requirement at § 447.205, which describes states' responsibilities to provide public notice when states propose significant changes to their methods and standards for setting payment rates for services, we added a new paragraph § 441.304(e) to remind states of their obligations under § 447.205. We further included a new paragraph § 441.304(f) directing that states establish public input processes specifically for HCBS changes. These processes, commensurate with the change, could include formalized information dissemination approaches, conducting focus groups with affected parties, and establishing a standing advisory group to assist in waiver policy development. These processes must be identified expressly within the waiver document and used for waiver policy development. The input process must be accessible to the public (including individuals with disabilities) and states must make significant efforts to ensure that those who want to participate in the process are able to do so. These

processes must include consultation with federally-recognized Indian Tribes in accordance with federal requirements and the state must seek advice from Indian health programs or Urban Indian Organizations prior to submission of a waiver request, renewal, amendment or action that would have a direct effect on Indians or Indian health providers or Urban Indian Organizations in accordance with section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, enacted on February 17, 2009).

We received 102 comments regarding § 441.304(e) and (f), which would clarify the public input and notice requirements for all section 1915(c) waiver actions.

Comment: One commenter thought the description of a public input process for any changes in services or operations of a waiver was too broad.

Response: The intent in the rule is to strengthen our current practice of encouraging states to engage in a public input process in order to ensure such input without being overly prescriptive to states in how that process is implemented. The language in the rule gives states examples for soliciting such public input, while not limiting additional methods that may work better in particular states and/or for particular waivers.

Comment: Several commenters asked CMS to provide more specific requirements around process, time frames and methods used for public input. One suggested adding a provision that states must provide public notice of waiver amendments and provide information, training, and technical assistance to stakeholders, including individuals enrolled in the waiver and their families, when waiver amendments include substantive changes. Another suggested that we require specific activities that would ensure real input, participation and transparency; such as minimum times for posting notice of changes (30 days), listing of specific mechanisms or venues for posting, a listserv, mandatory stakeholder meetings, posting on CMS Web sites of all active and pending waivers, submission of all public comments and state actions to address those comments. Other commenters suggested more generally that CMS establish some threshold for minimum public input process elements in the regulation. Another approach recommended was for CMS to provide a standard against which a state will be measured to demonstrate that a public input process is "sufficient."

Response: While we appreciate the suggestions of the commenters to

strengthen the public notice and input requirements in the regulation, we believe that the level of detail suggested in some of the comments is not appropriate for regulation; additionally, some of these suggestions may be addressed in future guidance. However, we do agree with the comment suggesting implementing a minimum amount of time for posting notice of changes. In the final rule, we have included language stating that we will require that the State provide the public a period of no less than 30 days in which to provide input on a rule change prior to implementation of that change or submission of the proposed change to CMS, whichever comes first.

Comment: One commenter was concerned that extensive public input periods could prove challenging.

Response: We believe that the time period specified is not extensive, but rather appropriate to allow for meaningful public input based on the breadth of the changes.

Comment: A commenter expressed concerns that since states are already required to develop a process for tribal consultation that meets ARRA requirements, requiring the state to consult with all the tribes would require a different process for waiver changes.

Response: We do not believe that the guidance in the rule is in conflict with provisions in 5006(e) of the American Recovery and Reinvestment Act of 2009 (ARRA), which required solicitation of advice from Indian health programs and urban Indian organizations.

Comment: A number of commenters thought CMS should provide further clarification on what types of actions are considered substantive and would be subject to a public input process; however, there were differing opinions as to what level of change required public input. Several commenters thought it should include changes in policies such as qualifications of service providers, eligibility requirements, and changes to services covered in the waiver. Others thought that any changes in services or operations of the waiver would require public notice and input.

Response: Consistent with our response to comments regarding waiver amendments with substantive changes, we believe that it would be difficult to come up with an exhaustive list of specific items that would be considered substantive beyond the general categories we listed in the proposed rule. Further, what may be a substantive change for one waiver may be less significant in a different waiver or in a different state depending on the waiver design and the service package. Therefore, we believe that the regulation

is currently worded to invite public input when it is appropriate; adding further detail in the regulation would not be beneficial.

Comment: A number of commenters made recommendations about accessibility standards to ensure that the broadest range of stakeholder input is obtained. Most specifically, commenters wanted to assure that people with disabilities, including people with vision and hearing impairments; other cognitive, mental, or physical disabilities; and people with limited English proficiency were included in the process in a meaningful way. One of the suggestions was to make sure they were included on standard advisory groups. Again, the suggested methods to accomplish this level of accessibility varied greatly. A commenter asked that CMS include language from the preamble in regulatory text that requires accessibility for public input. Others asked that CMS detail how individuals or organizations can submit oral or written input. While there were a few comments that service providers should be required to be part of an input process, we received more comments about making sure that people with disabilities have access to an input process.

Response: By requiring states to detail the processes they used to solicit input from the public in the waiver application, we will have an appropriate oversight mechanism to review the integrity of a specific waiver and specific state processes. We also have a mechanism, as noted in the proposed rule at § 441.304(f)(1), to specifically look at how the process included and was made accessible to people with disabilities. This requirement specifies that, “this process must be described fully in the state’s waiver application and be sufficient in light of the scope of the changes proposed, to ensure meaningful opportunities for input for individuals served, or eligible to be served, in the waiver.”

Comment: A theme from several commenters was that CMS should establish specific guidelines and accountability mechanisms for states around public notice. Some of the types of suggestions we received included requests for CMS to: add a requirement that the agency reply to public comments received; file the public comments and agency replies with CMS; include language to require written legal decisions for compliance with Open Meetings Act/Sunshine Laws; add an accountability measure to use a public input process for a state agency; and monitor compliance through subsequent audits that would

include interviews with people with disabilities and other stakeholders to determine the level of public input and decision making.

Response: By requiring states to describe in the waiver application the processes they used to solicit input from the public, we will have an appropriate oversight mechanism to review the integrity of the process, while allowing states flexibility to implement public input processes that make sense for the specific waiver and the state or are required under state law. We will consider whether further guidance along these lines would be helpful.

Comment: A commenter wanted CMS to clarify that the public input process should apply to new waivers and not just existing waivers.

Response: We concur with this comment and clarified in the rule that the public input process should be for both existing waivers that have substantive changes proposed, either through the renewal or the amendment process, and new waivers. We also clarified that the public input process must be fully described in a state’s waiver application.

Comment: Several other comments received went beyond the scope of the regulation, such as asking for more transparency in negotiations between CMS and states regarding review of waiver actions. Another asked for an assurance that input gathered from the public should influence change.

Response: The scope of the regulation was not intended to address our review process and review criteria, which is addressed further in the Instructions and Technical Guide for section 1915(c) HCBS waivers. We believe that the regulation changes strengthen requirements for states to solicit meaningful public input prior to waiver submissions to CMS, which will help states in making decisions about the design and operation of their waiver programs that benefit the populations to be served.

Comment: Commenters noted CMS was not clear on whether there were any differences between public input regarding rate changes and notice for operations and service changes, as these two areas were described separately in the proposed rule.

Response: Since there are already existing regulations that address notice requirements to methods and standards of setting payment rates across Medicaid authorities, we are reminding states of those obligations with the rule. In addition, in this rule we are adding new provisions regarding public notice for HCBS changes that are similar to those for setting payment rates.

Comment: There were several themes among the many commenters who agreed with the proposed language in the rule regarding public notice and input. Commenters supported the requirement that state agencies must provide public notice of any significant proposed change in their methods and standards for setting payment rates for services. They also appreciated the inclusion of stakeholders in the process. Commenters expressed agreement with CMS that public input is important for waiver development and that the input process must be accessible to the public (including persons with disabilities), and a state must be required to make efforts to ensure that those who want to participate can do so.

Response: We concur with these comments. We agree that the rule is being changed to achieve the purposes outlined by those commenters who support the proposed rule change.

c. Selecting Strategies To Ensure Compliance (§ 441.304(g))

In new paragraph, § 441.304(g), we added language describing additional strategies we may employ to ensure state compliance with the requirements of a waiver, short of termination or non-renewal. Our regulation at new § 441.304(g) reflects an approach to encourage state compliance. We are interested in working with states to achieve full compliance without having to resort to termination of a waiver. Therefore, we proposed strategies to ensure compliance in serious situations short of termination. These strategies include use of a moratorium on waiver enrollments or withholding federal payment for waiver services or administration of waiver services in accordance with the seriousness and nature of the state’s noncompliance. These strategies could continue, if necessary, as the Secretary determines whether termination is warranted. Our primary objective is to use such strategies rarely, only after other efforts to resolve issues to ensure the health and welfare of individuals served or to resolve other serious non-compliance issues have not succeeded.

Once CMS employs a strategy to ensure compliance, the state must submit an acceptable corrective action plan in order to resolve all areas of noncompliance. The corrective action plan must include detail on the actions and timeframe the state will take to correct each area of noncompliance, including necessary changes to the quality improvement strategy and a detailed timeline for the completion and implementation of corrective actions.

We will determine if the corrective action plan is acceptable.

We received 50 comments on § 441.304(g) regarding the actions we can take if a Medicaid agency is substantively out of compliance with waiver requirements.

Comment: One commenter stated that they believed the standard audit process was the best way to achieve compliance.

Response: Onsite visits and audits are a tool we utilize to ensure states clearly understand our guidance and adhere to regulatory requirements. After 30 years of running the section 1915(c) waiver program, it has become clear that other methods are needed to ensure the welfare of our beneficiaries.

Comment: Commenters stated their concern with the potential harm to beneficiaries that could result from moratoria on waiver enrollments and urged us to use the moratoria as a last resort.

Response: We understand the potential negative effects a moratorium on waiver enrollments may have on beneficiaries. Opportunities exist, such as technical assistance and corrective action plans, to assist a state to achieve compliance without the use of a moratorium. We will always be ready to assist states through these means before moving forward with a moratorium. We also note that the main compliance tool currently available to us, termination of the waiver, has the potential to harm an even higher number of individuals needing HCBS.

Comment: Many commenters agreed with the use of withholding a portion of federal payment.

Response: Certain tools, such as withholding a portion of federal payment, will only be utilized when necessary and after most other options have been exhausted. At this time, we believe we will see the necessary results to be assured that the care of our beneficiaries is foremost to states.

Comment: One commenter recommended transparency as to where withheld funds will go and how these funds will be used.

Response: We are committed to transparency. We will release the information we are legally allowed to make public.

Comment: One commenter suggested we clarify whether the opportunity for a hearing will be afforded when a state disputes compliance rulings similar to the processes and safeguards specified in part 430 subpart D.

Response: We reiterate that these additional enforcement measures are part of a broader array of approaches we may take to achieve and maintain full compliance with the requirements

specified in section 1915(c) of the Act, in addition to waiver termination. States will be afforded an opportunity to appeal. The procedures specified in subpart D of part 430 of this chapter are applicable to state requests for hearings on all non-compliance actions, including terminations.

Comment: Many commenters wanted assurances from CMS that due process procedure will be followed before a moratorium is set or funds are withheld and that enforcements should be waiver specific.

Response: The tools discussed to ensure compliance will only be utilized after we have tried several other remedies, including technical assistance and action plans. We will provide states with a written notice of the impending strategies to ensure compliance for a waiver program. The notice of our intent to use strategies to ensure compliance will include the nature of the noncompliance, the strategy to be employed, the effective date of the compliance strategy, the criteria for removing the compliance strategy and the opportunity for a hearing as specified in subpart D of part 430.

Comment: One commenter suggested that CMS develop a way to cover the cost of training while a state is under a compliance strategy.

Response: Compliance is a state's responsibility when accepting federal financial funding. That funding may be used to ensure compliance measures are in place.

Comment: One commenter expressed support for the use of compliance strategies other than termination or nonrenewal.

Response: We agree that additional options for promoting and ensuring state compliance with HCBS waiver requirements should be available. We have therefore added the phrase "or other actions as determined by the Secretary as necessary to address non-compliance with section 1915(c) of the Act" to the regulation text.

IV. Provisions of the Final Regulations

A. 1915(k) Community First Choice and 1915(i) State Plan Home and Community-Based Services

The provisions proposed as new subpart L, consisting of § 441.650 through § 441.677, added to part 441 will be codified as subpart M, consisting of § 441.700 through § 441.745.

For the most part, this final rule incorporates the provisions of the proposed rule. In response to comments as explained in the responses in the above section, those provisions of this final rule that differ from the proposed rule are as follows:

Under § 430.25 (waivers of State plan requirements), we added "and in a manner consistent with the interests of beneficiaries and the objectives of the Medicaid program." This was language from the preamble of the proposed rule, for which we received a comment requesting that it also be incorporated into the text of the final regulation.

In response to many comments received, and for the reasons provided in the responses above for each specific provision, we revised and added new language to § 441.530(a), regarding home and community-based setting requirements for 1915(k) and to § 441.710(a), regarding home and community-based setting requirements for 1915(i). In addition to those specific provisions, we examined the overall themes of the commentary received and our basis for the HCB settings requirements as a whole. All of the overall ideas may be found within the summary of comments and our responses in the above section, which are organized by specific provisions of the proposed rules.

In § 440.182(c)(8), which refers to conditions set forth at § 440.180 for persons with chronic mental illness, we have revised this reference to § 440.180(d)(2) to be more precise.

Under eligibility for home and community-based services under § 441.710(d), we corrected the reference to target criteria from (b)(2) to (e)(2).

Under § 441.710(e)(2)(ii), we corrected the reference to § 440.182(b) to § 440.182(c).

We have corrected § 441.715(b)(2) to replace the reference to (c)(7) to instead specify (c)(6).

We have corrected § 441.715(c) by replacing "the Secretary will approve" with "the Secretary may approve."

We have corrected § 441.715(d) to replace the reference to section 441.710(a)(1) to § 441.658.

In § 441.715(d)(2), we have revised the reference to § 441.656 so that it now reads correctly as a reference to § 435.219 and § 436.219.

At § 441.720(a)(1), we made a minor correction and added a cross reference after "person-centered process" to § 441.725(a).

At § 441.720(a)(1)(i)(A), we revised the language to be consistent with other language in this regulation.

We added "cognitive" to § 441.720(a)(4) in response to comments received, to specifically include assessment of needs related to cognitive impairment.

We have revised the first sentence of § 441.720(a)(5).

In response to numerous comments received regarding the section 1915(i) of

the Act person-centered planning process and person-centered service plan, and in order to align these requirements across sections 1915(c) and 1915(i) of the Act HCBS, we have modified the requirements in § 441.725 of this final rule. In addition, we examined the overall themes of the commentary received. An explanation of changes to regulation as a result of comments received may be found within the responses in the section above.

In § 441.730(c), we added “cognitive” and current knowledge of “available resources, service options, and providers” to this requirement.

We added a new statement to § 441.735(a) regarding the definition of individual’s representative to indicate that in instances where state law confers decision-making authority to the individual representative, the individual will lead the service planning process where possible and the individual representative will have a participatory role, as needed and as defined by the individual.

We revised § 441.735(c).

We revised § 441.740(b)(4).

For clarity, we have moved the requirement regarding financial management supports that was previously at both § 441.674(c)(2) and § 441.674(d)(4) of the proposed rule, to a new (5) under § 441.740(b) of this final rule.

We edited employer authority at § 441.740(c) to ensure consistency with statutory language, by replacing “or” with “and” so that it now reads as “the ability to select, manage, and dismiss providers of State plan HCBS.”

We revised § 441.740(e)(3).

Since advance notice is a topic in part 431, subpart E, we have added “advance notice” to the regulation at § 441.745(a)(1)(iii).

We revised § 441.745(a)(2)(vi) to specify that for renewal, the state’s 1915(i) benefit must meet the state’s objectives with respect to quality improvement and beneficiary outcomes.

We revised § 441.745(b)(1)(ii) to add language that was in the preamble of the proposed rule.

B. 1915(c) Home and Community Based Services Waivers

We have outlined in section III of this preamble the revisions in response to the public comments. Those provisions of this final rule that differ from the proposed rule are as follows:

Based upon the complexities of the comments received, we have reorganized the regulations to finalize the provisions proposed at § 441.301(b)(1)(i)(A) through

§ 441.301(b)(1)(i)(B)(12) as new paragraph § 441.301(c).

At § 441.301(c)(1) and (2), we made some general revisions to the terminology utilized to strengthen language regarding services. We added the term “supports” when referencing services to now use the language “services and supports.” We also revised person-centered plan as “person-centered service plan.”

At § 441.301(c)(1)(i) we added language to more clearly define the role of the individual’s representative and refer to the 1915(i) definition of the individual’s representative at § 441.735 in this rule.

We have revised § 441.301(c)(i)(ii) to more clearly state the individual’s role in directing the person-centered planning process.

We have revised § 441.301(c)(1)(iii) to include a requirement for timeliness.

We have revised § 441.301(c)(1)(v) to strengthen this language to direct that the state devise clear conflict-of-interest guidelines addressed to all parties who participate in the person-centered planning process.

We have added a new provision at § 441.301(c)(1)(vi) to clarify conflict of interest standards pertaining to providers of HCBS. The proposed text at § 441.301(b)(1)(i)(A)(6) through (8) all shifted down by one number and are included in the final rule at § 441.301(c)(1)(vii) through (ix).

We have revised § 441.301(c)(1)(vii) to clarify that individuals should be informed of all the possibilities from which they may choose regarding services, as well as the consequences of these choices.

We added a new provision at § 441.301(c)(1)(ix) to clarify that the setting in which an individual resides is an important part of the person-centered planning process.

We have revised § 441.301(c)(2) to align the language with other HCBS authorities.

We have added a new provision at § 441.301(c)(2)(i) to ensure that the individual’s choice of setting is documented in the person-centered service plan. The proposed text at 441.301(b)(1)(i)(B)(1) through (5) all shifted down by one number and is included in the final rule at § 441.301(c)(2)(ii) through (vi). In addition, we added language to ensure community integration.

We have revised § 441.301(c)(2)(iii) and (iv) to align the language with other HCBS authorities.

We have revised § 441.301(c)(2)(v) by adding further clarifying language regarding “natural supports.”

We have revised previously numbered § 441.301(b)(1)(i)(B)(6) to clarify privacy and control over personal information and have moved this requirement to § 441.301(c)(2)(ix).

We have revised § 441.301(c)(2)(vi) to strengthen the language regarding risks for individuals.

We removed § 441.301(b)(1)(i)(B)(8) from the final rule because this requirement is a part of the person-centered planning requirements at § 441.301(c)(1)(iii) and (vii).

We revised § 441.301(c)(2)(xi) to provide clarifying language regarding the requirement for self-direction of services.

We revised § 441.301(c)(2)(xii) to replace the term “care” with the term “services and supports.”

We added new language at § 441.301(c)(2)(xiii) and at § 441.301(c)(3) to align with other HCBS authorities.

We revised § 441.301(c)(4) by replacing the language with new standards for HCBS settings that are aligned with other HCBS authorities.

We added a provision at § 441.301(c)(5) to specify the settings that are not home and community-based.

We added a new provision at § 441.301(c)(6) to specify the requirements for States to achieve compliance with the HCB settings standards.

We revised § 441.302(a)(4) to clarify the expectations that each individual within a waiver, regardless of target group, has equal access to the services necessary to meet their unique needs. In addition, we made a technical correction by changing “selects to serve” to “elects to serve.”

We have added a new provision at § 441.302(a)(4)(i) directing states to annually report data in the quality section of the CMS–372 regarding serving multiple target groups in a single waiver to ensure that a single target group is not being prioritized to the detriment of other groups.

We revised § 441.304(d)(1) to be more specific about the kind of change that constitutes a “substantive change” regarding HCBS waiver amendments.

We added a new provision at § 441.304(f)(2) to strengthen the public notice and input process by including a minimum time limit for posting notice of changes.

We added a new provision at § 441.304(f)(3) to clarify when the public input process applies.

We revised § 441.304(g)(3)(i) to clarify that additional options for promoting and ensuring state compliance with

HCBS waiver requirements should be allowed.

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 (PRA) 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 solicited public comment on each of these issues for the following sections of this document that contain information collection requirements:

□ 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 are 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.

□ ICRs Regarding Eligibility for State Plan HCBS (§ 441.710) (Proposed § 441.656)

If a State elects to target the benefit to specific populations, § 441.710(e)(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.

□ ICRs Regarding Needs-Based Criteria and Evaluation § 441.715 (Proposed § 441.659)

Section 441.715(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 441.715(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 441.715(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 441.715(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 441.715(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 441.715(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 § 441.715(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 (§ 441.715(c), § 441.715(c)(1), and § 441.715(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 441.715(d) states that eligibility for the State plan HCBS benefit is determined, for individuals who meet the requirements of § 441.710(a)(1) through (5), through an independent evaluation of each individual that meets the specified requirements. Section 441.715(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 441.715(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 HCBS 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 developmental disability 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.

□ ICRs Regarding Independent Assessments § 441.720 (Proposed § 441.662)

Section 441.720 requires the State to provide for an independent assessment of need in order to establish a person-centered service plan. At a minimum, the person-centered service plan must meet the requirements as discussed under § 441.725.

While the burden associated with the requirements under § 441.720 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.

□ ICRs Regarding State Plan HCBS Administration: State Responsibilities and Quality Improvement § 441.745 (Proposed § 441.677)

Section 441.745(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 441.745(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 441.745(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 441.745(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 441.745(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 □ 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 6 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 (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
435.219(b) and 436.219(b)	0938-1148	3	3	30	90	34.34	1,030	0	1,030
441.656(e)(2) of proposed rule; 441.710(e)(2) of final rule	0938-1148	3	3	10	30	34.34	1,030	0	1,030
441.659(a) of proposed rule; 441.715(a) of final rule	0938-1148	3	3	24	72	34.34	2,472	0	2,472
441.659(b) of proposed rule; 441.715(b) of final rule	0938-1148	3	3	1	3	34.34	103	0	103
441.677(a)(1)(i) of proposed rule; 441.745 (a)(1)(i) of final rule	0938-1148	6	6	2	12	34.34	414	0	414
441.677(a)(2)(iii) of proposed rule; 441.745 (a)(2)(iii) of final rule	0938-1148	3	3	2	6	34.34	207	0	207
441.677(a)(2)(iv) of proposed rule; 441.745(a)(2)(iv) of final rule	0938-1148	3	3	2	6	34.34	207	0	207
441.677(b) of proposed rule; 441.745 of final rule	0938-1148	6	6	45	270	34.34	9,270	0	9,270
Total					489		14,733	0	14,733

VI. Regulatory Impact Analysis

A. 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 (DRA) 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 (CFR). Additionally, these regulations provide states with direction and clarity regarding the framework under which the programs can be established.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

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 final 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.

C. Overall Impacts

We estimate that, as a result of this final rule, the Medicaid cost impact for provisions under 1915(i) for fiscal year (FY) 2014 will be \$150 million for the federal share and \$115 million for the state share. The estimates are adjusted for a phase-in period during which states gradually elected to offer the state plan HCBS benefit. Furthermore, the estimated total annual collection of information requirements cost (including fringe benefits and overhead) to states is \$21,805 (see section V. Collection of Information Requirements).

Provisions in this rule pertaining to section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects (Waivers), Provider Payment Reassignments, section 2401 of the Affordable Care Act: 1915(k) Community First Choice State Plan

Option: Home and Community-Based Setting Requirements, and 1915(c) Home and Community-Based Services Waivers will not impact federal or state Medicaid funding. While States may incur costs in coming into compliance with these provisions in this rule, given the variability in State programs, and the varying extent to which some are already complying, it is difficult to estimate these costs.

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 adjust 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 person-centered service plan,

and the provision of needed HCBS in accordance with the person-centered 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 HCBS 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. 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 2014–2018, in \$millions]

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FYs 2014–2018
Federal Share	\$150	\$165	\$185	\$200	\$225	\$925
State Share	115	125	140	155	170	705
Total	265	290	325	355	395	1,630

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 benefit.

E. Alternatives Considered

This final 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 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.

1. Not Publishing a Rule

Section 1915(i) of the Act was effective January 1, 2007. States may propose state plan amendments (SPAs) to establish the state plan HCBS benefit with or without this final 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 concluded 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 the 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 federally funded benefits.

2. Modification of Existing Rules

We considered modifying existing regulations at § 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 and other impacts associated with the provisions of this final rule. This table provides our best estimate of the 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.

TABLE 3—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND OTHER IMPACTS, FROM FYS 2014 TO 2018
[In \$millions]^a

Category	Transfers	
Annualized Monetized Transfers	3% Units Discount Rate \$183.5	7% Units Discount Rate \$182.1
From Whom To Whom?	Federal Government to Beneficiaries and/or State Governments ^b	
Category	Transfers	
Other Annualized Monetized Transfers	3% Units Discount Rate \$138.6	7% Units Discount Rate \$137.5
From Whom To Whom?	State Governments to Beneficiaries and/or State Governments ^b	
Category	Costs	

Total Annual Collection of Information Requirements Cost to States is \$0.02.

^a The potential benefits of this rule have not been quantified. If beneficiaries who newly use HCBS as a result of this rule are currently being institutionalized at states' expense, the rule would generate some combination of savings to states (equal to the cost difference between institutionalization and HCBS) and benefits to beneficiaries of being at home or in some other setting in the community, rather than an institution. Similarly, there would be benefits to beneficiaries who newly use HCBS if they are currently not receiving needed services.

^b If the current status is that beneficiaries are paying for services alternative to HCBS themselves, then transfers are flowing from federal and state governments to beneficiaries. If beneficiaries are currently being institutionalized at states' expense, then transfers are from the federal government to state governments and possibly between pools of money within a state—from one pool with inflexible spending rules that require institutional care to another pool that allows for HCBS. Finally, to the extent that beneficiaries are currently not receiving needed services, then some portion of the impacts currently categorized as "transfers" would actually be societal costs.

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 analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.0 million to \$34.5 million in any 1 year. 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 final 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 final rule. The Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule does not offer a change in the administration of the provisions related to small rural hospitals. Therefore, the Secretary has determined that this final 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 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately \$141 million. This final rule does not mandate any spending by state, local, or tribal governments, in the aggregate, or by the private sector, of \$141 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 Subjects

42 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 amends 42 CFR chapter IV as set forth below:

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

n 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).

n 2. Section 430.25 is amended by revising paragraphs (h)(2) to 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.

(A) The initial waiver is for a period of 3 years and may be renewed thereafter for periods of 5 years.

(B) 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, and in a manner consistent with the

interests of beneficiaries and the objectives of the Medicaid program.

(ii) Waivers under section 1915(b) of the Act.

(A) 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.

(B) 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, and in a manner consistent with the interests of beneficiaries and the objectives of the Medicaid program.

(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

n 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).

n 4. Section 431.54 is amended by adding new 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

n 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).

n 6. Section 435.219 is added to subpart C under the undesignated center heading "Options for Coverage of Families and Children and the Aged, Blind, and Disabled" to read as follows:

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

If the agency provides State plan 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 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 § 441.715 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.

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

n 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).

n 8. Section 436.219 is added to read as follows:

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

If the agency provides State plan 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 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 § 441.715 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.

PART 440—SERVICES: GENERAL PROVISIONS

n 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).

n 10. Section 440.1 is amended by adding the new statutory basis 1915(i) in sequential 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.

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

§ 440.180 Home and community-based waiver services.

* * * * *

n 12. Section 440.182 is added to read as follows:

§ 440.182 State plan home and community-based services.

(a) *Definition.* State plan home and community-based services (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).
- (7) Respite care services.
- (8) Subject to the conditions in § 440.180(d)(2), 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

n 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).

n 14. Section 441.301 is amended by revising paragraphs (b)(1)(i) and (b)(6) and adding paragraph (c) to read as follows:

§ 441.301 Contents of request for a waiver.

* * * * *

(b) * * *

(1) * * *

(i) Under a written person-centered service plan (also called plan of care) that is based on a person-centered approach and is subject to approval by the Medicaid agency.

* * * * *

(6) Be limited to one or more of the following target groups or any subgroup thereof that the State may define:

- (i) Aged or disabled, or both.
- (ii) Individuals with Intellectual or Developmental Disabilities, or both.
- (iii) Mentally ill.

(c) A waiver request under this subpart must include the following—

- (1) *Person-Centered Planning Process.* The individual will lead the person-centered planning process where possible. The individual's representative should have a participatory role, as needed and as defined by the individual, unless State law confers decision-making authority to the legal representative. All references to individuals include the role of the individual's representative. In addition to being led by the individual receiving services and supports, the person-centered planning process:

(i) Includes people chosen by the individual.

(ii) 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.

(iii) Is timely and occurs at times and locations of convenience to the individual.

(iv) Reflects cultural considerations of the individual and is conducted by providing information in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter.

(v) Includes strategies for solving conflict or disagreement within the process, including clear conflict-of-interest guidelines for all planning participants.

(vi) Providers of HCBS for the individual, or those who have an interest in or are employed by a provider of HCBS for the individual must not provide case management or develop the person-centered service plan, except when the State demonstrates that the only willing and qualified entity to provide case management and/or develop person-centered service plans in a geographic area also provides HCBS. In these cases, the State must devise conflict of interest protections including separation of entity and provider functions within provider entities, which must be approved by CMS. Individuals must be provided with a clear and accessible alternative dispute resolution process.

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

(viii) Includes a method for the individual to request updates to the plan as needed.

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

(2) *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's 1915(c) HCBS waiver, the written plan must:

(i) Reflect that the setting in which the individual resides is chosen by the individual. The State must ensure that the setting chosen by the individual is

integrated in, and supports full access of individuals receiving Medicaid HCBS 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 to the same degree of access as individuals not receiving Medicaid HCBS.

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

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

(iv) Include individually identified goals and desired outcomes.

(v) 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 are unpaid supports that are provided voluntarily to the individual in lieu of 1915(c) HCBS waiver services and supports.

(vi) Reflect risk factors and measures in place to minimize them, including individualized back-up plans and strategies when needed.

(vii) Be understandable to the individual receiving services and supports, and the individuals important in supporting him or her. At a minimum, for the written plan to be understandable, it must be written in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter.

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

(ix) Be finalized and agreed to, with the informed consent of the individual in writing, and signed by all individuals and providers responsible for its implementation.

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

(xi) Include those services, the purpose or control of which the individual elects to self-direct.

(xii) Prevent the provision of unnecessary or inappropriate services and supports.

(xiii) Document that any modification of the additional conditions, under paragraph (c)(4)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(A) Identify a specific and individualized assessed need.

(B) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(C) Document less intrusive methods of meeting the need that have been tried but did not work.

(D) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(E) Include a regular collection and review of data to measure the ongoing effectiveness of the modification.

(F) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(G) Include informed consent of the individual.

(H) Include an assurance that interventions and supports will cause no harm to the individual.

(3) *Review of the Person-Centered Service Plan.* The person-centered service plan must be reviewed, and revised upon reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

(4) *Home and Community-Based Settings.* Home and community-based settings must 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 supports full access of individuals receiving Medicaid HCBS 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, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options including non-disability specific settings and an option for a private unit in a residential setting. The setting options are identified and documented in the person-centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes, but does not regiment, individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the qualities at § 441.301(c)(4)(i) through (v), the following additional conditions must be met:

(A) The unit or dwelling 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. For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS participant, and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law.

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

(1) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors.

(2) Individuals sharing units have a choice of roommates in that setting.

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

(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.

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

(F) Any modification of the additional conditions, under § 441.301(c)(4)(vi)(A) through (D), must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(1) Identify a specific and individualized assessed need.

(2) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(3) Document less intrusive methods of meeting the need that have been tried but did not work.

(4) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(5) Include regular collection and review of data to measure the ongoing effectiveness of the modification.

(6) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(7) Include the informed consent of the individual.

(8) Include an assurance that interventions and supports will cause no harm to the individual.

(5) *Settings that are not Home and Community-Based.* 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 individuals with intellectual disabilities;

(iv) A hospital; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. 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 any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

(6) *Home and Community-Based Settings: Compliance and Transition:*

(i) States submitting new and initial waiver requests must provide assurances of compliance with the requirements of this section for home and community-based settings as of the effective date of the waiver.

(ii) CMS will require transition plans for existing section 1915(c) waivers and approved state plans providing home and community-based services under section 1915(i) to achieve compliance with this section, as follows:

(A) For each approved section 1915(c) HCBS waiver subject to renewal or submitted for amendment within one year after the effective date of this regulation, the State must submit a transition plan at the time of the waiver renewal or amendment request that sets forth the actions the State will take to bring the specific waiver into compliance with this section. The waiver approval will be contingent on

the inclusion of the transition plan approved by CMS. The transition plan must include all elements required by the Secretary; and within one hundred and twenty days of the submission of the first waiver renewal or amendment request the State must submit a transition plan detailing how the State will operate all section 1915(c) HCBS waivers and any section 1915(i) State plan benefit in accordance with this section. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(B) For States that do not have a section 1915(c) HCBS waiver or a section 1915(i) State plan benefit due for renewal or proposed for amendments within one year of the effective date of this regulation, the State must submit a transition plan detailing how the State will operate all section 1915(c) HCBS waivers and any section 1915(i) State plan benefit in accordance with this section. This plan must be submitted no later than one year after the effective date of this regulation. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(iii) A State must provide at least a 30-day public notice and comment period regarding the transition plan(s) that the State intends to submit to CMS for review and consideration, as follows:

(A) The State must at a minimum provide two (2) statements of public notice and public input procedures.

(B) The State must ensure the full transition plan(s) is available to the public for public comment.

(C) The State must consider and modify the transition plan, as the State deems appropriate, to account for public comment.

(iv) A State must submit to CMS, with the proposed transition plan:

(A) Evidence of the public notice required.

(B) A summary of the comments received during the public notice period, reasons why comments were not adopted, and any modifications to the transition plan based upon those comments.

(v) Upon approval by CMS, the State will begin implementation of the transition plans. The State's failure to submit an approvable transition plan as required by this section and/or to comply with the terms of the approved transition plan may result in compliance actions, including but not limited to deferral/disallowance of Federal Financial Participation.

n 15. Section 441.302 is amended by adding paragraphs (a)(4) and (a)(5) to read as follows:

§ 441.302 State assurances.

* * * * *

(a) * * *

(4) Assurance that the State is able to meet the unique service needs of the individuals when the State elects to serve more than one target group under a single waiver, as specified in § 441.301(b)(6).

(i) On an annual basis the State will include in the quality section of the CMS-372 form (or any successor form designated by CMS) data that indicates the State continues to serve multiple target groups in the single waiver and that a single target group is not being prioritized to the detriment of other groups.

(5) Assurance that services are provided in home and community based settings, as specified in § 441.301(c)(4).

n 16. Section 441.304 is amended by—
n A. Revising the section heading as set forth below.

n B. Redesignating paragraph (d) as new paragraph (g).

n C. Adding new paragraphs (d), (e), and (f).

n D. Revising newly designated paragraph (g).

The additions and revisions read as follows:

§ 441.304 Duration, extension, and amendment of a waiver.

* * * * *

(d) The agency may request that waiver modifications be made effective retroactive to the first day of a waiver year, or another date after the first day of a waiver year, in which the amendment is submitted, unless the amendment involves substantive changes as determined by CMS.

(1) Substantive changes include, but are not limited to, revisions to services available under the waiver including elimination or reduction of services, or reduction in the scope, amount, and duration of any service, a change in the qualifications of service providers, changes in rate methodology or a constriction in the eligible population.

(2) A request for an amendment that involves a substantive change as determined by CMS, 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 effect on individuals adversely impacted by the change.

(e) The agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services in

accordance with § 447.205 of this chapter.

(f) The agency must establish and use a public input process, for any changes in the services or operations of the waiver.

(1) This process must be described fully in the State's waiver application and be sufficient in light of the scope of the changes proposed, to ensure meaningful opportunities for input for individuals served, or eligible to be served, in the waiver.

(2) This process must be completed at a minimum of 30 days prior to implementation of the proposed change or submission of the proposed change to CMS, whichever comes first.

(3) This process must be used for both existing waivers that have substantive changes proposed, either through the renewal or the amendment process, and new waivers.

(4) This process must include consultation with Federally-recognized Tribes, and in accordance with section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5), Indian health programs and Urban Indian Organizations.

(g)(1) If CMS finds that the Medicaid agency is not meeting one or more of the requirements for a waiver contained in this subpart, the agency is given a notice of CMS' findings and an opportunity for a hearing to rebut the findings.

(2) If CMS determines that the agency is substantively out of compliance with this subpart after the notice and any hearing, CMS may employ strategies to ensure compliance as described in paragraph (g)(3) of this section or terminate the waiver.

(3)(i) Strategies to ensure compliance may include the imposition of a moratorium on waiver enrollments, other corrective strategies as appropriate to ensure the health and welfare of waiver participants, or the withholding of a portion of Federal payment for waiver services until such time that compliance is achieved, or other actions as determined by the Secretary as necessary to address non-compliance with 1915(c) of the Act, or termination. When a waiver is terminated, the State must comport with § 441.307.

(ii) CMS will provide states with a written notice of the impending strategies to ensure compliance for a waiver program. The notice of CMS' intent to utilize strategies to ensure compliance would include the nature of the noncompliance, the strategy to be employed, the effective date of the compliance strategy, the criteria for removing the compliance strategy and the opportunity for a hearing.

n 17. 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 (a)(2) of this section.

(1) Home and community-based settings must 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 supports full access of individuals receiving Medicaid HCBS 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, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options, including non-disability specific settings and an option for a private unit in a residential setting. The setting options are identified and documented in the person-centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes but does not regiment individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the above qualities at paragraphs (a)(1)(i) through (v) of this section, the following additional conditions must be met:

(A) The unit or dwelling 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. For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in

place for each participant and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law.

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

(1) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors as needed.

(2) Individuals sharing units have a choice of roommates in that setting.

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

(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.

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

(F) Any modification of the additional conditions, under paragraphs (a)(1)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(1) Identify a specific and individualized assessed need.

(2) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(3) Document less intrusive methods of meeting the need that have been tried but did not work.

(4) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(5) Include regulation collection and review of data to measure the ongoing effectiveness of the modification.

(6) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(7) Include the informed consent of the individual.

(8) Include an assurance that interventions and supports will cause no harm 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 individuals with intellectual disabilities;

(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. 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 any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

(b) [Reserved]

n 18. A new subpart M, consisting of § 441.700 through § 441.745, is added to part 441 to read as follows:

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

Sec.

441.700 Basis and purpose.

441.705 State plan requirements.

441.710 State plan home and community-based services under section 1915(i)(1) of the Act.

441.715 Needs-based criteria and evaluation.

441.720 Independent assessment.

441.725 Person-centered service plan.

441.730 Provider qualifications.

441.735 Definition of individual's representative.

441.740 Self-directed services.

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

Subpart M—State Plan Home and Community-Based Services for the Elderly and Individuals with Disabilities

§ 441.700 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.

§ 441.705 State plan requirements.

A State plan that provides section 1915(i) of the Act State plan home and

community-based services must meet the requirements of this subpart.

§ 441.710 State plan home and community-based services under section 1915(i)(1) of the Act.

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

(1) Home and community-based settings must 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 supports full access of individuals receiving Medicaid HCBS 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, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options, including non-disability specific settings and an option for a private unit in a residential setting. The setting options are identified and documented in the person-centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes, but does not regiment, individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the above qualities at paragraphs (a)(1)(i) through (v) of this section, the following additional conditions must be met:

(A) The unit or dwelling 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. For settings in which landlord tenant laws do not apply, the State must ensure that

a lease, residency agreement or other form of written agreement will be in place for each HCBS participant and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law;

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

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

(2) Individuals sharing units have a choice of roommates in that setting; and

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

(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;

(E) The setting is physically accessible to the individual; and

(F) Any modification of the additional conditions, under paragraphs (a)(1)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(1) Identify a specific and individualized assessed need.

(2) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(3) Document less intrusive methods of meeting the need that have been tried but did not work.

(4) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(5) Include regular collection and review of data to measure the ongoing effectiveness of the modification.

(6) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(7) Include the informed consent of the individual.

(8) Include an assurance that interventions and supports will cause no harm 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 individuals with intellectual disabilities.

(iv) A hospital.

(v) Any other locations that have qualities of an institutional setting, as

determined by the Secretary. 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 any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

(3) Compliance and transition:

(i) States submitting state plan amendments for new section 1915(i) of the Act benefits must provide assurances of compliance with the requirements of this section for home and community-based settings as of the effective date of the state plan amendment;

(ii) CMS will require transition plans for existing section 1915(c) waivers and approved state plans providing home and community-based services under section 1915(i) to achieve compliance with this section, as follows:

(A) For each approved section 1915(i) of the Act benefit subject to renewal or submitted for amendment within one year after the effective date of this regulation, the State must submit a transition plan at the time of the renewal or amendment request that sets forth the actions the State will take to bring the specific 1915(i) State plan benefit into compliance with this section. The approval will be contingent on the inclusion of the transition plan approved by CMS. The transition plan must include all elements required by the Secretary; and within one hundred and twenty days of the submission of the first renewal or amendment request the State must submit a transition plan detailing how the State will operate all section 1915(c) HCBS waivers and any section 1915(i) State plan benefit in accordance with this section. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(B) For States that do not have a section 1915(c) waiver or a section 1915(i) State plan benefit due for renewal or proposed for amendments within one year of the effective date of this regulation, the State must submit a transition plan detailing how the State will operate all section 1915(c) waivers

and any section 1915(i) State plan benefit in accordance with this section. This plan must be submitted no later than one year after the effective date of this regulation. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(iii) A State must provide at least a 30-day public notice and comment period regarding the transition plan(s) that the State intends to submit to CMS for review and consideration, as follows:

(A) The State must at a minimum provide two (2) statements of public notice and public input procedures.

(B) The State must ensure the full transition plan(s) is available to the public for public comment.

(C) The State must consider and modify the transition plan, as the State deems appropriate, to account for public comment.

(iv) A State must submit to CMS, with the proposed transition plan:

(A) Evidence of the public notice required.

(B) A summary of the comments received during the public notice period, reasons why comments were not adopted, and any modifications to the transition plan based upon those comments.

(v) Upon approval by CMS, the State will begin implementation of the transition plans. The State's failure to submit an approvable transition plan as required by this section and/or to comply with the terms of the approved transition plan may result in compliance actions, including but not limited to deferral/disallowance of Federal Financial Participation.

(b) *Needs-Based Eligibility Requirement.* Meet needs-based criteria for eligibility for the State plan HCBS benefit, as required in § 441.715(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 § 441.720(a)(5).

(d) *Target Population.* Meet any applicable targeting criteria defined by the State under the authority of paragraph (e)(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 the following:

- (A) Age.
- (B) Diagnosis.
- (C) Disability.
- (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(c) of this chapter or to vary the amount, duration, or scope of those services, to one or more of the group(s) described in this paragraph.

§ 441.715 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 individuals with intellectual disabilities 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)(6) 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 may 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 of this chapter 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 level of care criteria to meet the requirements under paragraph (b) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, the State may adjust the modified institutional 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 this subpart. The independent evaluation complies with the following requirements:

(1) Is performed by an agent that is independent and qualified as defined in § 441.730.

(2) Applies the needs-based eligibility criteria that the State has established under paragraph (a) of this section, and the general eligibility requirements under § 435.219 and § 436.219 of this chapter.

(3) Includes consultation with the individual, and if applicable, the individual's representative as defined under § 441.735.

(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.

§ 441.720 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 who is independent and qualified as defined in § 441.730, and with a person-centered process that meets the requirements of § 441.725(a) and is 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 agent performing the assessment is independent and qualified as defined in § 441.730 and 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 person-centered service plan as required in § 441.725.

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

(5) For each service, apply the State's additional needs-based criteria (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 § 441.740(b), 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 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, 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.

§ 441.725 Person-centered service plan.

(a) *Person-centered planning process.* Based on the independent assessment required in § 441.720, 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 and is conducted by providing information in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter.

(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 the individual receives and from whom.

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

(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 written plan must:

(1) Reflect that the setting in which the individual resides is chosen by the individual. The State must ensure that the setting chosen by the individual is integrated in, and supports full access of individuals receiving Medicaid HCBS 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 to the same degree of access as individuals not receiving Medicaid HCBS.

(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 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 and strategies when needed.

(7) Be understandable to the individual receiving services and supports, and the individuals important in supporting him or her. At a minimum, for the written plan to be understandable, it must be written in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter.

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

(9) Be finalized and agreed to, with the informed consent of the individual in writing, 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 § 441.740.

(12) Prevent the provision of unnecessary or inappropriate services and supports.

(13) Document that any modification of the additional conditions, under § 441.710(a)(1)(vi)(A) through (D) of this chapter, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(i) Identify a specific and individualized assessed need.

(ii) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(iii) Document less intrusive methods of meeting the need that have been tried but did not work.

(iv) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(v) Include a regular collection and review of data to measure the ongoing effectiveness of the modification.

(vi) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(vii) Include informed consent of the individual; and

(viii) Include an assurance that the interventions and supports will cause no harm to the individual.

(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 § 441.720, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual.

§ 441.730 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 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 person-centered service plans 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, cognitive, or mental conditions trigger a potential need for home and community-based services and supports, and current knowledge of available resources, service options, providers, and best practices to improve health and quality of life outcomes.

§ 441.735 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. In instances where state law confers decision-making authority to the individual representative, the individual will lead the service planning process to the extent possible.

(b) Any other person who is authorized under § 435.923 of this chapter, or under the 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 uses substituted judgment on behalf of the individual. State policies must address exceptions to using substituted judgment when the individual's wishes cannot be ascertained or when the individual's wishes would result in substantial harm to the individual. 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 accordance with these policies or cannot perform the required functions. States must continue to meet the requirements regarding the person-

centered planning process at § 441.725 of this chapter.

§ 441.740 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 § 441.735.

(b) *Service plan requirement.* Based on the independent assessment required in § 441.720, the State develops a service plan jointly with the individual as required in § 441.725. 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. There must be state procedures to ensure the continuity of services during the transition from self-direction to other service delivery methods.

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

(c) *Employer authority.* If the person-centered service plan includes authority to select, manage, or dismiss providers of the State plan HCBS, the person-centered service plan must specify the authority to be exercised by the individual, any limits to the authority, and specify parties responsible for functions outside the authority the individual exercises.

(d) *Budget authority.* If the person-centered 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 person-centered service 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) 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) Make financial transactions on behalf of the individual when the individual has personal budget authority.

(iii) Maintain separate accounts for each individual’s budget and provide periodic reports of expenditures against budget in a manner understandable to the individual.

(3) Voluntary training on how to select, manage, and dismiss providers of State plan HCBS.

§ 441.745 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 § 441.725, 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 § 441.710(e)(2).

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

(iii) *Appeals.* A State must provide individuals with advance notice of and 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 § 441.715(d) and assessment of need for specific HCBS under § 441.720(a), prior to an individual’s receipt of State plan HCBS or determination of ineligibility for the benefit.

(B) If an individual the State has reason to believe may be eligible for the State plan HCBS benefit is evaluated and assessed under the presumptive payment option and found not to be eligible for the benefit, FFP 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 § 441.710(e)(2), 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.

(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 § 441.715(a) 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, in accordance with CMS sub-regulatory guidance. To the extent that the reimbursement methodologies for any self-directed services differ from those described, 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 § 441.710(e)(2)(i), 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 and the state meeting its objectives with respect to quality improvement and beneficiary outcomes.

(B) If a State does not elect to establish targeting criteria through § 441.710(e)(2)(i), 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 outcome measures for program performance, quality of care, and individual experience as determined by the Secretary.

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

(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

n 19. The authority citation for part 447 continues to read as follows:

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

n 20. Section 447.10 is amended by adding new 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 service 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.

* * * * *

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

Dated: September 18, 2013.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Approved: December 9, 2013.

Kathleen Sebelius,
Secretary, Department of Health and Human Services.

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