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42 CFR Part 441

Medicaid Program; Community First Choice Option; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 441

[CMS–2337–F]

RIN 0938–AQ35

Medicaid Program; Community First Choice Option

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

ACTION: Final rule.

SUMMARY: This final rule implements section 2401 of the Affordable Care Act, which establishes a new State option to provide home and community-based attendant services and supports. These services and supports are known as Community First Choice (CFC). While this final rule sets forth the requirements for implementation of CFC, we are not finalizing the section concerning the CFC setting.

DATES: These regulations are effective July 6, 2012.

FOR FURTHER INFORMATION CONTACT: Kenya Cantwell, (410) 786–1025.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This final rule implements section 2401 of the Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, which adds section 1915(k) to the Social Security Act (the Act). The Community First Choice Option established a new State plan option to provide home and community-based attendant services and supports at a 6 percentage point increase in Federal medical assistance percentage (FMAP). While this final rule sets forth the requirements for implementation of CFC, we are not finalizing § 441.530, ''Setting,'' at this time.

2. Summary of the Major Provisions

- This final rule sets out our interpretation of the statutory requirements for eligibility under the Community First Choice (CFC) Option. Specifically, this final rule clarifies that under the statute, individuals should be determined to need an institutional level of care to be eligible for CFC services. This rule also provides States with the option to permanently waive the annual recertification requirement for individuals if it is determined that there is no reasonable expectation of improvement or significant change in the participant's condition because of the severity of a chronic condition or the degree of impairment of functional capacity.
- This rule specifies the services that must be made available under the CFC State plan option. States electing this option must make available home and community-based attendant services and supports to assist in accomplishing activities of daily living, instrumental activities of daily living, and health-related tasks through hands-on assistance, supervision, and/or cueing. Additionally, the following services may be provided at the State's option: Transition costs such as rent and utility deposits, first month's rent and utilities, purchasing bedding, basic kitchen supplies, and other necessities required for transition from an institution; and the provision of services that increase independence or substitute for human assistance to the extent that expenditures would have been made for the human assistance, such as non-medical transportation services or purchasing a microwave.
- States are required to use a person-centered service plan that is based on an assessment of functional need and allows for the provision of services to be self-directed under either an agency-provider model, a self-directed model with service budget, or other service delivery model defined by the State and approved by the Secretary. States may offer more than one service delivery model.
- The final rule also implements the requirement that for the first full twelve month period in which a CFC State plan amendment is implemented, the State must maintain or exceed the level of expenditures for home and community-based attendant services provided under the State plan, waivers or demonstrations, for the preceding 12-month period.
- States will receive an additional 6 percentage point in Federal Medical Assistance Percentage (FMAP) for the provision of CFC services and supports.

3. Summary of Costs and Benefits

Provision description	Total costs	Total benefits
Provision of home and community based attendant services and supports.	The Federal and State impacts for FY 2012 are estimated at $820 million and $480 million, respectively.	This final rule provides States with additional flexibility to finance home and community-based services attendant services and supports. We anticipate this provision will likely increase State and local accessibility to services that augment the quality of life for individuals through a person-centered plan of service and various quality assurances, all at a potentially lower per capita cost relative to institutional care settings.

B. Section 2401 of the Affordable Care Act

The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted on March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010) (collectively referred to as the Affordable Care Act) established a new State plan option to provide home and community-based attendant services and supports. Section 2401 of the Affordable Care Act, entitled ''Community First Choice (CFC) Option,'' adds a new section 1915(k) of the Social Security Act (the Act) that allows States, at their option, to provide home and community-based attendant services and supports under their State plan. This option, available October 1, 2011, allows States to receive a 6 percentage point increase in Federal matching payments for medical assistance expenditures related to this option.

Under section 1915(k)(1) of the Act, States can provide home and community-based attendant services and supports for individuals who are eligible for medical assistance under the State plan whose income does not exceed 150 percent of the Federal Poverty Level (FPL) or, if greater, the income level applicable for an individual who has been determined to require an institutional level of care to be eligible for nursing facility services under the State plan and for whom there has been a determination that, but for the provision of such services, the individuals would require the level of care provided in a hospital, a nursing facility, an intermediate care facility for

the mentally retarded, or an institution for mental diseases, the cost of which could be reimbursed under the State plan. The individual must choose to receive such home and community-based attendant services and supports, and the State must meet certain requirements set forth in section 1915(k)(1) of the Act. Section 1915(k)(1)(A) of the Act requires States electing this option to make available home and community-based attendant services and supports to eligible individuals, under a person-centered service plan agreed to in writing by the individual, or his or her representative, that is based on a functional needs assessment. This assessment will determine if the individual requires assistance with activities of daily living (ADLs), instrumental activities of daily living (IADLs), or health-related tasks. The services and supports must be provided by a qualified provider in a home and community-based setting under an agency-provider model, or through other methods for the provision of consumer controlled services and supports as referenced in section 1915(k)(6)(C) of the Act. Section 1915(k)(1)(B) of the Act requires that States make available additional services and supports including the acquisition, maintenance, and enhancement of skills necessary for the individual to accomplish ADLs, IADLs, and health-related tasks, backup systems or mechanisms to ensure continuity of services and supports and voluntary training on how to select, manage, and dismiss attendants.

Section 1915(k)(1)(C) of the Act prohibits States from providing services and supports excluded from section 1915(k) of the Act, including room and board costs for the individual; special education and related services provided under the Individuals with Disabilities Education Act (Pub. L. 101–476, enacted on October 30, 1990) (IDEA) and vocational rehabilitation services provided under the Rehabilitation Act of 1973 (Pub. L. 93–112, enacted on September 26, 1973); assistive technology devices and services other than backup systems or mechanisms to ensure continuity of services and supports, medical supplies and equipment, or home modifications. However, some, although not all, of these services can be covered by Medicaid under other authorities. Section 1915(k)(1)(D) of the Act sets forth services and supports permissible under section 1915(k) of the Act that States can provide, including expenditures for transition costs such as rent and utility deposits, first month's rent and utilities, bedding, basic kitchen supplies, and other necessities required for an individual to make the transition from a nursing facility, institution for mental diseases, or intermediate care facility for the mentally retarded to a community-based home setting where the individual resides. States can also provide for expenditures relating to a need identified in an individual's person-centered plan of services that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

Section 1915(k)(2) of the Act provides that States offering this option to eligible individuals during a fiscal year quarter occurring on or after October 1, 2011 will be eligible for a 6 percentage point increase in the Federal medical assistance percentage (FMAP) applicable to the State for amounts expended to provide medical assistance under section 1915(k) of the Act.

Section 1915(k)(3) of the Act sets forth the requirements for a State plan amendment. States must develop and have in place a process to implement an amendment in collaboration with a Development and Implementation Council established by the State that includes a majority of members with disabilities, elderly individuals, and their representatives. States must also provide consumer controlled home and community-based attendant services and supports to individuals on a statewide basis, in a manner that provides such services and supports in the most integrated setting appropriate to the individual's needs, without regard to the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports the individual requires to lead an independent life.

In addition, for expenditures during the first full fiscal year of implementation, States must maintain or exceed the level of State expenditures for medical assistance attributable to the preceding fiscal year for medical assistance provided under sections 1905(a), 1915, or 1115 of the Act, or otherwise provided to individuals with disabilities or elderly individuals. States must also establish and maintain a quality assurance system for community-based attendant services and supports that includes standards for agency-based and other delivery models for training, appeals for denials and reconsideration procedures of an individual plan, and other factors as determined by the Secretary. The quality assurance system must incorporate feedback from individuals and their representatives, disability organizations, providers, families of disabled or elderly individuals, and members of the community, and maximize consumer independence and control. The quality assurance system must also monitor the health and well-being of each individual who receives section 1915(k) services and supports, including a process for the mandatory reporting, investigation, and resolution of allegations of neglect, abuse, or exploitation in connection with the provision of such services and supports. The State must also provide information about the provisions of the quality assurance required to each individual receiving such services.

States must collect and report information for the purposes of approving the State plan amendment, permitting Federal oversight, and conducting an evaluation, including data regarding how the State provides home and community-based attendant services and supports and other home and community-based services, the cost of such services and supports, and how the State provides individuals with disabilities who otherwise qualify for institutional care under the State plan or under a waiver the choice to receive home and community-based services in lieu of institutional care.

Section 1915(k)(4) of the Act requires that States ensure, regardless of the models used to provide CFC attendant services and supports, such services and supports are to be provided in accordance with the requirements of the Fair Labor Standards Act of 1938 and applicable Federal and State laws regarding the withholding and payment of Federal and State income and payroll taxes; the provision of unemployment and workers compensation insurance; maintenance of general liability insurance; and occupational health and safety.

Section 1915(k)(5) of the Act sets forth the requirements that States provide data to the Secretary for an evaluation and Report to Congress on the provision of CFC home and community-based attendant services and supports. States must provide information for each fiscal year for which CFC attendant services and supports are provided, on the number of individuals estimated to receive these services and supports during the fiscal year; the number of individuals that received such services and supports during the preceding fiscal year; the specific number of individuals served by type of disability, age, gender, education level, and employment status; and whether the specific individuals have been previously served under any other home and community-based

services program under the State plan or under a waiver. Section 1915(k)(5) also requires the Secretary to submit to Congress an interim report no later than December 31, 2013 and a final report no later than December 15, 2015. These reports must be available to the public.

Finally, section 1915(k) (6) of the Act sets forth the definitions of specific terms as they relate to CFC.

C. Background of Home and Community-Based Attendant Services and Supports

The CFC option expands States' and individual's Medicaid options for the provision of community-based long-term care services and supports. Consistent with the decision of the United States Supreme Court in *Olmstead* v. *L.C.,* 527 U.S. 581 (1999), this option will support States in their efforts to develop or enhance a comprehensive system of long-term care services and supports in the community that provide beneficiary choice and direction in the most integrated setting. Since the mid-1970s, States have had the option to offer personal care services under their Medicaid State plans. The option was originally provided at the Secretary's discretion, had a medical orientation and could only be provided in an individual's place of residence. Personal care services were mainly offered to assist individuals in activities of daily living, and, if incidental to the delivery of such services, could include other forms of assistance (for example, housekeeping or chores). In the 1980s, some States sought to broaden the scope of personal care services to include community settings for the provision of services to enable individuals to participate in normal day-to-day activities.

Through the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66, enacted on August 10, 1993) (OBRA 93), the Congress formally included personal care as a separate and specific optional service under the Federal Medicaid statute and gave States explicit authorization, under a new section 1905(a)(24) of the Act, to provide such services outside the individual's residence in addition to providing personal care to eligible individuals within their homes. This provision was implemented by a final rule published in the September 11, 1997 **Federal Register** (62 FR 47896) that added a new section at § 440.167 describing the option for States to provide a wide range of personal assistance both in an individual's residence and in the community. In 1999, we released additional guidance as an update to the State Medicaid Manual (SMM) to clarify that personal care services may include ADLs and IADLs that all qualified relatives, with the exception of ''legally responsible relatives'', could be paid to provide personal care services and that States were permitted to offer the option of consumer-directed personal care services.

Additionally, the Omnibus Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA 89), revised the Early and Periodic Screening, Diagnosis and Treatment Benefit to include the requirement that all section 1905(a) services are mandatory for individuals under the age of 21 if determined to be medically necessary in accordance with section 1905(r) of the Act.

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

Medicaid home and community-based services (HCBS) were established in 1981 as an alternative to care provided in Medicaid institutions, by permitting States to waive certain Medicaid requirements upon approval by the Secretary. Section 1915(c) of the Act was added to title XIX by the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35, enacted on August 13, 1981) (OBRA 81). Programs of HCBS under section 1915(c) of the Act are known as ''waiver programs'', or simply ''waivers'' due to the authority to waive certain Medicaid requirements.

Since 1981, the section 1915(c) HCBS waiver program has afforded States considerable latitude in designing services to meet the needs of people who would otherwise require institutional care. In 2010, approximately 315 approved HCBS waivers under section 1915(c) of the Act served nearly 1 million elderly and disabled individuals in their homes or alternative residential community settings. States have used HCBS waiver programs to provide numerous services designed to foster independence; assist eligible individuals in integrating into their communities; and promote self-direction, personal choice, and control over services and providers. The Deficit Reduction Act of 2005 (Pub. L. 109–171, enacted on February 8, 2006) (DRA) added section 1915(i) of the Act which affords some of the same flexibility and service coverage through the State plan without a waiver.

The section 1915(k) benefit does not diminish the State's ability to provide any of the existing Medicaid home and community-based services. States opting to offer the CFC Option under section 1915(k) of the Act can continue to provide the full array of home and community-based services under section 1915(c) waivers, section 1115 demonstration programs, mandatory State plan home health benefits, and the State plan personal care services benefit. CFC provides States the option to offer a broad service package that includes assistance with ADLs, IADLs, and health-related tasks, while also incorporating transition costs and supports that increase independence or substitute for human assistance.

Additional important aspects of this background are the passage of the Americans with Disabilities Act of 1990 (Pub. L. 101–336, enacted July 26, 1990) (ADA), and the *Olmstead* v. *L.C.,* U.S. Supreme Court decision. In particular, Title II of the ADA prohibits discrimination on the basis of disability by State and local governments and requires these entities to administer their services and programs in the most integrated setting appropriate to the needs of qualified individuals with disabilities. In applying the most integrated setting standard, the U.S. Supreme Court ruled in *Olmstead* that unnecessary institutionalization of individuals with disabilities constitutes discrimination under the ADA. Under *Olmstead,* States may not deny a qualified individual with a disability a community placement when: (1) Community placement is appropriate; (2) the community placement is not opposed by the individual with a disability; and (3) the community placement can be reasonably accommodated.

Finally, the self-direction service delivery model is another important aspect to the background of this provision and a key component of the CFC option. Two national pilot projects demonstrated the success of self-directed care. During the 1990's, the Robert Wood Johnson Foundation funded these projects which evolved into Medicaid funded programs under section 1915(c) of the Act and the ''Cash and Counseling'' national section 1115 demonstration programs. Evaluations were conducted in both of these national projects. Results in both projects were similar—persons directing their personal care experienced fewer unnecessary institutional placements, experienced higher levels of satisfaction, had fewer unmet needs, experienced higher continuity of care because of less attendant care provider turnover, and maximized the efficient use of community services and

supports. The DRA also established section 1915(j) of the Act which provided a State plan option for States to utilize this self-direction service delivery model without needing the authority of a section 1115 demonstration.

This rule finalizes many of the provisions set forth in the February 25, 2011 proposed rule, modifies some such provisions and allows that one provision, § 440.530 ''Setting'', will be subject to further comment.

II. Analysis of and Responses to Public Comments on the Proposed Rule

We received a total of 141 timely items of correspondence from home care provider representatives and other professional associations, State Medicaid directors, unions, beneficiaries, and other individuals. We received hundreds of individual comments within these items of correspondence, which ranged from general support or opposition to the proposed rule, to specific questions and detailed comments and recommendations regarding the proposed changes. A summary of our proposals, the public comments and our responses are set forth below.

A. General

Comment: Many commenters expressed support for the rule. Several commenters strongly believe that everything must be done to help keep individuals out of nursing homes and in the community. The commenters stated doing so will save taxpayer's money and increase the quality of life for individuals who receive services. The commenters believe individuals are valuable to communities and they deserve to have the ''cheaper'' option of staying home. Another commenter indicated that CFC could provide needed assistance to children with special health care needs and their families who wish to remain in their communities where they can direct their own service plan. Another commenter indicated that personal care is more humanely provided and more cost effective in the home rather than in an institution. The commenter believes infrastructure cost of running an institution and the need to protect the administration detracts from patient care efforts, and believes patient care becomes secondary to administrative function. Another commenter requests the CFC rule be implemented so that all disabled persons, such as the commenter's 31-year old son who is partially paralyzed by a stroke, have a choice of living their own life. Another commenter stated community-based reimbursed services provide access for the growing group of aging baby boomers. The commenter believes that CFC will support individuals in the setting appropriate to the individual's need and allow them to lead a more independent lifestyle. The commenters urged CMS to implement the final rule. One commenter was pleased the rule recognized the need for flexibility to ''meet States where they are'' with regard to the provision of home and community-based services with an eye toward expanding opportunities for consumers.

Response: We appreciate the commenters' perspectives.

Comment: A few commenters expressed opposition to the proposed rule. One commenter requested limiting excessive rules that would burden the States financially or would be time-consuming to implement. Another commenter believes CFC violates the 10th amendment of the United States Constitution by requiring States to perform services that the Federal Government is prohibited from doing by the Constitution. The commenter believes the regulation should be withdrawn.

Response: We disagree with the commenters' statement that the CFC program violates the 10th amendment of the United States Constitution. Section 1915(k) of the Act sets forth an option, not a mandate, for States to include such services in their Medicaid program.

We do not believe the regulation places excessive requirements on States, rather it provides States with the necessary guidance to implement section 1915(k) of the Act successfully. We also believe the regulation provides participant protections to ensure individuals exercise maximum control of home and community-based attendant services and supports.

Comment: One commenter expressed concern that section 1.B, Background of Home and Community-Based Attendant Services and Supports, omits the section 1930 Community Supported Living Arrangements program, which influenced the development of home and community-based services. The commenter believes this is an important cornerstone of the new program and should be included in the final rule.

Response: We agree that the section 1930 Community Supported Living Arrangement program has influenced the development of home and community-based services. However, we do not believe that its specific influence on the CFC option warrants inclusion in the final rule.

Comment: One commenter indicates that to implement CFC for the population eligible to receive home and community-based attendant services and supports, as well as to implement the array of services available to eligible individuals would be overly expansive. The commenter believes States would need additional staffing to assess the needs of the eligible CFC populations, develop and maintain the quality assurance systems, and report data. Another commenter expressed concern that the proposed rule creates some uncertainty about whether States can build upon existing State structures in delivering services under CFC.

Response: We recognize that States that do not currently have the infrastructure necessary to support implementation of CFC may experience higher initial administrative burdens and costs when designing their CFC program. We believe the enhanced FMAP provided under CFC will lessen the burden on States, allowing them to serve the population eligible for CFC. Additionally, States may use existing infrastructure, such as a current advisory council to act as the Development and Implementation Council, as long as the statutory requirements for the structure, composition, and collaborative and consultative role of the council are met.

Comment: One commenter wanted to know the impact CFC will have on the Early Periodic Screening Diagnosis and Treatment (EPSDT) benefit

Response: The EPSDT mandate under section 1905(r)(5) of the Act requires that any medically necessary health care service listed at section 1905(a) of the Act be provided to a Medicaid beneficiary under the age of 21 even if the service is not available under the State's Medicaid plan to the rest of the Medicaid population. CFC services are provided under section 1915(k) of the Act, which is outside the scope of section 1905(a) of the Act and therefore are not required under the EPSDT program. We note that this does not preclude a State from providing CFC services to any individual who meets the criteria to receive CFC services, regardless of age, and from receiving the added Federal support associated with providing CFC services. Furthermore, in addition to meeting EPSDT requirements through the provision of the section 1905(a) services, a State may also meet a particular child's needs under EPSDT through services that are also available through the section 1915(k) benefit.

Comment: One commenter expressed concern that the rule should include appeals for reductions in service based

on anything other than a documented change in need. The commenter indicated that his State allows requests for hearings, but stated that they are routinely denied. The commenter stated that the State's assurances with regard to due process are not reliable and recommended that there be a higher standard for the CFC option and other waivers with regard to appeals.

Response: We acknowledge the importance of a beneficiary's ability to appeal service reductions. States are required to adhere to the requirements specified in 42 CFR 431 subpart E for the Medicaid program in general, and for CFC specifically. It is important to note, however, that CFC is a State plan option and not an HCBS waiver.

Comment: One commenter explained that their State asserts they have no obligation to meet the client's needs in the community—only that the services authorized be indexed to actual needs. The commenter also stated that the risk of re-institutionalization is controlled by closing institutions, resulting in clients being placed into community placements without the same level of support provided in an institutional setting. The commenter believes that CMS ''turns a blind eye'' to these issues and that all waivers should respect the clients' rights to have their needs met in the community. Another commenter expressed concern that their State is intentionally limiting services and that the State has declared that they have no obligation to, or intention of, meeting the needs of vulnerable adults in the community. The commenter is concerned the choice guaranteed in the *Olmstead* decision is not upheld, and wonders why the Federal government goes through these pro-forma rulemaking processes when there is no intent to follow-up or enforce the ''reassuring words.''

Response: We want to clarify that the CFC is a State plan option, not a waiver. We respect the commenter's opinions, but do not agree with the commenter with regard to the Federal government not enforcing regulations or ignoring these important issues noted above. We also believe that the rulemaking process is a meaningful process that allows the public to have a voice in how laws passed by the Congress are implemented by CMS. We echo throughout the regulation that in implementing CFC, States must ensure that individuals are served in the most integrated settings appropriate to their needs. We have also worked closely with Medicaid beneficiaries, as well as States, over the years to assist in determining how the Medicaid program can support them in meeting their *Olmstead* obligations. This regulation will establish the parameters States must follow in implementing CFC. Additionally, the Data collection requirements described at § 441.580, and the Quality assurance system requirements described at § 441.585, require States to provide CMS with information regarding the provision of CFC services. We encourage all stakeholders to collaborate with States and CMS to ensure these parameters are met.

Comment: One commenter stated that to be consistent with *Olmstead,* personal choice is required to participate in the CFC option, and the proposed rule should be amended to expressly indicate this right and take care not to limit expressions of beneficiary choice to community options.

Response: We agree that personal choice is an important part of CFC and have taken steps throughout the regulation to illustrate its importance. Based on feedback received through the comment process, we have decided to amend language in the ''assessment of need'' and ''person-centered service plan'' sections, as described below, to strengthen this principle.

Comment: Another commenter stated that the current focus of their State's Home and Community-Based Services (HCBS) plans is on lowering costs, not meeting all the needs of individuals. The commenter is concerned that States have too much power and the CFC rule does not correct the imbalance between saving taxpayer money while still serving the needs of vulnerable adults.

Response: The Medicaid program is a State/Federal partnership. States have the flexibility to design and administer their Medicaid programs as long as they meet the Federal requirements set forth in the regulations. In addition, States have the choice of providing an array of optional services. The purpose of CFC is to afford States another option to provide home and community-based services as an alternative to institutional placement. This benefit is not like a waiver program in that it is not required to be cost neutral in terms of community versus nursing facility costs. While this program should not be viewed individually as the key to ensuring community access, it is an important tool for States to consider as they strive to meet their obligations under *Olmstead.*

Comment: We received many comments asking if CFC can be delivered through managed care under a section 1915(b) waiver authority, or a section 1915(b)/(c) waiver. One commenter expressed concern that the proposed rule does not reference the ability for States to deliver this rule's services through Medicaid health plans under a section 1915(b) waiver. The commenter believes that Medicaid health plans have demonstrated their ability to provide coordination across a range of services essential to facilitate the choice of community setting for individuals with disability. The commenter recommended CMS confirm in the preamble that States have the option of implementing the CFC option through Medicaid managed care programs. Another commenter requested States not be subject to additional limitations or restrictions if they elect to have a managed care organization administer their program.

Response: We are willing to consider the implementation of the CFC option through Medicaid managed care programs with a State interested in doing so; however, the State would need to ensure that the delivery system implemented through the (b) waiver would not impede the provision of services as specified in section 1915(k) of the Act. Therefore, we are not revising the regulation text.

Comment: One commenter requested clarification whether the additional 6 percentage point increase in Federal medical assistance percentage (FMAP) is for expenditures related to both direct services and administration.

Response: The 6 percentage point increase in FMAP is related to direct services only and does not apply to administrative costs.

Comment: One commenter expressed concern that regulatory requirements for CFC may be duplicative of, or in conflict with PACE regulations applicable to PACE organizations. The commenter requested clarification on the relationship of the PACE program and CFC for PACE participants who also meet the eligibility criteria for CFC. Specifically, the commenter questioned if home and community-based attendant services may be provided in a manner consistent with the PACE benefit under section 1934 of the Act. The commenter also questioned if PACE organizations may provide services under CFC under the agency-provider model or under another model established by a State.

Response: Section 1915(k) of the Act does not preclude PACE organizations, or any entity, from providing CFC services as a separate line of business, as long as provider qualifications established by the State are met. However, CFC is a separate and distinct program, with its own statutory and regulatory requirements, and may not be provided under the PACE authority.

Comment: One commenter requested CMS include a direct reference to a

State's obligation, in establishing processes for public notice and input, to comply with section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, enacted on February 17, 2009) (ARRA) prior to submission of a State plan amendment or other action under section 2401 of the Affordable Care Act that would have a direct effect on Indians or Indian health providers or urban Indian organizations.

Response: The consultation requirements of section 5006(e) of ARRA require solicitation of advice prior to submission of any State plan amendment, waiver request, or proposal for a demonstration project that is likely to have a direct effect on Indians, Indian Health Programs or Urban Indian Organizations, in any State in which one or more Indian Health Programs or Urban Indian Organizations furnishes health care services. These requirements apply to but are not unique to CFC. Therefore, we do not believe it is appropriate to include these requirements in this regulation specifically. CMS reviews State plan amendments, waiver requests, and demonstration proposals for compliance with the ARRA 5006(e) provisions.

Comment: One commenter requests Medicare expand options to allow individuals to stay at home.

Response: This rule implements section 2401 of the Affordable care Act, which is limited to the Medicaid program.

Comment: One commenter recommended CMS incorporate provisions within the CFC regulation to enable States to implement data systems to monitor the direct-care workforce.

Response: We believe the implementation of data systems to monitor the direct-care workforce would be an acceptable component of a State's Quality Assurance System. However, we do not believe there is a need to reference this specifically.

Comment: One commenter requests the term ''mentally retarded'' be replaced throughout the final document in its entirety with a term such as ''developmentally disabled'', ''individual with an intellectual disability'' or other more appropriate language.

Response: We appreciate the commenter's concern and note that the rule does not include the term ''mentally retarded'', but rather, includes the statutory term ''Intermediate Care Facility for the Mentally Retarded (ICF/MR).'' While CMS supports using the term ''individuals with intellectual disabilities,'' it would be beyond the scope of this regulation to change the statutory name of ICFs/MR. Since we are only using this term to refer to this specific setting, which has not been renamed in law, we do not believe we can make this change. However, in the October 24, 2011 **Federal Register**, we proposed in the Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction proposed rule to replace the term ''mentally retarded'' with ''intellectually disabled'' throughout our regulations.

B. Basis and Scope (§ 441.500)

We proposed to implement section 1915(k) of the Act, known as the CFC Option, to provide home and community-based attendant services and supports through the Medicaid State plan. We proposed the scope of the benefit include the provision of home and community-based attendant services and supports to eligible individuals, as needed, to assist in accomplishing ADLs, IADLs, and health-related tasks through hands-on assistance, supervision, or cueing.

Comment: One commenter indicated that CFC should be a mandatory benefit.

Response: Section 1915(k) of the Act amends the Medicaid statute to add CFC as an optional State Plan benefit, not a mandatory benefit. It is beyond the scope of a regulation to expand CFC to a mandatory benefit.

Comment: Many commenters stated that this section of the regulation should acknowledge that CFC is intended to make available home and community-based attendant services and supports to people with disabilities of all ages as an alternative to institutional placement. Another commenter stated the same, but also included individuals with serious mental illness.

Response: We agree with the commenters that the scope of CFC is to provide home and community-based services and supports as an alternative to institutional placement. Furthermore, we received comments supporting Congressional intent that all individuals receiving CFC services must meet an institutional level of care, consistent with the view that CFC is to provide services and supports as an alternative to institutional placement. We discuss this issue in further detail in the response to comments on Eligibility, § 441.510. We have revised the eligibility section to clarify that under the statute all individuals receiving CFC services must meet an institutional level of care; however, we do not believe it is necessary to revise the basis and scope section explicitly.

Comment: One commenter wanted to know if there is State flexibility to focus on a single modality (hands-on or supervision or cueing) or must all three modalities be covered.

Response: We believe the statutory language requires that all three modalities must be available to individuals.

Comment: One commenter stated that the regulation should allow for different ''benefit'' packages for people with different needs; for example, populations such as children versus adults, young adults versus older adults.

Response: Section 1915(k)(3)(B) of the Act requires that services must be provided without regard to the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports the individual requires to lead an independent life. Therefore, States may not differentiate the benefit package; however, services must be provided to individuals based on their needs.

Comment: A few commenters expressed concern with a State's ability to limit the amount, duration, and scope of CFC. One commenter believes States make arbitrary and capricious reductions in services due only to budget constraints. These reductions result in an individual's reliance on ''informal care contracts'' paid by the individual's small income to fill the gap of needed services. Another commenter expressed concern that States who take advantage of this new option may impose unnecessary restrictions on families (such as limiting in-home nursing supports to children who are on ventilators).

Response: CFC is a State plan optional service and States may set limits on the amount, duration and scope of services, as long as the amount, duration and scope are sufficient to reasonably achieve the purpose of the service. In addition, these limits must be applied without regard to the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life. We will be reviewing all State proposals to implement CFC under the State plan. Our review will include a review of any proposed limitations.

Comment: One commenter requested clarification of what is meant by ''severity of disability'' and asked if this definition would preclude limiting the CFC to the ''severely impaired'' population. In addition, this commenter raised the concern that if the definition does preclude limiting CFC population, States would lose the ability to ''effectively utilize CFC to serve unique populations.''

Response: As stated above, section 1915(k)(3)(B) of the Act indicates that the services must be provided on a statewide basis without regard to the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life as specified in § 441.515. Based on this requirement, the CFC population cannot be limited based on type or severity of disability, as long as the individual meets the eligibility requirement set forth in § 441.510. States cannot refuse access to CFC, or the ability to self-direct CFC services and supports, because of the severity of an individual's needs.

After consideration of the public comments, this section is being finalized without revision.

C. Definitions (§ 441.505)

We proposed several definitions specific to CFC.

Comment: Many commenters applauded CMS for prefacing the list of ADLs with ''including, but not limited to.'' The commenters believe this language recognizes that individuals may have additional needs for support.

Response: The intent of CFC is to assist individuals with receiving services necessary to have a lifestyle that is integrated into their community. Therefore, we do not believe it is appropriate to specify a prescriptive list that may not address each person's individualized needs.

Comment: One commenter wanted to know if States are allowed to define ADLs more expansively by adding activities since the definition of ADLs includes the phrase ''but not limited to.''

Response: Through the State Plan Amendment (SPA) process, States have the flexibility to propose additional factors to be included as components of ADLs.

Comment: A few commenters suggested removing the term ''self-directed'' from the definition of ''agency-provider model.'' The commenters believe the use of this term with the agency-provider model implies that services will be restricted to individuals who can fully manage services and supports, and will not allow individuals who are unable to fully manage them, or who do not wish to do so, from receiving services under the agency-provider model.

Response: We believe the commenter is applying a different definition of ''self-direction'' than what is specified within this rule. Section 1915(k)(6)(B) of the Act used the term ''consumer controlled'' to mean a method of selecting and providing services and supports that allow the individual, or where appropriate, the individual's representative, maximum control of the home and community-based attendant services and supports, regardless of who acts as the employer of record. In the preamble of the proposed regulation, we elected to use the term self-directed rather than consumer controlled to be consistent with terminology in other Medicaid provisions. We interpret this to mean that all CFC services are self-directed and it is up to the individual to determine the level of self-direction they want to have. Therefore we are not adopting the commenter's suggestions.

Comment: Several commenters requested more clarification around the ''agency-provider model.'' A few commenters wanted to know if the agency-provider model is the same as what is sometimes referred to as a ''co-employment'' model. One commenter disagreed with the proposed definition stating that an agency-provider model does not mean that an entity contracts for the provision of services and supports. The commenter states the agency-provider model has to do with who the employer is. The commenter also states that under an agency-provider model, the individual can still select, train, manage, and dismiss an attendant care provider. When the attendant care provider is dismissed, the attendant care provider is still employed by the agency and can be selected by someone else.

Response: The definition in the rule is from section 1915(k)(6)(C)(i) of the Act. In the preamble of the Service Model section of the proposed rule, we construed the ''agency-provider model'' to mean ''traditional agency model'' and an ''agency with choice'' model. Under the traditional agency model, the individual retains hiring and firing authority of personal care attendants, with regard to the receipt of services from a specific personal care attendant. In other words, the employment relationship between the personal care attendant and the agency does not change. The agency with choice model utilizes a co-employment relationship between the individual and an agency. We acknowledge that not all agency-provider models utilize a contractual relationship between the agency-provider entity and the State Medicaid agency for the provision of services. Rather, it is more common for a provider agreement to be used. Therefore, we are modifying the agency-provider definition to better reflect the various arrangements through which the provision of personal attendant services may occur. We will also modify the language at § 441.545(i) to reflect this change. Additionally, we acknowledge the confusion caused by our use of the terms ''hire'' and ''fire.'' We will replace such terms with ''select'' and ''dismiss'' throughout the regulation, as appropriate. We appreciate the commenter's description of an agency-provider model and believe it is one example of an agency-provider model that falls within the definition in the rule. We believe the definition in the rule is broad enough to encompass the various agency-provider types that exist.

Comment: We received a few comments requesting that we define the agency-provider model in a way that clearly includes States that provide long term care services and supports directly through public authority entities instead of private contractual arrangement.

Response: It is our understanding that the structure of the long-term care services and supports provided through public authority entities varies among States. It is possible that one State's public authority entities could meet the definition of an agency-provider type while another State's public authority entities meet the definition of ''other model.'' For this reason, we are requesting States to provide a description of such entities during the SPA process.

Comment: One commenter suggests we add ''as defined by the State and approved by the Secretary'' into the definition of ''backup systems or supports'' to ensure consistency with other home and community-based service programs.

Response: We do not agree the suggested language is necessary. All State plan amendments will require adherence to this regulation's service definitions and will be approved by CMS.

Comment: Some commenters suggested medication management be included to the definition of ''backup systems.'' Other commenters requested the definition be revised to ensure coverage of a broad variety of health support technologies, such as telehealth, independent living technologies, and remote patient monitoring. The commenter advised that currently 44 States reimburse for Personal Emergency Response Systems (PERS), 16 States reimburse for medication management technology, 1 State reimburses for home telecare/remote monitoring, and 7 States reimburse for home telehealth/telemonitoring under sections 1905(a), 1915, or section 1115 of the Act. The commenter states that it is important that all these technologies that ensure continuity of services and

supports are also available under CFC. One commenter requested that PERS, medication management technology, telecare/remote monitoring and telehealth/telemonitoring should be included in the definition of ''backup systems and supports.''

Response: Section 1915(k) of the Act indicates the purpose of backup systems or mechanisms is to ensure continuity of services and supports. We do not believe medication management complies with the intent of backup systems and supports; however, it could be a component of personal attendant services, or another Medicaid service. We agree with the commenters that telemedicine could be a useful method of providing backup systems or supports. We are available to discuss a State's interest in using such technology for this purpose, but do not believe the rule should be revised to specifically indicate this. Therefore, we are not revising the definition of backup systems to include explicit reference to medication management and telemedicine technologies.

Comment: We received many comments requesting that we expand the definition of ''backup systems and supports'' to include other approaches, such as written backup plans, action plans such as calling emergency agencies or personal emergency contacts, contacting other systems that support individuals in identifying backup attendant care providers when regularly scheduled attendants are unavailable, or other necessary planning to deal with a variety of possible situations which require additional services or supports. The commenters also added that backup systems should apply to all service models, stating that although backup systems are most often considered in the context of self-directed services they also apply to services and supports delivered through an agency-provider model.

Response: We agree with the commenters that backup systems and supports may include approaches in addition to electronic devices. This belief is supported by the inclusion in the definition described in the proposed rule of allowing people to be included as backup supports. Additionally, we agree that each individual, regardless of service delivery model, should have a backup plan to address how emergencies and unplanned events affecting the continuity of services will be handled. This belief is supported in the requirement of backup strategies as a measure of risk mitigation included in the person-centered service plan, which is required for all CFC participants regardless of service delivery model. We are modifying the requirements of the person-centered service plan to remove the ''as needed'' language, to indicate that all individuals should have an individualized backup plan.

Comment: One commenter noted that the rule requires backup systems be made available but excludes assistive technology devices and assistive technology services.

Response: Section 1915(k)(1)(C)(iii) of the Act indicates that assistive technology devices and assistive technology services are excluded, other than those under section 1915(k)(1)(B)(ii) of the Act. This authorizes the coverage of such devices and services when used as part of a backup system or mechanism to ensure continuity of services and supports.

Comment: One commenter asked that CMS clarify in both the preamble and regulatory text, whether cell phones, hand-held communication devices such as smartphones, and computers that allow participants to communicate with providers of home and community-based attendant services would be allowable expenditures. Another commenter recommended the definition include language explicitly stating that smartphones and more generally, any useful emerging applications or technologies which will become available, are allowable.

Response: We do not believe it is necessary to mention specific types of technology. To allow for the inclusion of future developments, we will replace the term ''pager'' with ''an array of available technologies.'' We believe the broad definition will support the inclusion of technological advances as they are developed.

Comment: One commenter requested clarification regarding the circumstances in which it would be appropriate for a State to reimburse expenditures for CFC services furnished by a person who is an identified backup support. The commenter also requested that CMS provide guidance on what back up support services a person can provide.

Response: The State may reimburse for any CFC service identified on the approved person-centered service plan, including those provided by a backup support person. However, the backup support person would need to be recognized by the State as an appropriate provider of CFC services and supports, for the State to reimburse those expenditures.

Comment: One commenter requested clarification regarding how the definition of ''health-related tasks'' as tasks that can be delegated or assigned by licensed professionals might interact with a State's statutory exemption from the Nurse Practice Act delegation requirements for health maintenance activities under a self-directed model. Specifically, the commenter questioned if the State is required to conform to the delegation expectation as defined. Another commenter suggested the definition for ''health-related tasks'' should include tasks that are exempted from State law and/or licensure requirements.

Response: The definition of ''health-related tasks'' specifies that tasks delegated or assigned by licensed professionals may be provided under CFC as long as the task being delegated is done in accordance with the State law governing the licensed professional delegating the task. Recognizing the variance among State laws governing the specific tasks licensed health-care professionals may delegate, we do not believe we should impose requirements that could cause a licensed professional to be out of compliance with the State law in which they provide services. We do acknowledge that this State variance will lead to a varied scope of activities meeting the definition of ''health-related tasks.''

Comment: One commenter questioned if a State can offer more than one self-directed option under different authorities of section 1915 of the Act where an item of specific difference is the delegation requirement.

Response: In addition to the section 1915(k) authority, self-directed services may be provided under other section 1915 authorities such as the section 1915(c) HCBS waiver authority, section 1915(j) Self-directed Personal Assistance Services Program State Plan Option, and section 1915(i) HCBS Plan Option. Each of these authorities has its own regulatory requirements that must be met, and each may be operated simultaneously with CFC as part of a State's Medicaid program. However, the 6 percent additional FMAP only pertains to services authorized under CFC.

Comment: One commenter requested clarification as to whether the definition of ''individual's representative'' would allow a State to select a self-direction model that limits direction by representatives, for example, to parents of minor children.

Response: Section 1915(k)(1)(A)(iv)(II) of the Act requires that services are controlled, to the maximum extent possible, by the individual or where appropriate, the individual's representative. It is an expectation that this control exists regardless of whether the individual is personally able and has chosen to make his or her own

decisions and direct his or her own services and supports, is represented by someone such as a guardian or parent who is authorized to make decisions for him or her under the laws of the State, or has selected or appointed a representative. This is true regardless of the service delivery model. The State may not place a limit on this statutory requirement.

Comment: Many commenters suggested the definition of ''individual's representative'' explicitly include spouse and partner. The commenters also suggested the definition specify that an authorized individual is someone who has been designated by the participant or family to represent the participant to the extent the participant wishes. One commenter requested the definition include paid and unpaid individuals chosen by the individual or family. One commenter requested the language be clear that the designation made by the individual does not require a formal process (such as guardianship). One commenter requested that we revise the definition of ''individual's representative'' to include a broad definition of ''family'' that recognizes a same-sex partner or a child of a partner as members of the individual's family. The commenter also requested the rule use the Office of Personnel Management's definition of ''family member.''

Response: In defining the term ''individual's representative'' we are aware that States have a variety of laws regarding selection, appointment, designation, or recognition of surrogate decision-makers with respect to personal, financial, and health care matters. We are not requiring a formal process for the appointment of an authorized representative for the purposes of CFC, but are aware that States may have procedures and requirements that may apply. We do not agree with the suggestions to amend the definition further to list specific relationships an individual may have, as we believe this could be inconsistent with the laws of the State, or overly prescriptive on an issue that is deeply personal and highly individualized. We believe the definition we proposed is broad enough to allow individuals the opportunity to exercise maximum choice with respect to the individual who will act as their representative. In some instances, the individual's representative under State law would have the authority to designate another individual as the representative for the purpose of participating in the planning and direction of services and supports under CFC. We expect the State to recognize the representative chosen by the individual if that choice is not inconsistent with State laws unless the State is aware of and can document through evidence that the representative is not acting in the best interest of the individual or is unable to perform the required functions. To reduce redundancy throughout the regulatory language, we are adding a definition for the term ''individual'' to mean the eligible individual and, if applicable, the individual's representative.

We are not requiring in this rule that an authorized representative be chosen using a formal process, such as a court-appointed guardian, or the execution of a Power of Attorney. The authorized representative may be any person an individual chooses to assist him or her in making decisions regarding his or her care unless that choice is prohibited by State law. We also note that § 435.908 provides that the single State Medicaid agency must allow an individual of the applicant's choice to accompany, assist and represent the application in the Medicaid eligibility application or renewal process. The individual assisting in the Medicaid application or renewal process need not be the same individual chosen in connection with the provision of services under section 1915(k) of the Act.

Comment: Many commenters requested the rule specify that the authorization of an individual's representative should be in writing or in some other verifiable manner. The commenters expressed concern that someone may say they are the authorized representative when they are not. The commenters believe a written authorization is necessary to assure a purposeful and clear authorization, as well as to eliminate confusion if several individuals state that they represent a person with a disability.

Response: We agree with the commenters that a written authorization is generally an appropriate safeguard to ensure individuals have an active role in electing a representative of their choice. Accordingly, we have revised the definition of individual representative as follows: ''a parent, family member, guardian, advocate, or other authorized representative of the individual with written authorization, when feasible, by the individual to serve as a representative.'' We note that a legal guardian would not need to obtain written authorization by the individual to serve as a representative. Likewise, it is not practical to require a minor child to provide written authorization for a parent to serve as a representative. States must have methods in place to ensure the individual was maximally involved in the choice of his or her representative, particularly in instances in which the individual is unable to provide written authorization.

Comment: One commenter questioned if an individual's representative assisting the individual to self-direct and manage their services can be paid as part of the service plan.

Response: Individuals acting as a representative are not paid to do so. Individuals acting as a representative also should not be a paid caregiver of an individual receiving CFC services and supports. This arrangement was prohibited in the section 1915(j) regulation, to avoid a conflict of interest. We are modifying the definition of ''Individual's representative'' to continue this prohibition.

Comment: One commenter indicated that the proposed language broadens the definition of IADLS from the definition in the SMM. The commenter recommends the rule use the SMM definition, and added that if we do not align the definition with the SMM, we clarify what is meant by ''traveling around and participating in the community.''

Response: We defined IADLs from the language used in section 1915(k)(6)(F) of the Act. We believe ''traveling around and participating in the community'' alludes to the premise that CFC services and supports should facilitate an individual's desire to be fully integrated into their community and not limit the provision of services to an individual's residence.

Comment: One commenter suggested the definition for IADLs include activities such as work life, parenting and basic home maintenance.

Response: We appreciate the commenter's suggestion, however, since the IADL definition includes the language, ''but is not limited to'' which allows for the inclusion of additional activities determined appropriate for the individual, we do not agree that a change to the definition is needed.

Comment: One commenter stated that the definition of IADLs includes the phrase ''but not limited to'' and asked if States be allowed to define these terms more expansively by adding activities to the definitions.

Response: Through the SPA process, States have the flexibility to propose additional services to be included as components of IADLs.

Comment: One commenter requested confirmation that since the definition of IADLs include managing finances, the financial management services defined at § 441.545(b)(1) can be included as an IADL. The commenter also adds that if these activities are permissible IADLs, then it is a required service under

§ 441.520(a)(1) and (2), meaning that States must provide them.

Response: Managing finances as an IADL activity pertains to assisting an individual with the management of personal finances. We believe such assistance is beyond the scope of the financial management activities defined at § 441.545(b)(1) which is for the exclusive purpose of assisting an individual to ensure CFC service budget compliance with regulatory requirements, and is only for those individuals in a ''self-directed model with service budget'' delivery system.

Comment: One commenter stated the definition for ''other models'' is not clear. The commenter asked for clarification as to whether States whose self-direction model recognizes the consumer as the employer, with the authority to hire and terminate employees, and makes available consumer and attendant care provider training opportunities, would meet the definition of ''other models.''

Response: Section 1915(k)(6)(C)(ii) of the Act defines other models as methods other than an agency-provider model, for the provision of consumer controlled services and supports. Such models may include the provision of vouchers, direct cash payments, or use of a fiscal agent to assist in obtaining services. Under the ''Service Models'' section of the preamble, we interpreted ''other models'' to mean ''self-directed model with service budget.'' We further described self-directed model with service budget in § 441.545(b)(1), (b)(2) and (b)(3). Based upon the commenter's information, it is difficult for us to determine if the model described would meet an agency-provider model or the self-directed model with service budget. We recognize that States utilize various models to provide individuals with different levels of self-direction to receive personal attendant services. It is possible for States to use existing models under either category, as long as the models meet the requirements of § 441.545.

To eliminate any confusion, we are adding a definition of ''Self-directed model with service budget'' to mean ''methods of providing self-directed services and supports using an individualized service budget. Such models may include the provision of vouchers, direct cash payments and/or the use of a fiscal agent to assist in obtaining services.''

To permit States to propose additional service delivery models not envisioned in this regulation, we will amend the definition of ''other models'' to mean ''methods other than an agency-provider model or the self-directed model with service budget, for the provision of self-directed services and supports, as approved by CMS.'' We will work with States through the SPA review process to review proposed models.

Comment: One commenter requested the regulation provide a definition for the term ''vouchers.''

Response: For the purpose of CFC, vouchers are given a specific monetary value to be used for a specific good or service. They are used in various forms, such as tokens, or tickets. We believe the use of vouchers is common among State programs and the form varies greatly. We believe the term ''voucher'' should be defined by the State if they elect to use this structure.

Comment: Several commenters shared their support of the ''self-directed'' definition included in the rule. One commenter recommended the definition of ''self-directed'' should specifically say that the individual or representative has control to hire, train, supervise, schedule, determine duties, and fire the attendant care provider.

Response: The definition reflects the language at section 1915(k)(6)(B) of the Act. However, we agree with the commenter the definition should include the specific tasks an individual should have authority to do when self-directing CFC services. Therefore, we have revised the definition to say: ''Self-directed means a consumer controlled method of selecting and providing services and supports that allow the individual maximum control of the home and community-based attendant services supports, with the individual acting as the employer of record with necessary supports to perform that function, or the individual having a significant and meaningful role in the management of a provider of service when the agency-provider model is utilized. Individuals exercise as much control as desired to select, train, supervise, schedule, determine duties, and dismiss the attendant care provider.''

Upon consideration of the public comments received, we are finalizing § 441.505 with revision to the definition of ''individual'' to incorporate the individual's representative as applicable, to add the definition of ''Self-directed model with service budget'' and to modify the definitions of ''agency-provider model'', ''backup systems and supports'', ''individual's representative'', ''other models'' and ''self-directed.''

D. Eligibility (§ 441.510)

Section 1915(k)(1) of the Act requires that to receive services under CFC, individuals must be eligible for Medicaid under an eligibility group covered by the State plan. This section does not create a new eligibility group but rather a new benefit option. Individuals who are not eligible for Medicaid under a group covered under the State Medicaid plan are not eligible for the CFC, even if they otherwise meet the requirements for the option. The proposed rule interpreted the statute as providing that individuals eligible under the State Medicaid plan whose income does not exceed 150 percent of the FPL are eligible for CFC without requiring a determination of institutional level of care. In determining whether the 150 percent of the FPL requirement is met, the regular rules for determining income eligibility for the individual's eligibility group under the State plan apply, including any income disregards used by the State for that group under section 1902(r)(2) of the Act. We proposed that individuals eligible under the State Medicaid plan whose income is greater than 150 percent of the FPL are eligible for CFC if it has been determined such individuals need the level of care required under the State Medicaid plan for coverage of institutional services. Specifically, we proposed that States must determine that, but for the provision of the home and community-based attendant services and supports, the individual would require the level of care provided in a hospital, a nursing facility, intermediate care facility for the mentally retarded or an institution for mental diseases, the cost of which would be reimbursed under the State plan. Additionally, we proposed that individuals who are eligible for Medicaid under the special home and community-based waiver eligibility group defined at section 1902(a)(10)(A)(ii)(VI) of the Act could be eligible to receive CFC services. We stated that these individuals would have to receive at least one section 1915(c) home and community-based waiver service per month. As we interpreted the statute in the proposed rule, the need for a level of care determination would be directly related to an individual's income level in section 1915(k)(1) of the Act. Thus we proposed to require an annual verification of income for all individuals receiving services under the section 1915(k) State plan option. We proposed to implement this requirement at § 441.510.

Comment: We received many comments both in support and opposition of the proposed language specifying the institutional level of care requirement. Two commenters supported the proposed eligibility

language because they believe it gives States the opportunity to prevent or delay institutional care, and that providing better integration and coordination of services in less costly settings creates the potential for significant cost savings. Some of the commenters believe that by not requiring all individuals to meet the standards for an institutional level of care, States would have the option of using CFC program funds for less needy individuals who cost less to serve. One commenter believes the eligibility language furthers the spirit of the *Olmstead* decision. Several commenters indicated that some States use nursing facility level of care assessments that do not consider the cognitive impairments of individuals, such as those with traumatic brain injury or Alzheimer's Disease and that these individuals may not be able to conduct ADLs without cuing or compensatory strategies. Several commenters supported the provision specifying that the institutional level of care standard should only be applied to individuals with incomes above 150 percent of the FPL, and such a limiting requirement should not be applied to individuals with incomes at or below 150 percent. One commenter indicated that this population is especially vulnerable, with the poorest health status and the least resources to pay for services and supports. Some commenters expressed concern with the requirement that the level of care determination only applies to individuals whose income is above 150 percent FPL. Commenters indicated that section 1915(k) of the Act is based upon the Community Choice Act [legislation introduced in the 110th (H.R. 1621/S. 799) and 111th (H.R. 1670/S. 683) Congress, but not enacted] which required all eligible individuals to have an institutional level of care. The commenters believe that requiring States to serve individuals with both institutional and non-institutional care needs could have the unintended effect of driving up the cost of implementing this program, and expressed concern that this will be a major deterrent for States to elect CFC.

While many of the commenters acknowledged the statutory language is confusing, these commenters believe the interpretation provided in the regulation does not reflect Congressional intent. They indicated that the intent of the provision was to make CFC available only to individuals requiring an institutional level of care with the goal of deterring institutionalization or encouraging transitions for institutionalized individuals back to the community. Some commenters provided legislative history to support this conclusion. The commenters indicated the income eligibility was intended to match the State's income eligibility for institutional placement, stating that 150 percent of the poverty line is established as a baseline for all States, but if a State allows a higher income level for nursing facility services then the higher income eligibility is what applies. The commenters indicated that the intent was to assure that if an individual could be income eligible for institutional placement then the individual would be income eligible for this benefit. The commenters believe this interpretation is underscored by the requirement in the statute that individuals be given a choice to receive the transitional services, described in section 1915(k)(1)(D)(i) of the Act, which only applies to the population who would be otherwise eligible for institutional placement.

One commenter requested we not apply an institutional level of care to anyone. Another commenter believes the requirement for individuals with incomes above 150 percent of the FPL to meet a nursing facility level of care is more restrictive than some State's existing financial criteria for some eligibility groups (for example, working disabled). Because of this, the commenter believes that many individuals eligible for State plan services would not be eligible for CFC. The commenter requested we reconsider requiring individuals to meet a nursing facility level of care so that those who are in need are not left out.

Some commenters recommended the rule be amended to require States to limit eligibility to individuals with income of up to 300 percent of the maximum Federal SSI benefit and an institutional level of care need. The commenters suggested that only after a State addresses this eligibility group, may a State opt to expand the eligibility to serve lower income persons who do not have an institutional level of care need. Furthermore, the commenters recommended amending the regulation to allow States the option to only cover individuals who have an institutional level of care need.

Several commenters requested clarification on the flexibility States have to limit who can receive CFC services. Several commenters expressed concern that States should not be allowed to establish a CFC program that only serves low income individuals who do not have to meet an institutional level of care.

One commenter indicated the eligibility language in § 441.510(b)(2) appears to be inconsistent with the eligibility language in the ''Background'' section. The commenter stated that being eligible for nursing facility services in Medicaid differs from requiring an institutional level of care. For example, an individual with a developmental disability may require an institutional level of care at an ICF/MR, but that individual would not be eligible for nursing facility services. The commenter recommended the regulation expressly state that an individual must be eligible for nursing facility services or require an institutional level of care. Another commenter requested clarification around the institutional level provided in an institution for mental diseases (IMD). The commenter stated that IMDs are a payment exclusion, not a facility type, service or level of intensity.

One commenter indicated that it appears that the first reference to eligibility for NF services may be redundant in § 441.510(b)(2), and requests we remove or provide clarification as to its purpose.

Response: The statute specifically sets forth the eligibility requirements for CFC. In our proposed rule, we interpreted the statute based on reading the clause ''* * * and with respect to whom there has been a determination that, but for the provision of such services, the individuals would require the level of care provided in a hospital, a nursing facility, an intermediate care facility for the mentally retarded, or an institution for mental diseases * * *'' to pertain only to the phrase immediately preceding it, which describes individuals with incomes greater than 150 percent of the poverty line. However, based on many comments, including those from the Congressional sponsors of CFC and from advocacy groups from the disability community, we have reconsidered the interpretation of the statute discussed in the proposed rule. We believe that the language, purpose, and history of the statute require a different interpretation. Commenters outlined the detailed historical efforts to have similar legislation passed since the 105th Congress and cited statements made during the 111th Congress' health reform debate, that the intent of section 1915(k) is to develop a program that improves access to community-based alternatives for individuals requiring services at an institutional level of care. Thus, the requirement in section 1915(k)(1) of the Act that the individual require an institutional level of care should be read as an independent requirement, and not as a requirement that modifies only the higher income

level. After careful review and consideration of the comments, we agree that section 1915(k)(1) of the Act should be read to require that an institutional level of care determination apply to all individuals who would be eligible for community-based attendant services and supports. Thus, we are issuing this interpretive rule to clarify that under the statute the institutional level of care requirement applies to those described earlier in the paragraph whose income does not exceed 150 percent of the poverty line, as well as to those with higher incomes. For individuals whose income is above 150 percent of the FPL, the individual must be part of an eligibility group that provides access to the nursing facility benefit.

We are revising § 441.510 to state that, regardless of income, for individuals to receive CFC services, it must be determined, on an annual basis, that but for the provision of CFC services, the individual would meet an institutional level of care. We are also revising § 441.510 to allow States, at their option, to waive the annual level of care requirement if the State, or designee, determines that there is no reasonable expectation of improvement or significant change in the participant's condition because of the severity of a chronic condition or the degree of impairment of functional capacity. Lastly, we acknowledge the confusion created by using the term ''level of care furnished in an IMD''. We are revising § 441.510 to specify that this means a level of care furnished in ''an institution providing psychiatric services for individuals under age 21'' and ''an institution for mental diseases for individuals 65 or over''. This clarification is now expressed at § 441.510(d).

Comment: One commenter questioned whether CFC is an entitlement program.

Response: The CFC program is an optional service available under the Medicaid program. States have the choice of whether to include this service in their Medicaid State plan. As an optional service, States also have the flexibility of offering this service to individuals qualifying for Medicaid under the categorically needy group only, or to both the categorically and the medically needy under the Medicaid State plan. Once the service is offered under a State plan, all eligible individuals who qualify for the service must be provided the care.

Comment: We received many comments requesting clarification on whether CFC established a new eligibility group. Several commenters specifically requested that we allow States, at their discretion, to make the CFC population a separate categorical population for the purposes of automatically qualifying for Medicaid. The commenters stated this would allow people in need of CFC services to qualify for Medicaid in the same way individuals qualify for nursing facility services, HCBS waiver services, and HCBS State plan (section 1915(i)) services. The commenters believe the proposed regulation's language for access to CFC is more limited. The commenters do not believe that the Congress intended the eligibility pathways to CFC to be inferior to the pathways of other similar services and programs. Additionally, commenters noted that a separate CFC eligibility category is needed to allow individuals who could qualify for Medicaid in the medically needy category to receive CFC services in States that do not provide State plan services to the medically needy eligibility category. Another commenter believes the statutory language authorizes eligibility for a special-income level categorical population. Specifically the commenter believes the following statutory language ''individuals who are eligible for medical assistance under the State plan whose income does not exceed 150 percent of the poverty line, or, if greater, the income level applicable for an individual who has been determined to require institutional care'' is a clear reference to the special income level categorical populations authorized by 42 U.S.C. § 1396a(a)(10)(A)(ii)(V) and (VI) (relating to institutionalized individuals and HCBS waiver recipients, respectively). The commenter believes this language demonstrated Congressional intent to allow States to make the CFC benefit available to individuals with incomes up to 300 percent of the Federal SSI benefit rate, the same way that States may make nursing facility services, HCBS waiver services, and HCBS State plan benefit services available to them. In addition to the CFC statutory language, the commenter believes that the statutory language in the Deficit Reduction Act and the Affordable Care Act show that the Congress intended to create a new, income-based categorical eligibility population for HCBS State plan and CFC beneficiaries. The commenter believes that failure to create a separate categorical eligibility for CFC would result in unfair outcomes for beneficiaries. The commenter believes CMS has discretion to authorize separate eligibility categories. Another commenter requests clarification of the meaning of ''eligible for medical assistance under the State plan'' with regard to States that have opted to use the special income standard at section 1902(a)(10)(A)(ii)(V) of the Act for institutionalized individuals. The commenter believes the CFC statute and the proposed regulation would prohibit access by those who would only be eligible for Medicaid by virtue of residing in a medical institution.

Response: Section 1915(k) of the Act did not amend section 1902(a)(10) of the Act to the establish a new eligibility group of individuals receiving 1915(k) services. Section 1915(k) of the Act created new pathways for Medicaid eligible individuals to receive home and community-based attendant services and supports. To receive services under 1915(k), individuals must be eligible for medical assistance under the State's Medicaid plan, must meet an institutional level of care, and be in an eligibility group under the State plan that includes nursing facility services. If the individual is in an eligibility group under the State plan that does not provide coverage of nursing facility services, the individual must have income that is at or below 150 percent of the federal poverty line.

Comment: One commenter believes that individuals must only be *eligible* for section 1915(c) HCBS waivers or section 1115 demonstrations, rather than be enrolled and receiving waiver services, to be eligible for CFC.

Response: Section 1915(k)(1) of the Act provides that individuals must be eligible for Medicaid under an eligibility group covered by the State plan. As noted above, to be eligible for Medicaid under the special HCBS waiver group, individuals must receive at least one section 1915(c) waiver service per month.

Comment: One commenter requested with regard to § 441.510(b)(3), we confirm that there is not an eligibility group specific to waiver programs, but that section 1902(a)(10)(A)(ii)(V) of the Act allows individuals in institutions to be eligible under the 300 percent Special Income Group and section 1902(a)(10)(A)(ii)(VI) of the Act allows for application of the 300 percent Special Income Group to those individuals receiving HCBS as an alternative to institutional care.

Response: We included the reference to the special income group in the CFC regulation to highlight that States may offer section 1915(k) services to individuals who qualify for Medical assistance under the special home and community-based waiver eligibility group defined at section 1902(a)(10)(A)(ii)(VI) of the Act and who receive at least one home and

community-based waiver service per month. The special income group is an example of an eligibility group States may cover under the special home and community-based waiver group. It is our intent to permit people in section 1915(c) home and community-based waiver programs to receive section 1915(k) services also. We are moving this language to § 441.510(e), removing paragraph (b)(3), and making a technical correction to replace the term ''Medicaid assistance'' with ''medical assistance.''

Comment: One commenter requested we clarify whether an individual qualifying for Medicaid under the Family and Children's and Medicare savings eligibility categories are eligible to receive CFC services.

Response: Individuals must be eligible for Medicaid under an eligibility group covered by the State plan. If these are eligibility groups the State covers under its Medicaid State plan, they could be eligible to receive services under CFC as long as the individuals meet all other eligibility criteria. However, we note that Medicare beneficiaries eligible for Medicaid only for Medicare cost-sharing, such as Qualified Medicare Beneficiaries, would not be eligible for CFC services unless they are eligible for full Medicaid benefits under another State plan group.

Comment: Some commenters requested we clarify whether a State is required to cover all of the income levels defined at § 441.510 or whether a State could limit eligibility to only one or two of the income levels. One commenter questioned if a State could exclude State plan individuals qualifying under the medically needy group from receiving CFC services.

Response: If an individual is eligible for medical assistance under the State plan, meets an institutional level of care; and is part of an eligibility group with access to the nursing facility benefit (or if part of an eligibility group without access to the nursing facility benefit with an income at or below 150 percent FPL) then the State must allow the provision of CFC services if the State elects to include the CFC state option as part of its State plan. Please note that CFC is an optional service, therefore, as with any other optional service available under the State plan, it is at the State's discretion to provide these services to the medically needy group in addition to the categorically eligible group.

Comment: Some commenters questioned if a State has the flexibility to limit CFC recipients to their current FPL or whether they would have to expand to 150 percent FPL. Another commenter questioned if a State could impose stricter eligibility than 150 percent of the FPL.

Response: Section 1915(k) of the Act does not permit States to increase income standards or to impose stricter income standards for covered eligibility groups. If the income standard for a covered group is less than 150 percent of the FPL, States may not increase it or decrease it for individuals who will receive CFC services.

Comment: One commenter requested clarification regarding eligibility groups that are automatically eligible for Medicaid without regard to income, and the application of the 150 percent limit above which institutional level of care is required. For example, some States provide eligibility without an income test to children eligible for foster care or adoption assistance, women receiving treatment for breast or cervical cancer, and individuals with section 1619(a) or (b) status. The commenter requests clarification as to whether States are required to identify income for these groups to determine eligibility for CFC services, or whether States should assume that all individuals in these ''automatic'' categories are eligible, regardless of level of care status.

Response: As indicated above, we have revised the regulation to require all individuals receiving CFC services to meet an institutional level of care. Individuals who meet the eligibility requirements for a Medicaid group for which the State provides full State plan services may receive CFC services if: (a) They satisfy the institutional level of care requirement; and (b) they are in an eligibility group that includes nursing facility services under the State plan, or, if their eligibility group does not include nursing facility services under the State plan, their income is at or below 150 percent of the FPL.

Comment: One commenter requested clarification on what is considered a ''special population.''

Response: We did not use the term ''special population'' in the preamble or regulatory text. If the commenter is referring to our reference to the ''special home and community-based waiver eligibility'' group defined at section 1902(a)(10)(A)(ii)(VI) of the Act and our use of the term ''special income level group'', we are referring to individuals eligible for Medicaid through meeting the eligibility for HCBS waivers services under institutional rules.

Comment: One commenter questioned how an individual's assets are considered in determining financial eligibility for the CFC option.

Response: An individual receiving services under the CFC option must be eligible for Medicaid under the State plan. Therefore, the State's usual Medicaid eligibility rules would determine whether and how the individual's assets are counted in determining eligibility for Medicaid. This may vary from group to group. There are no additional special CFC rules regarding assets.

Comment: Several commenters recommended the regulation allow individuals who would qualify for Medicaid under the medically needy eligibility group to qualify in the low-income category. The commenters believe individuals with income over 150 percent FPL in the medically needy group should be included in the low-income group because the medically needy group is required to spend down to 75 percent of FPL to qualify for Medicaid. The commenters believe it would be costly and administratively burdensome for States to implement two sets of eligibility criteria for CFC. Several commenters indicated that as written, the proposed rules potentially exclude individuals who would otherwise qualify for a Medicaid-funded nursing facility placement because their gross income would be too high. The commenters recommend the regulation be revised to have language clarifying that individuals who may spend down to Medicaid eligibility under the medically needy category would also be eligible for the CFC benefit.

Response: The rule does not preclude States from providing 1915(k) services to individuals who are Medicaid eligible as medically needy. If a State covers the medically needy eligibility group under its State plan, the State can elect to provide section 1915(k) services to the medically needy. In determining Medicaid eligibility for medically needy individuals receiving section 1915(k) services, the State must use the same income and resource methodologies approved under its State plan (for the medically needy), including spend down and any methodologies approved under section 1902(r)(2) of the Act.

Comment: One commenter recommends paragraph § 441.510(c) be amended to add language articulating that the regular rules for determining income eligibility for an individual's eligibility group under the State plan apply when determining whether the individual's income is below 150 percent of FPL.

Response: We agree with the recommendation made by the commenter and will revise this provision accordingly.

Comment: One commenter indicated that cash payments to purchase personal attendant services or used to purchase

services that substitute for human assistance should not be counted as income or resources when determining eligibility for public benefit programs or income tax purposes. The commenter indicated that problems could arise if the cash benefit is treated as income, that when added to the individual's actual income would disqualify the individual from the public benefit programs.

Response: Disbursement of cash to individuals in accordance with § 441.545(b)(2) is for the sole purpose of purchasing program approved services and supports identified in an individual's person centered service plan. Therefore, for the purpose of determining an individual's Medicaid eligibility, receipt of such monies should not be considered income, nor should it have any effect on an individual's eligibility for Medicaid. Determining the treatment of income for the income tax purposes is beyond the scope of this rule, as such, we do not have the authority to opine on tax related issues.

Comment: Many commenters recommended the regulation be modified to explicitly address the Affordable Care Act's modification to the spousal impoverishment statute that goes into effect January 1, 2014. The commenters expressed concern that if CFC is limited strictly to individuals who qualify under an eligibility group covered under the State plan before they may receive coverage for the benefit, the community spouse resource allowance will be meaningless for most CFC beneficiaries, because most CFC beneficiaries will have been screened against the more limited ''couple'' resource standard applicable to the category under which they originally qualified. Additionally, commenters requested the full spousal impoverishment protection be extended.

Response: The rule does not need to be modified to reflect section 2404 of the Affordable Care Act because eligibility for the CFC services hinges on independent eligibility under an eligibility group in the State's plan. Guidance on section 2404 of the Affordable Care Act is outside the scope of this regulation.

Comment: One commenter stated that the eligibility criteria included in the regulation does not include a needs assessment element. The commenter believes that CFC services and supports are not medical and as such it is not appropriate for a State to set ''medical necessity'' criteria to establish who can receive CFC services. The commenter recommends CMS consider adding a new eligibility element to specifically assess an individual's need for attendant services.

Response: We disagree with the commenter. Section 441.535 requires an assessment of functional need for each individual receiving CFC services. The information gathered in the assessment must support the determination that an individual requires CFC services.

Comment: One commenter requested the regulation clarify whether both non-institutional and institutional individuals must be served.

Response: Although the eligibility criteria require individuals to meet an institutional level of care, services are only available to individuals residing in a home and community-based setting. Recognizing the purpose of these services includes providing individuals living in institutions the opportunity to transition to a home and community-based setting, we understand that individuals may be residing in an institution during the assessment process of the program. However, CFC may not be provided until the individual is residing in the community, with the exception of transitional services.

Comment: A few commenters recommended revising the regulation to add a paragraph to § 441.510, clarifying that the CFC option is not mutually exclusive and can be provided to eligible Medicaid enrollees in the State who are receiving other non-CFC services and supports under another waiver program. Specifically, the commenters recommend that a paragraph (d) should be added to § 441.510 providing that ''Individuals receiving services through CFC will not be precluded from receiving other home and community-based long term care services through other waiver or State plan authorities.''

Response: We agree with the commenter and have included the recommended language in a new paragraph (e).

Comment: Several commenters requested we clarify whether States have the flexibility to establish medical or functional eligibility criteria. One commenter asked if a State can impose the same functional eligibility requirements that exist for a State's personal care State plan option. Several other commenters requested we allow States to establish medical eligibility criteria that would limit eligibility for the program to individuals who have an institutional level of care, regardless of their income. The commenters believe that without this clarification, States could perceive the option as too expensive to adopt if they have to serve both non-institutional and institutional level beneficiaries. Alternatively, one commenter recommended the regulations require that any medical or functional criteria States establish for CFC not be more restrictive than the State's nursing facility or other institutional level of care requirements.

Response: As indicated in an earlier response, we are interpreting the statute to include a requirement that States make determinations for all individuals receiving CFC services that an institutional level of care would be required but for the provision of home and community-based services.

Comment: One commenter supports the eligibility and statewideness requirements in the regulation, indicating that this will prevent States from limiting services to a numeric amount or to a geographic area, with the result being increased access to home and community-based services by those in need. The commenter stated that States still have flexibility to set medical necessity. The commenter requested CMS monitor State efforts to educate all beneficiaries of the program, expressing concern that States may tailor public relations activities, such as limiting outreach efforts, to certain geographic areas of the State.

Response: States must offer CFC services on a statewide basis. As indicated in an earlier response, all individuals must meet an institutional level of care to receive CFC services. Thus, there is no need for States to establish separate medical necessity criteria, for the purpose of determining who may receive CFC services.

Comment: Some commenters recommended the rule be amended to require States to limit eligibility to individuals with income of up to 300 percent of the maximum Federal SSI benefit and an institutional level of care need. The commenters suggested that only after a State addresses this eligibility group, may a State opt to expand the eligibility to serve lower income persons who do not have an institutional level of care need. Furthermore, the commenters recommended amending the regulation to allow States the option to only cover individuals who have an institutional level of care need.

Response: As we have stated, we are setting forth in this final rule our interpretation that under the statute all individuals must meet an institutional level of care to receive CFC services.

Comment: One commenter does not want the institutional level of care requirement applied to the special income group.

Response: The special income group is an institutional eligibility group.

Therefore, States must follow the rules pertaining to the eligibility requirements for the special income group defined at section 1902(a)(10)(A)(ii)(V) of the Act, which includes the requirement that individuals must meet an institutional level of care.

Comment: With regard to the special income group, commenters questioned if case management or monthly monitoring would satisfy the requirement that individuals must receive at least one home and community-based waiver service per month. Additionally, the commenters requested the language be revised to say ''is receiving at least one home and community-based waiver service per month or monthly monitoring.''

Response: The purpose of this language is to ensure that people in the special income group maintain their eligibility for Medicaid, thereby adhering to the CFC eligibility criteria that people must be eligible for the State plan. If monthly monitoring is an approved waiver service in the State, this would satisfy the requirement.

Comment: A few commenters requested clarification on whether States had to extend CFC services to individuals in the waiver program. The commenters recommended revising § 441.510(b)(3) to state ''eligible if the State elects to expand CFC service coverage to its waiver program.'' Another commenter expressed concern about the potential overutilization of services if individuals eligible for waivers are required to continue to receive one waiver service to maintain eligibility for CFC.

Response: Individuals enrolled in section 1915(c) waivers are eligible to receive any State plan service. Individuals in the special home and community-based waiver group are required to receive at least one waiver service per month. Section 1915(k) of the Act did not change this requirement. We expect States to implement policies and procedures to prevent overutilization and duplication of services when individuals receive services through a 1915(c) waiver and the CFC State plan option.

Comment: We received many comments both opposed to and in support of the annual income requirement set forth in § 441.510. Some commented on the methods for verification, such as recommending ''Passive redetermination'' and that income recertification for CFC should not be more burdensome, for individuals or for States, than the existing Medicaid programs.

Response: As explained above, in the final rule, we are modifying our regulations to make clear that the 150 percent of FPL income determination would only be necessary in cases where an individual is not in a Medicaid eligibility group under the State plan that already provides coverage for nursing facility services. In such cases, there would need to be an annual verification of income for the purpose of determining an individual's eligibility for CFC services.

States that employ passive eligibility re-determination methods for the purpose of Medicaid eligibility could continue to do so. Additionally, we believe it is appropriate for the State to align this CFC requirement with the annual recertification process for Medicaid.

Upon consideration of public comments received, we are modifying § 441.510, and are issuing an interpretive rule to clarify the statutory requirements for eligibility. We are revising the language in § 441.510(b) as originally proposed. We are clarifying the statutory requirement that individuals must be in an eligibility group under the State plan that includes nursing facility services. Individuals in an eligibility group that does not include such nursing facility services must have an income at or below 150 percent of the FPL. We added the language proposed at § 441.510(c) to § 441.510(2) with clarification that in determining whether 150 percent of the FPL requirement is met, State must apply the same methodologies as would apply under their Medicaid State plan, including the same income disregards in accordance with section 1902(r)(2) of the Act. We replaced the language proposed at § 441.510(c) with the provision that all individuals meet an institutional level of care, removing the term ''an institution for mental diseases'' and replacing it with ''an institution providing psychiatric services for individuals under age 21'' and ''an institution for mental diseases for individuals age 65 or over,'' and adding § 441.510(c)(1) and (2) to allow for State administering agencies to permanently waive the annual level of care recertification if certain conditions are met. We have relocated the language proposed at § 441.510(b)(3) to a new paragraph (d), and removed the term ''Medicaid assistance'' and replaced it with ''medical assistance.'' We are also adding a new paragraph (e) to indicate that receipt of CFC services does not impact receipt of other long-term care services provided through other Medicaid State Plan, waiver, or grant authorities.

E. Statewideness (§ 441.515)

To reflect the requirement at section 1915(k)(3)(B) of the Act, we proposed that States must provide CFC services and supports on a statewide basis, in a manner that provides such services and supports in the most integrated setting appropriate to the individual's needs, and without regard to the individual's age, type or nature of disability, or the form of home and community-based attendant services that the individual requires to have an independent life.

Comment: Many commenters supported the provisions under § 441.515. One commenter applauded CMS for recognizing that people should receive services and supports based on their need rather than a predetermined assumption based on characteristics, such as age or disability. Several commenters further emphasized the ability of this program to enhance State adherence to the *Olmstead* decision and providing services in the most integrated setting appropriate to the individual's needs.

Response: We appreciate the perspectives these commenters had in support of this provision of the rule.

Comment: One commenter asked CMS to clarify how we will define the ''most integrated setting appropriate to the individual's needs.''

Response: This requirement is not defined in the statute and we do not believe that is it appropriate to define this phrase in this regulation. Rather, we expect States implementing CFC to have meaningful interactions with each individual electing to receive CFC services and supports. Through the assessment of functional need and the development of the person-centered service plan, individuals should be made aware of all living arrangements available for their consideration. As indicated below at ''Person-centered service plan'' (§ 441.540), a requirement of the service plan is a description of these options and a reflection of the individual's choice. These protections represent significant advances in facilitating individuals' rights to live in the most integrated setting appropriate to their needs. We plan to publish a separate proposed rule to define home and community based settings and issue additional guidance which should further assist States in these efforts.

Comment: One commenter recommended that CMS clarify that it is within the State's discretion to limit the amount, duration, and scope of the required services within CFC.

Response: As indicated in the responses to questions received in the ''Basis and Scope'' (§ 441.500) section of

the regulation, CFC is an optional benefit and a State may set limits on the amount, duration and scope of the services provided under the option, consistent with the regulation at § 440.250. However, section 1915(k)(3)(B) of the Act indicates that the services must be provided on a statewide basis without regard to the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life. There requirements are reflected at § 441.515. A State cannot set limits on the amount, duration, and scope based on any elements listed above.

Comment: A few commenters indicated that the language in § 441.515(c), ''in a manner that provides the supports that the individual requires to lead an independent life'' is broad. One commenter suggested removing the language, but offered the suggestion of defining such supports in § 441.520, ''Required Services,'' if the language is not removed. Another commenter asked if a State could set reasonable parameters on the level of support commitment such as an annual service budget amount limit or a cap on the hours of paid care per day.

Response: As noted above, States maintain the flexibility to set limits on the amount, duration and scope, except based on the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life. While the majority of the language in § 441.515(c) was taken from the statute, we realize that making this language separate from the language in § 441.515(b) could create confusion, so we are taking this opportunity to remove § 441.515(c) and incorporate its language in § 441.515(b) to more directly align with the statute.

Comment: One commenter encouraged CMS to issue guidance or add language to the regulation to ensure that CFC is provided to all qualified applicants in the State regardless of sexual orientation, gender identity or expression, or marital status.

Response: Section 441.500(b) addresses this concern specifying that CFC is designed to make available services and supports to eligible individuals. It is not permissible for a State to deny the provision of medical assistance services to eligible individuals based on sexual orientation, gender identity or expression, or marital status. We do not agree that additional language needs to be added to the regulation to clarify.

Comment: A few commenters asked whether States would be afforded the flexibility to target specific populations.

Response: As noted above, States electing CFC must provide CFC services and supports on a statewide basis and without regard to the individual's age, type or nature of disability, severity of disability or the form of home and community-based services and supports that the individual requires to lead an independent life. This requirement does not allow States to target any specific population.

Comment: One commenter requested clarification regarding the statewide implementation of the CFC. Specifically, the commenter asked if CFC can be implemented throughout the State incrementally over time or if the option must be statewide upon implementation.

Response: If a State chooses to implement CFC, it must be implemented on a statewide basis, not phased-in incrementally throughout the State.

After consideration of the public comments, we are revising this section to remove § 441.515(c) and incorporate its language in § 441.515(b) to more directly align with the statute.

F. Included Services (§ 441.520)

We proposed to reflect the requirements at sections 1915(k)(1)(A) and (B) of the Act that States electing CFC must provide:

- Assistance with ADLs, IADLs, and health-related tasks through hands-on assistance, supervision, or cueing;
- The acquisition, maintenance and enhancement of skills necessary for the individual to accomplish ADLs, IADLs, and health-related tasks;
- Backup systems or mechanisms to ensure continuity of services and supports; and
- Voluntary training on how to select, manage, and dismiss attendants.

We also proposed to require that States choosing to provide for permissible services and supports as set forth at section 1915(k)(1)(D) of the Act, must offer at a minimum, expenditures for transition costs such as rent and utility deposits, first month's rent and utilities, bedding, basic kitchen supplies, and other necessities required for an individual to transition from a nursing facility, institution for mental disease, or ICF/MR to a community-based home setting where the individual resides. States choosing to provide for permissible services and supports set forth at section 1915(k)(1)(D) of the Act may also include expenditures that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for human assistance.

Comment: One commenter indicated that the proposed rule is not clear regarding whether all services and supports listed at § 441.520(a) must be provided to all individuals served under CFC, and the commenter provided cost estimates if each potential participant were provided a pager (including device and monthly service charges). The commenters indicated that it would be cost prohibitive for their State to provide each participant all the services and recommended it be made clear that the services and supports listed in (i) through (iii) are to be made available based on parameters indicated in each State Medicaid plan. For example, backup systems that include electronic devices may only be needed by persons who have high level of care needs, while persons with greater functioning across ADLs or IADLs may simply require advance planning in case their attendant fails to show up for work.

Response: The ''Background'' and the ''Provision of the Proposed Rule'' sections both indicated that the services listed under *Required Services* must be made available by States electing CFC. This does not mean that each and every individual participating in CFC would receive each of these services. Each individual's needs must be assessed, and only those required services needed by the individual must be provided. As indicated above, States have the flexibility to decide what backup systems and supports will be offered in their CFC programs as long as these systems will sufficiently meet the needs of individuals served under CFC.

Comment: One commenter asked if States could design a CFC program where each participant may not receive all of the four required services in paragraph (a).

Response: All services listed in § 441.520(a) must be made available by any State that elects the CFC. The services authorized for individuals must be based upon their individualized assessment of functional need.

Comment: One commenter specifically asked if CFC could be used to support consumers' employment goals.

Response: As indicated at section 1915(k)(1)(C) of the Act, vocational rehabilitation services under the Rehabilitation Act of 1973 are specifically excluded by the statute; however, we affirm that attendant services and supports under the CFC

could be utilized by an individual while at their place of employment.

Comment: One commenter urged CMS to provide additional guidance regarding the frequency with which required services may be provided stating that individuals with mental illness may not require assistance with ADLs and IADLs 24 hours a day/7 days a week as these individuals are often able to accomplish these tasks independently, particularly when personal assistance is supplemented by skills training. The commenter suggested that CMS clarify at § 441.520(a)(1) that assistance need not be furnished on a constant, 24/7 basis.

Response: While we agree with the commenter that individuals may not require assistance with ADLs and IADLs 24 hours a day/7 days a week, we do not agree that this needs to be clarified in the regulation. The amount of supports and services provided under this option are determined based on an individualized assessment of functional need.

Comment: One commenter requested that CMS clarify ''health-related tasks'' and asked if these include medication administration and other paramedical tasks such as g-tube feeds, ostomy care, wound care, etc. and if so, for individuals self-directing their personal care, would these tasks be furnished by personal care attendant care providers who are employed by the individual (responsible for training and supervising the attendant care provider) where there is no nurse involvement. The commenter also inquired how assistance with medications is accounted for. Another commenter added that State Nurse Practice Acts vary greatly and have very specific requirements regarding what types of health-related tasks may be delegated and/or overseen by licensed medical professionals, such as registered nurses. In addition, the commenter requested that CMS add language acknowledging that the scope of the health-related tasks may vary by State and added that for health services that are not delegated under a State Nurse Practice Act or in States without nurse delegation, such services would have to be delivered under State plan home health or waiver skilled nursing benefits.

Response: The statute specifically defines ''health-related tasks'' as ''specific tasks related to the needs of an individual, which can be delegated or assigned by licensed health-care professionals under State law to be performed by an attendant.'' Given this definition, activities that are not able to be delegated or assigned by a licensed professional under State law are not ''health-related tasks.'' Recognizing the variance among State laws governing the specific tasks licensed health-care professionals may delegate, we recognize that the scope of ''health-related tasks'' will differ by State. This will be the case regardless of the service delivery model utilized by the State, including self-direction. We agree with the commenter that activities outside the scope of ''health-related tasks'' may continue to be claimed, as appropriate, through other Medicaid authorities such as home health, rehabilitative services, services provided by other licensed practitioners, etc.

Comment: One commenter indicated strong support for inclusion of the phrase ''hands on assistance, supervision, or cueing'' in § 441.520(a)(1), as persons with different disabilities require different types of assistance. Another commenter urged CMS to consider whether the use of ''and/or'' in ''hands on assistance, supervision, or cueing'' would make it clear that a combination of methods may be used for any particular individual, depending on what is needed. One commenter asked if there is State flexibility to focus on only a single modality (hands-on or supervision or cueing) or if all 3 modalities must be covered.

Response: We understand that what is needed to assist with ADLs, IADLs, and health-related tasks will vary from individual to individual and expect that any one, or a combination of, hands on assistance, supervision, or cueing could be necessary to accomplish these tasks. As such, all three modalities must be available, however, it is an individual's assessed needs and person centered plan that will determine which will be provided. We agree with the commenter and have revised the rule to include ''and/or'' to make our intent clear.

Comment: A few commenters asked if there was any additional guidance regarding what services constitute the ''acquisition, maintenance, and enhancement of skills necessary for the individual to accomplish ADLs, IADLs, and health-related tasks.'' Several commenters indicated that States should have the same discretion they already exercise in structuring their waiver programs and recommended that CMS make explicit that States will have the discretion to define the services that will be provided to assist consumers with the ''acquisition, maintenance and enhancement of skills necessary for the individual to accomplish ADLs, IADLs, and health-related tasks'' and suggested the following language be added to the rule: ''*as defined by the State and approved by the Secretary.''* Another commenter added that to assure consistency with other home and community-based services programs and to allow States to define services, CMS should revise paragraph (a) to add ''If a State elects to provide the Community First Choice Option, the State must provide all of the following services as defined by the State and approved by the Secretary.''

Response: The ''acquisition, maintenance, and enhancement of skills necessary for an individual to accomplish ADLs, IADLs, and health-related tasks'' is a direct provision of the statute and we agree with the commenters that States should have the same discretion they currently have to define their programs, particularly, since CFC is an optional benefit.

We have chosen not to specifically define this component of the CFC benefit to facilitate State flexibility. States will need to define how they will implement this component through their SPAs. States could choose several methods to meet their obligations for this component of the benefit, including, but not limited to, incorporating functional skills training and/or the use of permissible services and supports that facilitate the acquisition, maintenance, and enhancement of skills through the purchasing of services and/or supports that increase independence or substitute for human assistance. We are available to provide technical assistance to States in determining alternative ways to satisfy this requirement.

Comment: A commenter noted that for the acquisition, maintenance and enhancement of skills, such services may be unrealistic or unnecessary for elderly persons in extremely fragile health, or whose health is deteriorating (such as cancer patients), but appropriate for other persons with disabilities. The commenter believes that the statute gives States flexibility in these cases by identifying the acquisition, maintenance and enhancement of skills as an ''included service and support'' and recommends the CMS clarify in the regulations that States provide these services to individuals likely to benefit from them, based on the assessment of functional need and individual service plan, and consistent with the CFC philosophy of self-direction.

Response: We appreciate the perspective of this commenter. Ultimately, each individual's assessment of functional need should determine whether or not an individual needs the acquisition, maintenance, and enhancement of skills necessary for accomplishment of ADLs, IADLs, and

health-related tasks. If it is determined that an individual needs them, a State would be required to provide them, according to the parameters of the person-centered service plan discussed at § 441.540. However, we do reiterate a State's ability to put limits on the amount, duration and scope of CFC services, as long as these limits are not based on the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life, as prohibited in the statute.

Comment: A commenter stated strong support for both the inclusion of backup systems or mechanisms to ensure continuity of services and supports, and the training of how to select, manage and dismiss attendants referenced at § 441.520(a)(3) and (4), respectively. One commenter questioned if cell phones funded under Federal programs (for example, Safe Link) can be considered for use to meet backup system requirements. Another commenter recommended amending this rule to allow for plans of action in case of emergency, such as identifying a friend or relative who could be called upon if a provider does not show up, or calling for emergency backup through a local public registry. One commenter suggested that the plan for continuity of services (if existing services are disrupted) should be flexible and participant-driven, much like the plan for services.

Response: There are various options for backup systems. We agree with the commenters that backup systems and supports may include approaches in addition to electronic devices. This belief is supported by the inclusion in the definition described in the proposed rule of allowing people to be included as backup supports. We agree that a cell phone funded under another program (Federal or otherwise) could be used as part of a backup system, assuming doing so does not violate any terms of use required by the other program. However, it is important to note that items or services provided through another program or benefit are not eligible for Federal financial participation (FFP) under CFC.

Comment: One commenter voiced concern that States will develop a ''canned'' ''one size fits all'' voluntary training package or program specified in § 441.520(a)(4), and suggested that the voluntary training needs to be very flexible and individualized. Another commenter recommended that training be a required step in demonstrating that the individual has the tools to select, manage, and dismiss attendants. One commenter indicated that, consistent with the philosophy of self direction, this training must be voluntary and not a mandatory requirement for the individual to receive services under CFC, and requested that CMS allow States to provide established, existing consumer training programs already available to consumers/employers. Another commenter stated that, it is important that all training content and procedures be driven by the participants themselves, and while the proposed rule specifies that training be ''developed'' by States, the commenter pointed out that various training curricula already exist, and suggested that one method to control costs would be to modify and adopt existing training approaches, as long as such training is agreed upon by participants and the methods are sensitive to the training needs of the targeted groups (for example, accessible format, at no cost, web-based, etc.). Another commenter encouraged CMS to allow States to retain the authority to develop this training with a level of flexibility that would be appropriate to meet the needs of all potential CFC participants.

Response: As the commenters indicated, many States currently have existing consumer training programs available that could potentially be leveraged or modified to meet this requirement. These training programs should be able to meet the needs of individuals at varying levels of need with regard to selecting, managing, and dismissing attendants. As we stated in the proposed rule, consistent with the philosophy of self direction, and in keeping with the statute set forth at section 1915(k)(1)(B)(iii) of the Act, this training must be voluntary, and may not be a mandatory requirement for the individual to receive services under this option.

Comment: A few commenters suggested that CMS create a separate section for permissible purchases to reduce confusion. One commenter added that since § 441.520(b) begins a list of optional services, CMS should begin a new section here to clarify that these services are not required services. The commenter added that CMS should clarify at (b)(1) that ''the waiver'' would not cover rent as this is excluded.

Response: We are renaming § 441.520 as ''Included Services'' to reduce confusion and to highlight that permissible services and supports in paragraph (b) are at the State's option. We also reiterate that CFC is not a waiver program, but rather a new optional service authorized under the Medicaid State plan. With regard to the commenter's suggestion about the exclusion of rent, while ''room and board'' are excluded services, expenditures related to transition costs, including the first month's rent, are the exception. Therefore, we do not agree that revisions are necessary.

Comment: One commenter asked whether an individual receiving services through CFC and a section 1915(c) waiver could receive assistive devices if they are covered services in the waiver.

Response: Assistive devices and assistive technology services may be provided under CFC if the requirements under § 441.520(b) are met. It would be up to the State to choose whether to provide these items through a waiver, or through CFC, if an individual is participating in both programs.

Comment: One commenter asked that CMS clarify the minimum services that must be offered if a State chooses to provide permissible services.

Response: While we proposed to require that States offering permissible services and supports must at a minimum provide for transition costs, we realized that the statute does not provide a basis to require such services and supports. Therefore, the provision of permissible services and supports are at the State's option. We strongly encourage States to consider providing for the transition services and supports at paragraph (b)(1) under § 441.520.

Comment: One commenter indicated that States need to have the flexibility in permissible purchases to set limitations on these costs including the total amount, recurrence, etc.

Response: States have the flexibility to design their CFC benefit as long as all requirements are met. States maintain the flexibility to set reasonable limitations on the costs of permissible services and supports. We encourage States to consider the ability of beneficiaries to actually return to the community when establishing limits on these services and supports. We will work with States on an individual basis to ensure the intent of the legislation is met, while acknowledging the realities of State fiscal situations.

Comment: One commenter voiced concern that permissible purchases, including expenditures necessary for an individual to transition from institutional care and expenditures for items that could increase independence or substitute for human assistance, are considered optional for States electing to offer CFC. The commenter added that these optional services in many cases would make the difference between whether an individual can live successfully in the community or not

and suggested that CMS should more strongly encourage States to allow the purchase of these services, perhaps by providing some additional incentive for States to do so, financial or otherwise.

Response: We agree with the commenter that transition costs can be crucial for an individual as it relates to being able to transition from an institution to the community. We also agree that many items that increase independence or substitute for human assistance have the potential to make a significant difference in an individual's life while also being cost-effective. We hope that the enhanced match included in CFC, and the potential for cost savings, will be an incentive to States to include permissible services and supports in their CFC programs. We are also revising the language in paragraph (b)(1) under § 441.520 to reference a ''home and community-based setting'' rather than a ''community-based home setting.''

Comment: One commenter suggested that expenditures related to transition costs should include funding for basic home modifications to expand the supply of physically accessible housing options. Such modifications to entrances or bathrooms, for example, could make an otherwise inaccessible unit accessible at a reasonable cost. This commenter also indicated that while the proposed rule states that individuals are not required to save an amount in a budget to purchase items that increase independence or substitute for human assistance, it should be made clear that individuals should not be pressured to purchase items if it would unduly reduce the hours of personal assistance in a manner that negatively impacts overall service needs.

Response: At the State's option, and consistent with the statute, where a service is based on a need identified in the person-centered service plan, qualifying home modifications may be provided either as a transitional costs or as a way to increase an individual's independence or as a substitute for human assistance. We further address this in § 441.525(e). We also agree that individuals should not be pressured to purchase any items if such purchases would reduce the number of hours of assistance in a manner that would negatively impact them.

Comment: One commenter suggested that institutions other than nursing facilities, IMDs, or ICF–MRs should be included among the list of institutions from which individuals could transition, as often individuals with serious mental illness reside in smaller institutional settings such as adult homes or large group homes. The commenter indicates that these funds would be necessary for transitions from those settings. The commenter suggested that paragraph (b)(1) be amended to include ''adult homes for people with mental illness and group homes with over four residents.''

Response: Section 1915(k)(1)(D)(i) of the Act sets forth requirements that expenditures for transition costs are available ''for an individual to make the transition from a nursing facility, and institution for mental diseases, or intermediate care facility for the mentally retarded.'' Therefore, we are not revising the regulation as suggested.

Comment: One commenter asked if States can limit the CFC transition benefit to individuals not eligible for transition services under either section 1915(c) of the Act or Money Follows the Person (MFP) program. The commenter also asked whether the transition benefit can differ from what is already offered in the State through section 1915(c) of the Act.

Response: CFC services must be provided without regard to the individual's age, type, or nature of disability, severity of disability, or the form of home and community-based attendant services and supports the individual requires to lead an independent life. Thus, a State may not propose to provide a service to only to a subset of the population eligible for CFC services. We recognize there may be instances in which individuals are eligible for similar services under more than one Medicaid authority. As indicated in § 441.510(e) individuals receiving CFC services will not be precluded from receiving other home and community-based long-term care services and supports through other waiver, State plan or grant authorities. To prevent duplication of the provision of services to the same individual, steps must be taken when developing the person- centered service plan, to prevent the provision of unnecessary or inappropriate care, as required at § 441.540(b)(12).

Comment: One commenter asked if States will need to contemplate and detail in the State plan amendment, all potential supports/services that may be allowed (presumably under permissible services) and whether or not States can define specific exclusions. Another commenter asked that CMS clarify whether permissible purchases are only available under the self-directed service model or if it applies to the agency model as well.

Response: A State would not be required to detail each item they would allow under permissible services and supports. States will need to indicate in the State plan amendment electing CFC whether they will be offering such services and supports, and any limitations they propose to include. States will also be asked to identify whether they will include items that increase independence or substitute for human assistance as permissible services and supports. Permissible services and supports are available at the State's option regardless of service model.

Comment: Several commenters strongly supported the first component of section 1915(k)(1)(D)(ii) of the Act that permits States to make expenditures available for individuals to acquire items that increase independence or substitute for human assistance and also supported the inclusion of this flexibility in the CFC proposed rule, but stated that the second component of this statement (''to the extent that expenditures would otherwise be made for human assistance and are related to a need identified in an individual's person-centered plan'') may actually lead to more restrictions than necessary. The commenters stated that the purchase of innovative goods and services may not replace human assistance, but rather make such assistance more effective (for example, the use of devices to support transferring individuals from their bed to a wheelchair) and suggested that addressing independence or substituting for human assistance is more appropriate. The commenters also stated that it is also important to recognize that some people who require CFC will not have the benefit of increasing independence, but rather may be successful at sustaining current functional ability or minimizing the restriction of independence that is occurring due to changes in health status and suggested that the CFC rule should be reflective of this reality.

Response: We appreciate the points made in this comment and fundamentally agree with them. The language in the proposed regulation was taken directly from the authorizing legislation. However, we believe that ''increase independence or substitute for human assistance'' is sufficiently broad to encompass all the scenarios identified by the commenter. We do not interpret the term ''substitute'' to mean only the total replacement of human assistance; therefore, the regulation would allow the purchase of items that just decrease the need for human assistance. We also agree that independence may be viewed to be ''increased'' by purchases aimed at preventing its decline.

Comment: One commenter questioned including the same language at § 441.520(b)(3) as in § 441.525 regarding the potential for providing some otherwise excluded services if they are based on a need in the service plan, as the language in paragraph (b)(3) is broad when applied to all permissible services, and this language could put a difficult burden on consumers to identify all possible future support needs during the care assessment phase.

Response: We do not anticipate a burden being placed on individuals to determine possible future needs during the functional need assessment or development of the person-centered plan. Both the assessment and the plan must be revised, as indicated in § 441.535(c) and § 441.540(e), respectively, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual or the individual's representative. These protections are sufficient to address any future needs.

Comment: One commenter asked specifically who coordinates the assessment and person-centered plan and whether there is a requirement that a separate Targeted Case Management service accomplish these tasks. The commenter also asked if these coordination services would be eligible for the enhanced match. Another commenter encouraged the addition of care coordination as a permissible service as this is essential for individuals with long-term care needs, and added that States may be more inclined to utilize CFC if this is a component that would also receive the enhanced FMAP.

Response: Targeted Case Management is a Medicaid service separate and distinct from CFC. There is no Targeted Case Management requirement in CFC. States may choose to use Targeted Case Management to assist with coordination and linkage functions for individuals participating in CFC, as long as all Targeted Case Management requirements are met. While we agree that care coordination is a beneficial service component for individuals with long-term care needs, care coordination was not a component that was included in the CFC statute, and therefore, would not be eligible for the enhanced FMAP.

Comment: One commenter indicated that States should be allowed to provide services in CFC that are currently allowable under section 1915(c) waivers, such as home delivered meals, adult day services, and non medical transportation if these services are an identified need in the service plan, as these services allow seniors and those with disabilities to live as independently as possible in their own homes and communities.

Response: States that choose to offer permissible services and supports have the option to provide for items that increase independence or substitute for human assistance, to the extent that expenditures would have been made for human assistance, as long as the item meets the requirements at § 441.520(b).

Upon consideration of public comments received, we are finalizing § 441.520 with revision, changing the title of this section to ''Included Services'', modifying paragraph (a)(1) to refer to ''* * * hands-on assistance, supervision, and/or cueing'', modifying paragraph (b) to indicate that items covered under transition costs must be linked to an assessed need and adding the phrase ''At the State's option'' to clarify that paragraphs (b)(1) and (2) that follow are both at the State's option, revising the language in paragraph (b)(1) to reference a ''home and community-based setting'' rather than a ''community-based home setting.'' and removing paragraph (b)(3) and relocating the language to 441.520(b).

G. Excluded Services (§ 441.525)

Consistent with section 1915(k)(1)(C) of the Act, we proposed to exclude the following services from CFC:

- Room and board costs for the individual, except for allowable transition services described in § 441.520(b)(1) of this subpart.
- Special education and related services provided under the Individuals with Disabilities Education Act that are related to education only, and vocational rehabilitation services provided under the Rehabilitation Act of 1973.
- Assistive devices and assistive technology services other than those defined in § 441.520(a)(3) of this subpart (incorrectly specified as § 441.520(a)(5) in the proposed rule, which does not exist) or those that are based on a specific need identified in the service plan when used in conjunction with other home and community-based attendant services.
- Medical supplies and equipment.
- Home modifications.

Consistent with section 1915(k)(1)(D) of the Act, we proposed to allow certain otherwise excluded items if they related to an identified need in an individual's service plan that increase an individual's independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

Comment: One commenter noted that the rule required backup systems to be made available, but excluded assistive technology and assistive technology services.

Response: We appreciate this commenter's perspective. The statute provides that the excluded services and supports are ''subject to subparagraph (D)'' which defines permissible services and supports to include expenditures relating to a need identified in an individual's person-centered service plan that increases independence or substitutes for human assistance. From our experience with Cash and Counseling demonstrations, section 1915(j) and 1915(c) authorities, we know that assistive technology devices and services often fall under the category of items that increase independence or substitute for human assistance. Therefore, we proposed in the rule that some items or services that could be classified as assistive technology devices or services could be covered, but only when based on a specific need in the person-centered service plan. We are maintaining this flexibility in the final rule.

Comment: Several commenters recommended that CMS include in the final regulation that Medicaid reimbursement for room and board for a personal attendant is an allowable expenditure as this is consistent with the SMD letter included with the section 1915(c) waiver guidance and CFC should be consistent with current CMS policy.

Response: We appreciate the commenters' suggestion and acknowledge that section 1915(c)(1) of the Act indicates that excluded ''room and board'' costs shall not include amounts States may define as rent and food expenses for an unrelated personal caregiver residing in the same household with the individual. Such amounts are part of the cost of delivering the service; they are not room and board for the individual. No such clarification was included in the statute for section 1915(k) of the Act; it speaks only to excluded room and board costs ''for the individual.'' To continue efforts to align CMS policy across Medicaid authorities whenever appropriate, we agree with the commenter. Room and board costs attributable to an unrelated attendant residing in the same household would be considered appropriate for reimbursement as a CFC service, as these costs are part of service delivery for ''assistance in accomplishing ADLs, IADLs, and health-related tasks.''

Comment: Multiple commenters stated that it is appropriate to pay for assistive technology, medical equipment, and home modifications

when coverage is based on an identified need in a service plan and used in conjunction with other home and community-based attendant services. One commenter added that the proposed regulation was in keeping with the intent of CFC to be primarily an attendant services benefit and indicated that it made sense to allow States to balance the use of these items in relation to attendant services. Multiple commenters supported the proposal to only exclude coverage of assistive devices, medical equipment, and home modifications in circumstances where they would be the sole needed service in an individual's service plan. Another commenter added that coverage of other services and supports encourages increased independence which is a key goal of person-centered services and is cost effective. Multiple commenters commended the inclusion of the language referencing the exclusion of services ''that are related to education only'' in paragraph (b). One commenter indicated that they understood the reasoning behind allowing some items that increase independence or substitute for human assistance, but were unclear how the requirement that they be used in conjunction with another CFC service furthered that goal, as there are many forms of assistive technology that, independent of all other services, can reduce dependency and substitute for human assistance.

Response: We agree that it is appropriate to pay for items that increase independence and substitute for human assistance. However, after reviewing comments and further consideration of the statute, we do not believe it is necessary to require that such items must be used in conjunction with other home and community-based attendant services. Section 1915(k)(1)(C) of the Act indicates that excluded services are subject to subparagraph (D) which indicates that States may cover ''expenditures relating to a need identified in an individual's person-centered plan of services that increase independence or substitute for human assistance * * *'' There is no statutory requirement that these items be provided ''in conjunction with other home and community-based attendant services.'' We are concerned that maintaining this requirement could result in an individual not receiving needed services. Therefore, we are revising § 441.525(c) to remove the requirement that assistive devices and assistive technology services meeting the requirements of § 441.520(b)(2) have to be used in conjunction with other home and community-based attendant services.

Comment: Several commenters urged CMS to ensure that the actual text of the regulation reflect the intent expressed by CMS to allow assistive technology, medical equipment, and home modifications when coverage is based on an identified need in the service plan.

Response: We have revised § 441.525(d) and (e) to clarify the treatment of medical supplies, medical equipment, and home modifications. We believe this flexibility for assistive technology devices and assistive technology services is already clear.

Comment: Multiple commenters indicated that the preamble language on page 10740 of the proposed rule stating that CFC ''would not include services furnished through another benefit or section under the Act'' is overly broad and should be amended to read ''would not include certain specific types of services furnished through another benefit or section under the Act.''

Response: The language in the preamble excluding services from CFC when furnished through another benefit or section under the Act was not included in the actual regulation text. Since section 1915(k) of the Act specifies the services that are available under the CFC State plan option, and such a prohibition was not specified in statute, we have decided to not include such a prohibition in the CFC regulation. As indicated earlier, steps must be taken when developing the person-centered service plan to prevent the provision of unnecessary or inappropriate care, as required at § 441.540(b)(12). To meet this requirement, we expect States to implement policies and procedures to prevent the duplication of services that may be available under more than one Medicaid benefit.

Comment: One commenter indicated that the statute excludes assistive technology devices and services and acknowledged that the proposed rule noted that the statute does not define the terms, which could be read broadly to exclude devices or services allowed under sections 1915(k)(1)(D)(i) or (ii) of the Act. The commenter stated that because CMS only excludes devices and services that do not serve a specific need in the person-centered service plan, the implementation of this regulation may become too restrictive as advances in technology may be accommodated too slowly because individuals may have imperfect information on the devices and services that may suit their particular needs.

Response: The statute is clear at section 1915(k)(1)(D)(ii) of the Act that these expenditures must be related ''to a need identified in an individual's person-centered plan of services.'' If advances in technology result in an item that would meet an individual's identified need, it would potentially be allowable as a permissible service or supports. Both the assessment and the service plan must be revised, as indicated in § 441.535(c) and § 441.540(e), respectively, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual or the individual's representative. These protections are sufficient to address any future needs. It is also important to note that States have the flexibility to choose whether or not to provide for permissible services and supports as they are not a required service.

Comment: One commenter asked CMS to clarify whether examples such as a walk-in shower to allow for a wheeled shower chair to be used for bathing, kitchen adjustments to permit someone with functional limitations to prepare his or her own meals, or moving a washer/dryer upstairs may qualify under such a definition. One commenter urged CMS to include additional examples of eligible assistive technology devices and services that could be included including medication management technology, home telecare/remote monitoring, and telehealth/telemonitoring, as these may assist personal attendant and health-related services under CFC in the future. Another commenter strongly supported inclusion of items such as environmental controls and telecare, stating that these could be very cost-effective and improve the independence of persons with disabilities as such technology or devices could reduce the need for human assistance. Other commenters provided additional examples of items that increase independence or substitute for human assistance such as adaptive utensils that allow a participant to eat meals and a voice activated system that allows a participant with quadriplegia to control various aspects of the home environment (lights, windows, door locks, etc.) and added that the exceptions to the excluded services as outlined in the proposed rule are of the utmost importance to glean the benefits of the Cash & Counseling model. Another commenter requested that CMS clarify the actual scope of services under this exception that could be provided.

Response: We appreciate the commenters' requests for clarification and suggestions regarding what items may be allowable under permissible services and supports. We do not believe it is appropriate for CMS to define a finite list of items that can be provided as a service or support. As we noted above, the statute set forth that ''expenditures relating to a need identified in an individual's person-centered plan of services that increase independence or substitute for human assistance, to the extent that expenditures would other-wise be made for the human assistance'' are allowable as permissible services and supports. States have the choice to provide any of the permissible services and supports that meet the requirements at § 441.520(b).

Comment: Another commenter noted that the prohibition on home modifications seems extreme as access to keyless entries and accessible bathrooms are important to increase both access to affordable and accessible housing and quality of life. The commenter added that ''Assistive Technology services'' seems too narrowly defined to address important supports such as bathroom modifications.

Response: The term ''assistive technology services'' is taken directly from statute as an excluded service. Section 1915(k)(1)(C) of the Act indicates that excluded services are subject to subparagraph (D) which indicates that States may cover ''expenditures relating to a need identified in an individual's person-centered plan of services that increase independence or substitute for human assistance * * *.'' Therefore, we believe some services that would otherwise be excluded may be covered when related to an identified need for items that increase independence or substitute for human assistance.

Comment: Several commenters supported CMS' proposal to provide for coverage of assistive devices in certain circumstances while at the same time promoting appropriate allocation of resources within the service plan and the program. The commenters noted that under the self-directed service delivery model proposed for CFC, the State must approve a service budget or cap that meets specified requirements, including specifying a dollar amount that an individual may use for services and supports under the program. The commenters added that States must also satisfy criteria for the budget methodology that it employs including a process for describing any limits the State places on CFC services and supports and the basis for the limits. The commenters believe that these provisions work in concert with § 441.525(c) to provide a framework for coverage that is compatible with implementation of the required exclusion and recommended that CMS point out this linkage in the preamble to the final rule.

Response: We appreciate comments but do not believe that it is necessary to point specifically to the linkage of these particular provisions in the final regulation.

Comment: One commenter voiced concern that explicitly indicating that States may determine at what point the amount of funds to purchase such devices and adaptations places them in the statutorily excluded categories will lead to an unreasonable limitation on this category with an over-emphasis on cost rather than need and relation to the other home and community-based attendant services. Another commenter added that the regulation does not contain any language related to the proposal to allow States to determine the point at which the funding amount would place items into the statutorily excluded categories and is concerned that regulatory language might confuse the cost of the service with the type or purpose of the service and that States should not have absolute discretion to target exclusions strictly based on cost. One commenter suggested that there should be some annual spending limits on the more costly and technologically advanced of the available assistive technologies such as an annual monetary limit per individual. Another commenter recommended that there be guidelines for the States to determine the cost threshold which would place the services and modifications into the excluded categories. The commenter asked if this was a onetime expenditure measured against the cost savings from reducing human assistance over the period of a month/year, or multiple years. The commenter noted concern that if the State sets a cap on the amount of funding that can be used to purchase devices and adaptations, this could prevent people from getting those supports even if it increases independence and saves money over the long term.

Response: As noted above, States have the choice to provide permissible services and supports. While we encourage States to allow for transition costs and for items that increase an individual's independence or substitute for human assistance, States have the flexibility to determine which, if any, permissible services and supports they will provide. All determinations regarding coverage of allowable items that meet the criteria in the final regulation, including the costs associated with the items, are the State's to make.

We acknowledge that the preamble language regarding the proposal to allow States to determine the point at which the funding amount would place items into the statutorily excluded category did not carry over into the regulation. We are not incorporating this language into the final regulation, but we are clarifying here that States retain the ability to establish amount, duration and scope limitations relative to the provision of these items, as long as such limits are not prohibited by the statute, which among other requirements, specifies that they must not be based on the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life.

With regard to the costs measures and timeframes for the determination of cost savings related to the substitution for human assistance, we do not intend to set forth the methodology for determining this threshold as this is also at the State's discretion.

Comment: One commenter interpreted the proposal to allow for coverage of assistive technology, equipment or home modifications when used in conjunction with other attendant services as integrated with the general principle that coverage under CFC is available only when there is no other coverage available under Medicaid or otherwise, and noted that at first impression, the proposal would seem to be inconsistent with section 1915(k)(1)(D) of the Act. The commenter stated that if this is not the case, it would be helpful if CMS could offer an estimate as to the potential cost of these services if included in the program.

Response: The correlation between the commenter's interpretation and the request for a potential cost estimate is not clear. We note that there is nothing included in the final regulation that would make coverage under CFC available only when there is no other coverage available under Medicaid or otherwise. As noted earlier, we have also removed the requirement that these items must be used in conjunction with other home and community-based services.

Comment: One commenter noted that medical equipment and home modifications are an essential component of any person-centered plan and that these items may assist a person in the transition from institutionalized

care to community care. The commenter questioned why they were listed as excluded services in the first place and recommended that they be added to the list of included services at § 441.520.

Response: These items were listed as excluded services in the statute at section 1915(k)(1)(C) of the Act, subject to section 1915(k)(1)(D). We agree that these items may assist an individual in the transition from an institution into the community and we also believe that these items may also assist an individual choosing to remain in their own homes. As such, and consistent with section 1915(k)(1)(D) of the Act, we proposed to allow States to cover such items as permissible services and supports long as the criteria described in § 441.520(b)(1) or (b)(2) are met.

Comment: Several commenters noted that while the exclusion of vocational rehabilitation services provided under the Rehabilitation Act of 1973 is well understood given its existence in other Medicaid programs, CMS and States should be reminded of the importance of allowing CFC participants to utilize their CFC services and supports within employment settings.

Response: We agree that individuals requiring attendant services and supports should be allowed to receive those services as needed/required in any home and community-based setting in which normal life activities take the individual, including the workplace.

Comment: One commenter indicated that access to State vocational rehabilitation services is extremely limited for individuals with serious mental illness and recommended that services excluded from CFC should be limited to those services that vocational rehabilitation agencies are, in fact, paying for and not services for which they might pay, but are not providing to the specific individual. The commenter added that the regulation as written creates a ''catch-22'' for people with severe disabilities whom vocational rehabilitation agencies reject, and encouraged CMS to amend paragraph (b) to clarify that the intent is to prevent Medicaid paying for services already covered and paid for under vocational rehabilitation.

Response: The statute specifically excludes vocational rehabilitation services (direct services to individuals with disabilities which teach specific skills required by an individual to perform tasks associated with performing a job to help them to become qualified for employment) from being provided under CFC. Therefore, we disagree with the suggestion to amend paragraph (b) as these services are not related to the services provided under CFC and should not impact vocational rehabilitation services being provided to an individual.

Comment: A few commenters noted that the proposed rule indicates at § 441.525 (c) that assistive technology devices and assistive technology services are excluded, other than those defined in § 441.520(a)(5), but pointed out that the proposed regulation does not include a § 441.520(a)(5).

Response: We have revised the regulation to reference § 441.520(a)(3).

Upon consideration of public comments received, we are finalizing § 441.525 with revision, modifying paragraph (c) to correct a reference to paragraph (a)(3) and to remove the requirement that assistive devices and assistive technology services meeting the requirements of § 441.520(b)(2) have to be provided in conjunction with other home and community-based attendant services, and modifying paragraphs (d) and (e) to allow medical supplies, medical equipment and home modifications when coverage is based on an identified need in the service plan.

H. Setting (§ 441.530)

We proposed that States must make available attendant services and supports in a home and community setting and specified that such settings did not include the following:

- A nursing facility;
- An institution for mental diseases;
- An intermediate care facility for the mentally retarded;
- Any settings located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment or custodial care; or
- A building on the grounds of or immediately adjacent to, a public institution or disability-specific housing complex, designed expressly around an individual's diagnosis that is geographically segregated from the larger community, as determined by the Secretary.

We received multiple thoughtful comments related to this section of the proposed regulation. These comments provided a rich and varied array of perspectives for our consideration. Several commenters were supportive of CMS' efforts to add parameters regarding home and community-based settings and some were supportive of the proposed language. Several commenters were strongly supportive of the proposed setting exclusions specifically. Multiple commenters expressed their concerns related to the proposed regulation and offered suggestions for revision of the criteria. These comments are reflected as follows:

- One commenter indicated the need for a more specific definition of setting adding that facilitating residents' engagement with and participation in the community is an essential component of services provided in a home and community-based setting.
- One commenter noted that the ambiguity surrounding the definition of home and community-based desperately needed to be remedied.
- One commenter noted that CMS proposed to adopt the statutory definition at section 1915(k)(1)(A)(ii) of the Act and recommended that CMS rely on this definition for purposes of CFC.
- One commenter recommended that CMS continue exploring how to clarify that certain settings are ''outside of what would be considered home and community-based because they are not integrated into the community.'' The commenter suggested that CMS consider that such clarification could be process-based and service-based and explore which processes and services characterize integration. The commenter recommended that CMS ensure that any clarification of the definition does not eliminate important community-based options for Medicaid beneficiaries, including assisted living communities, group homes, and settings that happen to be located near institutional settings. The commenter also suggested that when a clarification is developed, CMS should initially limit the use to one HCBS program until it is determined that there are no unintended or unanticipated problems caused by the clarification. Another commenter requested we clarify if CFC services may be provided in other residential community-based settings such as Assisted Living Facilities. The commenter believes the criteria should ensure participant independence and choice in residential settings that meet the unique needs and preferences of each individual.
- Several commenters requested that CMS convene meetings of stakeholders to address the definition of home and community-based.
- Other commenters encouraged CMS to ensure that the regulation recognizes that some populations need and choose to reside in settings that are similar to assisted living, so that they can maximize their independent living while still being able to access support services to keep them healthy and safe, and that some people with disabilities with very particular functional limitations need to receive support

services in more structured environments.

• Another commenter added that any criteria for setting should allow individuals to access services that aim to integrate individuals into community life and that organizations that are accredited by a national accreditation group that meet standards for person-centered planning and community integration as established by the accrediting body for programs serving people with disabilities should be eligible providers.

• One commenter indicated that ''community'' is defined as a unified body of individuals; people with common interests living in a particular area; a fellowship; a social state or condition, and pointed out that a community is more than a place or a location, and is defined not just by where people live but how they interact. The commenter added that in many States the word ''inclusion'' means that adults with special needs live in isolated settings like group homes, separated by a radius of 1000 feet where there is little or no contact with neighbors but is nevertheless considered being in the community and thus ''included.'' The commenter stated that individuals and their families are the primary decision makers regarding where and with whom to live and that they should be able to choose where they want to be rather than where they are forced to be included. The commenter pointed out that the stated values of CMS include ''promoting initiative and choice in daily living,'' yet HCBS waiver funding would be denied to those who would benefit from the choice of residential options, and recommended that Medicaid waiver funding should be person-centered, choice based, consumer driven and the money should follow the person, not ''idealist ideology.'' Finally, the commenter stated that ''inclusion'' must not exclude individuals with developmental disabilities from the rights afforded to all other citizens, including the right to live next to peers in a setting of choice.

• Another commenter indicated that as proposed, these exclusions, which they believe to be based on artificial considerations, might actually lead to greater isolation of individuals. The commenter indicated that despite the locations where some individuals reside, the sense of community there is much greater than the individual might have if they were living by themselves in an apartment with limited social opportunities, access to assistance and amenities, and vulnerable to exploitation. The commenter added that as written, this apartment would be considered ''integrated'' while a planned residential retirement community where individuals and their friends live alongside one another with access to services would not be considered a community setting.

• One commenter recommended a more robust set of standards to evaluate the ''quasi-institutional'' setting to determine whether they are to be excluded and suggested that these standards include whether the setting is segregated from the community at large, whether the residents are limited in terms of meal times, meal sources, and visitors, whether the setting limits the choice of caregivers, whether the setting controls or limits the resident's abode in terms of normal actions as furniture, food storage, paint colors, and use of TVs etc., and whether the facility has any contractual or other obligation to provide personal care to residents.

• One commenter indicated that there is a limited supply of affordable, handicap accessible housing that is available for low income individuals and that establishing a strict definition of settings could have a negative impact on access to CFC.

• Several commenters voiced concern regarding whether services will still be authorized in settings if these proposed criteria are adopted broadly across Medicaid. One commenter indicated that their organization serves frail elderly individuals, most of whom are Medicaid beneficiaries, on a campus that includes 6 buildings (1 with 20 nursing care beds, 1 with 16 memory care beds, 3 assisted living buildings, and one building of independent living with 12 apartments). The commenter added that the nursing care beds are the only nursing beds in the entire county and they were moved to this location when the rural critical access hospital closed down due to funding issues. The commenter voiced concern as they have been involved with the waiver program since its inception and as written, these exclusions would have a negative impact on the lives of many elderly individuals currently being served.

• One commenter requested that CMS regulations and State Plan Amendments assure that a State's decision to access CFC does not adversely impact assisted living settings for American Indians and Alaska Natives (AI/AN) individuals who reside in/near Indian communities where living settings may differ according to the cultural norms of those communities. The commenter indicated that certain assisted living settings, even though they may be large congregate settings, should be considered appropriate home and community-based settings under certain conditions. The commenter recommended that the regulation affirmatively state that those culturally appropriate settings in/near Indian communities, including assisted living settings for persons of retirement age, without regard to disability, where the individual is to be served is an Indian or resides in/near an Indian community where group living arrangements are culturally acceptable, are not excluded from home and community-based settings.

• One commenter suggested that CMS had not gone far enough to assure that settings are truly community-based, stating that the language only lists three types of institutions, and proposed language, similar to that used in the Money Follows the Person (MFP) program, that provides an exclusion that they felt would capture an institutional setting regardless of its licensure category. Other commenters suggested using the definition of ''community housing'' developed for the MFP program to clarify whether and what type of Assisted Living Facility will or will not be allowed as a setting under CFC. Several other commenters suggested using the 2011 MFP application definition of ''qualified residence'' and one commenter added that this would prevent HCBS dollars from being used to house people on congregate campuses. Another commenter suggested further clarifying the community nature of the setting where services may be provided to ensure that States are not using this option to further entrench institutional placements in the State and suggested defining ''community setting'' in the definition section using guidelines similar to those used in MFP: A home owned or leased by the recipient or that individual's family; a residence in a community-based residential setting in which no more than four unrelated individuals reside; or assisted living facilities or settings that offer a lease, as long as those residences include living, sleeping, bathing and cooking areas, offer residents lockable access and egress and cannot require that services be provided as a condition of tenancy or from a specific company. One commenter indicated that ''inpatient institutional treatment'', ''custodial care'' and ''provides'' were not defined in the proposed regulations and added that it is important that CMS clarify the meaning of these terms, as how they are defined could have a significant impact on the settings where individuals may receive CFC services. The commenter also pointed out the definition of custodial care in the Medicare Benefit

Policy Manual and added that some of the services offered under CFC are these same services. Another commenter asked if individuals who live in any building that provides custodial care by the Federal definition would be precluded from receiving services under CFC.

• One commenter asked what was meant by using the phrase ''publicly or privately operated facility that provides custodial care'' while several commenters voiced concern that the reference in subparagraph (d) to ''custodial care'', depending on how it is defined, could preclude individuals who live in any building that provides assistance with activities of daily living from receiving CFC. Another commenter indicated that depending how terms in both paragraphs (d) and (e) are defined and interpreted, the current proposed language could prevent the provision of CFC services in any residential setting where personal care is provided other than an individual's own private home. One commenter added that States have innovative housing with services models of care that promote consumer choice for home and community-based services and that at times, HUD funded section 202 and 811 housing are located on the same campus as a nursing home. The commenter stated that many times these programs provide ''custodial care'' to help older individuals and persons with disabilities age in place. The commenter also stated that as part of their rebalancing efforts, some States are encouraging nursing homes to decertify beds and establish independent living for older individuals and persons with disabilities and because this independent living is located in a nursing home, the consumers would not be eligible for CFC, even though their residences are currently considered independent living. The commenter indicated that the definition of setting in the proposed rule for CFC could be a barrier in many States where older frail individuals with chronic diseases and persons with disabilities choose to live in the least restrictive setting in their community that offer the services that they need to remain independent.

• Another commenter added that if efforts are made to dismantle settings that would now be excluded, that people with disabilities in congregate housing complexes ''in the community'' be provided with ample phasing-in time or consider grandfathering- in settings for people who do not wish to move to continue receiving their services as people should not have to choose between housing and supports.

• One commenter indicated that individuals receiving self-directed services generally must live in a setting that is not provider owned and operated and asked if such settings are excluded under the CFC program as it is not clear.

• One commenter indicated that denying access to CFC funds for an individual who resides ''in a building on the grounds of, or immediately adjacent to, a public institution or disability-specific housing complex'' does not reflect the purpose of section 1915(k) of the Act, which is to improve access to personal attendant services, and other services required under § 441.520 for individuals in the community. The commenter added that there was no statement in the *Olmstead* ruling that required that the setting for care delivery cannot be located in a building on the grounds of, or immediately adjacent to, a public institution or disability-specific housing complex. One commenter suggested that terms in paragraph (e) like ''disability specific housing complex'' be clarified while another suggested that it be removed altogether as individuals living in these settings are currently eligible to receive home and community-based services and supports. One commenter requested that community-based settings not be excluded based on proximity to congregate care or the fact that they only serve individuals with disabilities as community integration is a large part of their programs.

• Several commenters voiced concern about the definition excluding those settings that are geographically segregated from the community and urged that size alone not become part of the definition. The commenter indicated that small campus settings can provide rich staffing and supervision and a continuum of care model needed for individuals with traumatic brain injuries etc. Another commenter expressed concern that the proposed definition of home and community-based setting might exclude important options for services that assist people with disabilities, especially cognitive disabilities related to severe brain injuries, to live in and be part of the community. Specifically, the commenter is concerned that services could be denied to individuals currently receiving Medicaid benefits from post-acute brain injury rehabilitation service programs that are enrolled in Medicaid and other State programs serving people with brain injury. Another commenter with a family member in a facility for individuals with traumatic brain injury stated that this setting was much better for her daughter than a nursing home and that she is part of community there.

• Other commenters indicated that some companies have various settings ranging from a campus to group homes and apartments and individuals as well as families and guardians choose these settings. Another commenter suggested that rather than including geographical segregation when setting a standard, CMS should impose a standard for community integration that is applied to service plans, including access and involvement in the community and the level of social interaction in the residence of the individual.

• One commenter voiced concern about the tension between the need for affordable, accessible housing for people with developmental disabilities (including HUD's section 811 and 202 housing programs) and the need for that housing to be provided in integrated settings rather than clustered or segregated housing that primarily or exclusively serves people with disabilities. Other commenters shared concerns that housing used by the elderly and individuals with disabilities as allowed by the Senior Housing Exemption to the Fair Housing Act and under HUD's subsidized apartments (811 and 202 housing programs) would be restricted by the phrase ''disability specific housing segregated from the larger community'' and recommended that these settings be allowed. Another commenter questioned what type of setting this language intended to address and voiced concern that individuals in these 811 and 202 housing programs might be affected or lose services. Several commenters expressed concern that the proposed definitions would exclude the delivery of attendant services in many settings that are the most appropriate setting to an individual's needs, especially those residing in HUD funded section 811 and 202 housing designated specifically for targeted populations with disabilities.

• Another commenter added that to exclude certain settings goes beyond the Congressional intent of the CFC option as the Congress only excluded CFC in particular settings and urged CMS to remove the reference to disability-specific housing in this section.

• One commenter indicated that some individuals need and choose to receive services in ICFs/MR and the provision of a range of service options is supported by Federal law including Medicaid and the U.S. Supreme Court (*Olmstead*).

• One commenter requested that in addition to excluding settings that are co-located with current institutions that CMS also exclude settings created on the grounds of former institutions as it should be clear that the reorganization and reclassification of an institution

would not meet the criteria of a community-based setting.

• Another commenter added that CMS should clarify instances where paragraph (e) would not apply. One commenter referred to this proposed rule as providing clarifications of setting at § 441.530 with the purpose of disallowing HCBS Waiver funding for living arrangements in ''alternative or subsidiary residential settings on the ground of or located adjacent to such institutional facilities'' and recommended language revisions. The commenter appreciates explicit clarification that would prevent the practice of reconfiguring institutions to access funds not intended for institutional settings.

• One commenter indicated that community-based care settings like adult foster care, assisted living and residential care should qualify as a permitted setting under CFC.

• One commenter indicated that the preamble of the Home and Community-Based Services Waivers proposed rule published in the April 15, 2011 **Federal Register** (76 FR 21311), listed 8 conditions for an assisted living home to be included as a community setting. The commenter stated that, with the exception of aging in place, the conditions are common to, and actually regulated for the licensing of assisted living homes in their State. The commenter stated that the view that assisted living is not part of the larger community is due to lack of experience with it and recommended that the emphasis be on the character of a building inside the walls rather than the location or foundation within the larger community or sharing grounds or walls with a nursing facility.

• Many commenters expressed concern that the definitions of setting would exclude assisted living facilities and other specific settings that they felt should be settings in which individuals could receive CFC services. Many commenters noted that individuals often choose to reside in these settings and continue to be part of the community rather than moving into a nursing facility.

• Several commenters indicated that any definition of home and community-based service settings applied across the Medicaid program should include assisted living facilities as well as group homes, disability-specific and non-institutional settings providing services to individuals and encouraged CMS to recognize the need for some populations to reside in settings that are similar to assisted living to maximize independence while at the same accessing support services to keep them healthy and safe.

• Several commenters recommended the following criteria be added to the section for a setting to be considered community-based:

++ The Unit/room must be a specific place that can be owned or rented and include the same protections from eviction under the State's landlord/tenant law;

++ The individual must have privacy in the unit (lockable entrance doors, freedom to furnish and share the unit only by choice, the inclusion of individual bathroom), unless partners/spouses share a room);

++ There is freedom/support to control one's own schedules and activities including access to food at any time; and

++ The individual may have visitors of their choosing at any time.

• One commenter proposed adding the following language to the list of excluded characteristics:

++ Any residence that requires that services must be provided as a condition of tenancy;

++ Any setting that requires notification of absence from the facility;

++ Any setting that does not have lockable access and egress controlled by the individual; and

++ Any residence where the lease reserves the right to assign apartments or change apartment assignments.

• One commenter indicated that the new proposed rule seems vague and seems to give the Secretary great latitude in describing what kind of setting is ''geographically segregated'' from the larger community (and therefore ineligible for waiver reimbursement for brain injury services). The commenter indicated that they support the freedom of consumers' choice and the option to live in a setting where community integration is maximized. The commenter does not support any definition that uses size of a home or the adjacency of homes on a small ''campus'' as the criteria for defining ''geographic segregation.'' The commenter added that in terms of small campus settings for individuals who are catastrophically injured and severely limited cognitively and physically and who require a good deal of medical oversight, this kind of living arrangement may provide the necessary richness of staffing to facilitate, rather than inhibit community integration to the highest degree possible for particular individuals. The commenter stated that while home size can matter, one size does not fit all, especially where the results from brain injury are profound for the consumer. Finally, this commenter urged the inclusion of the following specific criteria, other than simply size of the home, in the definition of settings:

++ The facility provides post-acute residential care to individuals with an acquired brain injury.

++ The facility is accredited by the Commission on Accreditation of Rehabilitation Facilities(CARF) as a community integrated brain injury rehabilitation facility.

++ There is handicap access to the community. (One example would be an accessible wheelchair path).

++ There is evidence of a robust level of community participation on the part of individuals living in the homes. (The commenter noted that one significant measure of the levels of community participation can be highlighted by applying the Maya-Portland inventory; the internationally recognized, standardized assessment in brain injury populations). Other evidence of such community participation may be access to jobs in the community, recreational outings, participation in community programs and prolific voting in local and national elections etc.

++ There is consideration given to the functional level of the people living in that home. For some individuals with profound limitations due to brain injury, a small campus in close proximity to a town or urban center is frequently the most effective way to provide the intensity of staffing, medical oversight, and richness of rehabilitation services that will enable people living in the home to access the social capital of community life.

++ There is a continuum of care available at the facility, so that as individuals gain functionally and can negotiate the community more safely, they can move from small campus settings in the community to even smaller group homes and independent apartments.

++ There is evidence of consumer choice in selection of the residential setting.

++ The home is not on the grounds of a hospital, nursing home or ICF.

• Several commenters strongly disagree with CMS' proposed clarifications and stated that proximity of a community setting to an institutional setting or disability-specific housing complex has little, if any, bearing on the degree of community integration experienced by residents. The commenters added that geographic separation should not matter if a residence is well integrated with the larger community. They believe that a better way to clarify community integration would be to look at the

services available and provided by the setting and to ensure that processes, such as care planning, promote beneficiary choice. The commenters stated that because all States license or certify assisted living providers, Medicaid beneficiaries living in these communities receive services with greater government oversight than those receiving services in freestanding homes. The commenters also added that in recent years, as residents' levels of disability and the proportion of residents with Alzheimer's and other related diseases have increased, States have responded by increasing regulatory standards applying to assisted living communities and that due in part to the fact that Medicaid cannot pay for room and board in community-based settings, the extent of Medicaid coverage in assisted living already is much more limited than Medicaid coverage for nursing homes and other long term care options. The commenters urged CMS to reconsider its clarification of ''home and community-based'' and recommended that CMS utilize the definition in law and explore a clarification that relies on services available and provided by the setting, and ensure that processes, such as care planning, promote choice.

• One commenter suggested that consideration be given to including the list of factors characterizing settings included in the recently proposed rule revising section 1915(c) HCBS waiver provisions published in the April 15, 2011 **Federal Register**. The commenter shared language from § 441.301(b)(1)(iv) that states that attendant services may be provided ''only in settings that are home and community-based, integrated in the community, provide meaningful access to the community and community activities, and choice about providers, individuals with whom to interact, and daily life activities.''

Response: We appreciate these thoughtful comments. Several commenters referenced waivers in their comments and we would like to clarify that this regulation pertains to the CFC State plan option, not the HCBS waiver program.

In consideration of the comments received, we are not finalizing the setting provisions of proposed § 441.530 at this time. The comments received indicated to us that the proposed provisions caused more confusion and disagreement than clarity and we believe further discussion and consideration on this issue is necessary. In addition, similar language proposed in the notice of proposed rulemaking for revisions to the 1915(c) waiver program garnered significant public comment. Therefore, we intend to issue a new proposed regulation that will provide setting criteria for CFC that we developed in light of the comments received and to invite additional public comment on our proposal. We plan to propose home and community-based settings shall have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

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

• The setting is selected by the individual from among all available alternatives and is identified in the person-centered service plan;

• An individual's essential personal rights of privacy, dignity and respect, and freedom from coercion and restraint are protected;

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

• Individual choice regarding services and supports, and who provides them, is facilitated;

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

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

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

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

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

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

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

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

++ The setting is physically accessible to the individual.

We also plan to propose that home and community-based settings do not include the following:

(1) A nursing facility;

(2) An institution for mental diseases;

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

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

(5) Any other locations that have qualities of an institutional setting, as determined by the Secretary. The Secretary will apply a rebuttable presumption that a setting is not a home and community-based setting, and engage in heightened scrutiny, for any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment in a building on the grounds of, or immediately adjacent to, a public institution or disability-specific housing complex. CMS will engage States in discussion and review any pertinent information submitted during the SPA review process to determine if these facilities meet the HCBS qualities set forth in the proposed rule.

While we are proposing the aforementioned setting requirements in a new proposed rule, the CFC option is in full effect. CMS will rely on the proposed setting provision as we review new 1915(k) State plan options and we will fully expect States to comply with the setting requirements and design and implement the benefit accordingly. To the extent there are changes when this language is finalized, we are committed to permitting States with an approved section 1915(k) State plan amendment a reasonable transition period, at a minimum of one year, to make any needed program changes to come into compliance with the final setting requirements. We are committed to minimizing disruption to State systems that have been established based upon compliance with these proposed regulations.

It is our intent to and to apply this criteria to sections 1915(c) and 1915(i) of the Act authorities.

As expressed earlier, we believe further discussion is necessary and we believe this can be accomplished by soliciting public comments on the modified criteria. Therefore, we are not finalizing the setting provision at this time.

I. Assessment of Need (§ 441.535)

We proposed that States must conduct a face-to-face assessment of the individual's needs, strengths and preferences that supports the determination that an individual requires attendant services and supports available under CFC, as well as the development of a person-centered service plan and, if applicable, a service budget. We also proposed that this assessment must be conducted at least every 12 months, as needed when the individual's support needs or circumstances change significantly, necessitating revisions to the service plan, or at the request of the individual, or the individual's representative, as applicable.

Comment: One commenter indicated support for this section and appreciated the emphasis on understanding and honoring an individual's personal goals and preferences for the provision of services.

Response: We believe that an individual's preferences and goals for the provision of services is an important aspect of both an assessment and the person-centered service plan.

Comment: Several commenters indicated that it is unclear whether the term ''may'' in § 441.535(a) makes the entire subpart optional and suggested that CMS clarify that States must gather information on all the items listed in the proposed rule at paragraphs (a)(1) through (8). The commenters also indicated that it is unclear what role the consumer has in selecting (or prohibiting) the use of specific processes and techniques used to obtain information about an individual, and pointed out that the list of items included in paragraph (a) does not clearly correspond to ''processes and techniques.'' The commenters suggested that CMS change ''processes and techniques'' to ''criteria'' and recommended that certain criteria be mandatory to assure that the assessment is based on a comprehensive information set. The commenters recommended that the other criteria should be optional, but in all cases should not exceed the scope of the conversation with the individual, adding that collateral contacts should not be allowed unless requested by the individual. Finally, the commenters recommended that ''health condition'' at § 441.535(a)(1) be expanded to read ''health condition and treatments'', and that ''household'' at § 441.535(a)(7) be edited to read, ''household and physical living arrangements, including the safety of those arrangements'' as ''household'' may be relevant to understanding the individual's functional limitation, but should not be a basis for lowering a needs determination based on availability of other people. One commenter requested that CMS amend § 441.535(a)(1) to read ''health and mental health condition.''

Response: With regard to the ''processes and techniques'' to gather information for the assessment, the intent of this language was to indicate that States have the flexibility to utilize multiple methods to gather this information. Therefore, we do not agree with the commenters' suggestion to modify this language. With regard to the individual's role in the processes or techniques the State chooses to utilize, an individual should have the opportunity to discuss any gathered or related information during the assessment, and the individual must approve the person-centered service plan which is based on the assessment of need.

In the absence of other statutory requirements, we proposed language in the assessment section for CFC that was consistent with the section 1915(j) Self-Directed Personal Attendant Services final rule, in an effort to streamline State requirements where possible across the programs. In addition, we indicated in the preamble that we are currently working to determine universal core elements to include in an assessment for consistency across programs. This initiative is directly related to the work being done regarding the Balancing Incentives Payment Program (Balancing Incentive Program) created under section 10202 of the Affordable Care Act.

Based on multiple comments and the acknowledgement that additional policy work is necessary to maximize the extent to which consistency can exist across the Medicaid programs as it relates to assessments for HCBS programs, we are revising the language, as some commenters suggested, to reflect the broad assessment requirements in statute. As such, we are reflecting this assessment throughout the final rule as the ''assessment of functional need.'' We are also taking more time to consider all of the thoughtful comments from this rule and the forthcoming comments from the proposed rule that will be published to implement changes to the section 1915(i) HCBS State Plan option required by the Affordable Care Act, and to have additional policy discussions both internally and with stakeholders. Our intent is to share any finalized universal core elements that are developed under the Balancing Incentive Program with States to use as examples of elements to be incorporated into the assessment of functional need for CFC and other HCBS assessments as determined by CMS. As such we are revising the language to add that the assessment must include other requirements as determined by the Secretary. Finally, we are clarifying the scope of the assessment to indicate that it is the individual's need for the services and supports provided under CFC that must be assessed. This is in no way meant to limit a State from implementing a comprehensive assessment that would determine an individual's need for a broader scope of services. We are simply clarifying in this rule that the assessment described at § 441.535 is only required to assess the need for CFC services and supports.

Comment: One commenter stated that the proposed regulation does not recognize that there may be other services and programs that can meet the needs of those applying for CFC and indicated that a comprehensive assessment should include a determination as to whether the individual is appropriate for this and other State plan and/or home and community-based services so that the consumer can be offered a choice of programs and not be limited to one model of care. The commenter added that such an assessment tool is recognized as a vital component of other Federal programs including the State Balancing Incentive Program and is used by some States.

Response: We agree with the commenter that it would be ideal for a State to have one comprehensive streamlined assessment for an individual that would serve to inform a person-centered service plan, and that the entity that coordinates and/or conducts these functions be able to present an array of possible services and supports to meet the individual's needs to provide a choice among these services to the individual. States have the flexibility to offer this kind of assessment and service plan and as the commenter pointed out, some States have implemented their programs in this manner.

Comment: One commenter appreciated that CMS decided not to prescribe a specific assessment tool to determine an individual's functional needs. Another commenter pointed out that the preamble clearly states that CMS will not dictate the assessment tool and asked that CMS clarify in the rule that States may design and/or select the assessment tool to determine functional eligibility, as well as identify needed services as long as such tools contain the required CMS elements. Another commenter asked CMS to clarify

expectations about the face-to-face assessment process and instrument proposed for use in CFC, the more universal level of care assessment and service planning process, and instruments used in a State's section HCBS 1915(c) waiver programs. The commenter asked if there is flexibility for a State to use the same fundamental processes and instruments but with different threshold levels for program participation or if a State may choose different processes and instruments. The commenter also asked if States may set an assessment standard to operationalize the determination that an individual requires CFC. One commenter asked if States were expected to develop new assessment tools or if they can use existing assessment tools that establish level of care and service planning if the current tools conform to the requirements in the CFC regulation. The commenter added that States should be permitted to use assessment processes and person-centered service planning to allow individualized determinations of the most integrated setting appropriate to the individual's needs and preferences, as well as eligibility for this option. Other commenters asked if States will have flexibility in selecting an assessment instrument and if the instrument could focus on specific types of disabilities (physical, intellectual, developmental, etc.).

Response: We have not specified the instruments or techniques that should be used to secure the information necessary to determine an individual's functional need for the attendant services and supports offered under CFC or to develop the service plan and/or service budget. States continue to have the flexibility to develop their own assessment tools or to utilize existing tools to the extent possible to meet the requirements under CFC. While this regulation does not specifically address the assessment process or tool States utilize in their section 1915(c) programs for assessments or level of care determinations, States have the flexibility to use any existing assessment tools if the CFC requirements are met. As States are not permitted to target attendant services and supports provided under CFC to any particular population or disability, we do not anticipate States will tailor an assessment of need to focus on any such population or disability.

Comment: One commenter indicated that the most important aspect of legislative intent that is not captured in the proposed rule is a clear statement of a State obligation to provide services and supports to meet the individuals' assessed needs. The commenter suggested that language be added to paragraph (a) to say ''so as to meet the individual's assessed needs'' and recommended that this language be included elsewhere in the regulation as needed to ensure that a State has to meet the assessed needs of the individuals to receive funding.

Response: An individual's person-centered service plan must be based on that individual's assessment of functional need. We expect that as needs for the required attendant services and supports available under CFC are identified and incorporated into the person-centered service plan, these services would be made available to the individual to meet those needs. Therefore, we disagree with the suggestion to add this proposed language as we believe this expectation is clear. In fact, we do reiterate the ability of a State to establish limits on the amount, duration and scope of CFC services, as long as those limits are not based on the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life, as prohibited in the statute.

Comment: One commenter voiced concern that States might ''poorly integrate'' the CFC assessment into their current assessment processes for HCBS and suggested, along with another commenter, that States be required to have a publicly available written plan explaining how the CFC assessment will work, interact with existing assessments for HCBS, and ensure that the regulatory requirements are met.

Response: States have the flexibility to design a new assessment tool, or utilize current assessment tools as long as the requirements in the CFC regulation are met. We do not agree with the commenter's recommendation to require States to have a written plan regarding their assessment, as we do not require a CFC-specific assessment. States electing CFC must submit a State plan amendment that shows how they propose to implement CFC and how the program requirements will be met. Once approved, this will become part of a State's Medicaid plan, which is a public document.

Comment: One commenter recommended that CMS consider adding the concept of an independent assessment found in section 1915(i) of the Act and suggested that CMS add an independent assessment descriptor to § 441.535. The commenter indicated that in paragraph (b), an independent assessment would also address concern about recipients needing the service, as an objective assessment would establish medical necessity for the services.

Response: We agree that consideration should be given to the proposed requirements of the assessment for the section 1915(i) State plan option. As noted above, in addition to the comments received for this proposed rule, we will be considering the forthcoming section 1915(i) proposed rule public comments related to assessments as we move forward with the development of the universal core assessment elements and methods to streamline requirements across the Medicaid program.

Comment: One commenter pointed out that CMS states in the preamble that ''the assessment should include a determination of whether there are any persons available to support the individual, including family members. These persons may be able to provide unpaid personal assistance * * *'' and added that inclusion of such language in the preamble implies that CFC includes a waiver of comparability as found at section 1915(j)(3) of the Act. The commenter indicated that they have not identified a corresponding provision in section 2401 of the Affordable Care Act or in the proposed section 1915(k) rule and requested that CMS clarify whether such a waiver of comparability is intended and add language authorizing such a waiver.

Response: We can confirm that no waiver of comparability was included in the authorizing legislation, or in the implementing regulation for CFC. However, we do not believe that comparability of services is violated based on an individualized determination of the impact of available unpaid personal assistance on the CFC services and supports required.

Comment: One commenter indicated that the preamble mentions the identification of natural supports but the proposed rule related to assessment does not. The commenter recommended that if CMS mentions natural supports in the rule that we specify that the assessment and service plan take into account, but do not compel, natural supports, as case managers or other entities conducting the assessment and/or planning process should not automatically make judgments about what families ought to provide and reduce needed services accordingly.

Response: We mention the identification of natural supports in the assessment preamble section as understanding an individual's natural supports is an important aspect in determining an individual's needs. It is a requirement in the person-centered

service plan that these supports be reflected in the person-centered service plan. We expect that identification of these natural, unpaid supports be taken into consideration with the purpose of understanding the level of support an individual has, and should not be used to reduce the level of services provided to an individual unless these unpaid supports are provided voluntarily to the individual. We have incorporated this philosophy into the ''Person-Centered Service Plan'' section, as discussed below.

Comment: A few commenters indicated that they did not understand the purpose of paragraph (b) which states that ''assessment information supports the determination that an individual requires CFC * * *'' and suggested clarification or deletion. One commenter requested that in paragraph (b) CMS substitute the word ''requires'' with the words ''would benefit from'' CFC services.

Response: Information gathered in the assessment should support the determination that an individual requires the services and supports available under CFC. If an individual does not meet the State's medical necessity criteria for the receipt of attendant services and supports, the individual would not participate in the option. Therefore, we do not agree with the suggested language change.

Comment: One commenter voiced concern that the proposed rule does not address the gap between the actual support needs of individuals and the needs typically assessed in current assessment tools which are generally limited to ADLs and IADLs.

Response: While we appreciate the commenter's concern, CFC is a benefit to provide attendant services and supports to individuals to assist in accomplishing ADLs and IADLs. While States are not limited to assessing an individual's needs based solely on ADLs and IADLs, CFC as a benefit is centered around these services and supports.

Comment: Several commenters referenced and supported the requirement at § 441.535(c) that the assessment must be conducted at least every 12 months, as needed when the individual's support needs or circumstances change significantly, necessitating revisions to the service plan, or at the request of the individual. One commenter appreciated these caveats and noted that without them, 12 months could be too long a period considering how quickly an individual's needs may change. A few commenters indicated that § 441.535(c) uses the word ''or'' to link the clauses whereas § 441.540(e) uses the word ''and'' and suggested that CMS be consistent and use ''and' in both sections. One of the commenters added that the policy should guarantee that a service plan would always be reviewed at the request of the individual and suggested that this meaning is best implemented by using the word ''and.'' Some commenters added that assessments often need to be conducted more often than every 12 months for some populations due to frequent changes in needs due to behavior, improved cognitive skills, and other emerging health issues. Several commenters suggested that CMS clarify either in the regulation or in future guidance that an individual's circumstances or needs change significantly when a participant's support network changes, including friends and family that the participant relies on for physical or emotional support and these protections should explicitly include Lesbian, Gay, Bisexual and Transgender individuals and their families. Other commenters recommended that CMS provide specific timeframes for conducting these assessments including both a standard timeframe and an emergency timeframe to address situations where a consumer's health or safety may be in jeopardy. One commenter asked if it was possible for the State to require more frequent assessments but not exceed an annual authorization as this would assure consistency across other home and community-based services and the potential for moving between service modalities.

Response: We believe that an assessment of functional need should be conducted at least every 12 months, at a minimum, to ensure that an individual's needs are commensurate to the services authorized in the service plan, as we understand that an individual's needs can change significantly over time and as a result of various circumstances. Regarding the comment that mentioned changes in a participant's support network, we expect this paragraph and all parts of this rule to apply to all individuals equally regardless of disability, age, sexual orientation, or any other factor. We include several provisions related to the reassessments that we believe capture various circumstances necessitating a reassessment and updates to the service plan. Therefore, we do not agree that we need to change the language. In addition, States have the option to choose how many reassessments they offer as long as the requirements in the final rule are met. We appreciate the commenters pointing out the discrepancy between the use of ''and'' and ''or'' in different sections of the regulation. We are modifying § 441.535(c) to incorporate the word ''and'' to ensure appropriate reassessments as necessary.

Comment: Several commenters voiced support for the face-to-face assessment. Other commenters added that in-person assessment meetings allow for the building of rapport to improve information sharing. Two commenters added that CMS should specify that CFC applicants should have the right, though not the requirement, to have the face-to-face assessment conducted in their own home as this would decrease undue burden on the individual who may have mobility issues and would have the added benefit of providing the State with increased information about the individual's living situation and support system. Another commenter asked that CMS clarify the statement that the assessment be conducted at the site where the services are to be provided to assure a comprehensive assessment of need. Another commenter suggested that it be clarified in the regulations that the annual reassessment should be conducted face-to-face. One commenter suggested that the initial assessment be conducted face-to-face but CMS should allow subsequent assessments to be conducted via a variety of other health technologies and tools as appropriate for an individual's needs, accessibility and preference.

Response: We agree that ideally, the assessment of functional need would be conducted face-to-face in order for the entity conducting the assessment to get a better overall understanding of an individual's needs. However, we recognize that many States are developing infrastructure and policies to support the use of telemedicine and other ways to provide distance-care to individuals to increase access to services in rural areas or other locations with a shortage of providers. To support these activities, we are indicating here that the ''face-to-face'' assessment can include any session(s) performed through telemedicine or other information technology medium if the following conditions apply:

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

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

(3) The individual is provided the opportunity for an in-person assessment

in lieu of one performed via telemedicine.

We have modified the regulation to allow for use of these technologies to meet this requirement. With regard to the location of the assessment, we continue to encourage that these assessments be conducted in the individual's place of residence, as this would provide the best picture of the individual's needs, allow the State to monitor the health and welfare of the individual, and allow the State to get a sense of how well the services and supports in the service plan are meeting the individual's needs. But we note that the CFC proposed rule did not require the assessment to be conducted at the site where the services are to provided. In addition, as the assessment of functional need and the person-centered planning process may take place at the same visit, the service planning process section at § 441.540 indicates that this process take place at times and locations of convenience to the individual.

Comment: Several commenters indicated that assessments, when overdone, can be draining and somewhat de-humanizing for participants and requested that CMS and States be sensitive to this as they design tools and policies for the frequency of assessments. The commenters added that recognizing that some people may not experience a change in functional status over time, trigger questions that allow the assessor to shorten the assessment and minimize intrusiveness, when possible, can be beneficial to all. One commenter disagreed with the proposed requirement that an assessment be conducted at a minimum of every twelve months and indicated, along with another commenter, that States should have the discretion to both allow for exceptions where an individual's living situation is stable, medical condition is non-degenerative, and abuse risk factors are low, and to conduct telephone or paper reassessments in similar situations. The commenter indicated that less frequent assessments promote efficient use of governmental resources and are less burdensome on the recipient, but did support the allowance for more frequent reassessments if necessary or at the individual's request. Similarly, multiple commenters recommended that CMS identify certain circumstances in which it would not be necessary to conduct a face-to-face assessment of need every 12 months such as when an individual can document that their needs are unlikely to change from year to year.

Response: We agree that the assessment process should not be overdone or burdensome for individuals participating in CFC. States may want to design their assessments to accommodate the needs of individuals whose needs are not likely to change significantly from year to year. This could save both the individual and the State time, but the requirements in the final rule would still apply to these circumstances. Assessments must be conducted at least every 12 months. We appreciate the commenter's suggestions to identify circumstances in which it would not be necessary to conduct reassessments face-to-face. While we believe that a face-to-face visit is ideal for the reasons previously indicated, we have revised the regulation to allow for the use of telemedicine or other information technology medium if certain conditions apply. We strongly advise States to consider a face-to-face meeting to allow for the closer monitoring of health and welfare and appropriate services and supports.

Comment: One commenter recommended additional guidance for States regarding the reauthorization periods for services, stating that frequent reauthorizations can be burdensome for individuals with long-term care needs and often serve as an opportunity to reduce services despite no decrease in need.

Response: We believe that the regulation is clear that the service plan is based on the assessment of functional need. If an individual requires a particular level or amount of attendant services to meet these needs, the services should not be decreased at any time unless an individual no longer requires that level of support. An individual must agree to and sign any service plan, and therefore, we do not believe that we need to issue any further guidance to States regarding the reduction of services absent a decrease in need. We do reiterate the ability of a State to implement limits on the amount, duration and scope of CFC services, as long as these limits are not based on an individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life, as prohibited in the statute.

Comment: One commenter suggested that the assessments not be limited to only 1 hour as such planning and discussion requires more time and only allowing for 1 hour of payment for the assessment creates barriers to preparing an effective plan.

Response: We do not require that an assessment be limited to 1 hour. While the Regulatory Impact Analysis section of the proposed rule included an estimate of 1 hour to conduct an assessment, this estimate was based on an average amount of time, and we did not limit the assessment to 1 hour in the regulation.

Comment: Multiple commenters recommended that the regulations require the assessment to be conducted in a linguistically and culturally appropriate manner for the individual (and/or their appointed representative) as determined by the individual in a fully accessible way.

Response: We agree with the commenter. We expect that States will conduct assessments of functional need and the subsequent person-centered planning process in a linguistically and culturally appropriate manner for the individual and as appropriate, their representative in a fully accessible way. Such a requirement already exists for the development of the person-centered service plan, as identified at § 441.540(a)(4).

Comment: Several commenters indicated that participants should be treated with dignity in the needs assessment, regardless of their sexual orientation or gender identity.

Response: We expect that all individuals will be treated with dignity in the assessment process and all other aspects of CFC.

Comment: Two commenters pointed out that the statutory language includes a requirement that the assessment be agreed to in writing in section 1915(k)(1)(A)(i) of the Act and suggested that the regulation explicitly include this language in § 441.535.

Response: Section 1915(k)(1)(A)(i) of the Act indicates that the ''person-centered plan of services and supports that is based on an assessment of functional need'' be agreed to in writing by the individual or, as appropriate, the individual's representative. We reflect this statutory requirement at § 441.540(d).

Comment: One commenter asked if CMS intends for an individual to have a right to appeal the assessment.

Response: Rather than appealing the assessment, individuals have the right to appeal their person-centered service plan. The person-centered service plan must be based on the assessment of functional need and agreed to in writing by the individual. If the individual does not agree with the findings of the assessment or the proposed service plan based on these findings, an individual does not have to agree to or sign the service plan. The individual would have the right to disagree with the assessment and service plan at any time during the process. States electing the CFC Option

are required as specified in § 441.585, to have procedures for appeals of denials and reconsideration of an individual service plan in place as part of their quality assurance system for the CFC. The fair hearing requirements of 42 CFR part 431, Subpart E apply to CFC in the same manner as they apply to other Medicaid State plan services.

Comment: One commenter asked if the requirement that States conduct the assessments allows for the State to contract with a private entity and if so, urged CMS to require that States demonstrate that the private entity is complying with the law and regulations.

Response: States are required to comply with all requirements related to CFC regardless of whether they contract with private entities to fulfill any function of CFC. Contracting with an entity does not absolve the State of making sure that all requirements are met in accordance with the final regulation.

Comment: One commenter requested that States be granted the discretion to determine the qualifications of persons who may conduct functional assessments. Another commenter recommended that the assessment of need standards include the qualifications of the person conducting the assessment. Another commenter asked who coordinates the responsibilities of the assessment and person-centered plan.

Response: States are responsible for determining the provider qualifications of the entities who will conduct the assessments and the person-centered planning process. With regard to who coordinates the responsibilities of the assessment and the person-centered service plan, that is also up to the State. Many States choose to utilize service coordinators to fulfill this role.

Comment: One commenter suggested that the designated representative participate fully in the assessment of need and that any representative also be evaluated regarding competency to undertake the role of representative.

Response: We agree with the commenter that if an individual has a representative, that representative should have an active role in the assessment and person-centered planning process to the extent that the individual chooses to include that representative. However, we are not revising the regulation to make this a requirement. With regard to evaluating the competency of an individual to undertake the role of representative, we do not believe it is necessary to require such a step, although States would have the ability to do so.

Comment: One commenter indicated that assessments and service plans should include an assessment of the consumer's interest and ability to self-direct. Another commenter recommended that the assessment include an evaluation of the individual's ability to receive care in the delivery model available under the State's program, particularly if the program is limited to self-directed care, as it would be harmful to an individual or his or her representative to permit placement in a self-directed care model when the individual, or his or her representative was not able and/or willing to take on the responsibilities under the self-directed model. While these elements are included to an extent in the support system section, they should be integrated in the assessment process.

Response: States may include as part of their assessments and service plans a determination of an individual's interest and ability to self-direct. If the State is only offering CFC via a self-directed model with service budget, and the individual or individual's representative is not able or willing to assume responsibilities inherent in this model, the entity conducting the assessment or development of the service plan should identify other programs for which the individual would be eligible.

Comment: Several commenters suggested that CMS should be more prescriptive regarding the specific elements incorporated into assessments, as they have the capacity to inform quality assurance monitoring and measurement of quality outcomes, and suggested that CMS require States to develop an assessment of need that includes these ''standardized elements, key system functionality, and workflow that will be sufficiently comprehensive.''

Response: We appreciate the commenters' suggestions. As indicated above, and in the preamble of the proposed rule, a set of universal core assessment elements is being developed. As these elements are developed, we will work with States to determine the extent to which these elements, if not already part of a State's assessment for CFC, could be incorporated. States have the flexibility to design a quality assurance system that integrates current and future assessment elements. We also set forth our expectation in the preamble to the proposed rule that States will include a standardized set of data elements, key system functionality, and workflow that will be sufficiently comprehensive to support the determination that an individual would require attendant care services and supports under CFC and the development of the individual's subsequent service plan and budget. For these reasons, we do not believe it is necessary to add an additional requirement for this purpose.

Comment: Multiple commenters provided feedback specifically regarding the statement in the preamble that CMS is currently working to determine the universal core elements to include in a standard assessment for consistency across programs. Several commenters supported our effort in seeking consistency across authorities, including the attempt to create commonalities within assessment processes. Several commenters expressed various concerns regarding standardized assessments. Multiple commenters offered suggestions regarding what should be included in a universal assessment. Other commenters added that ensuring participants are involved in the prioritization of core elements may help to identify elements that have a clear link to the planning process, and a few commenters expressed interest in commenting on any proposed list. The specific comments as summarized above are as follows:

- One commenter suggested that the core elements should include an assessment of an individual's ability to perform ADLs and IADLs without assistance, assess the ability to self-direct his or her services, and should reflect and be consistent with the State's functional eligibility criteria for the service.
- One commenter indicated that functional assessments should consider that a person's disability can change over time.
- One commenter indicated that functional assessments should address the complexities of independent living and active daily living outside the home, such as what supports are needed to go to a community bathroom.
- Several commenters recommended that universal core elements include discussion of unique needs of families, such as whether there are needs of children and partners that should be addressed in the home. The commenters added that these assessments are important for all families because assessing the needs of others in the home will help identify the unique needs of the individual requiring assistance.
- Another commenter voiced concern about the development of universal assessment tools and requested that CMS recognize during its universal core elements development process that core elements likely will vary by population

and recommended, along with other commenters, that rather than specific assessment elements, CMS develop universal domains that cut across programs and populations, and added that program and/or population specific elements could be developed. The commenter urged CMS to convene a meeting of stakeholders to discuss our vision and the viability of universal core domains with elements that might vary by population and program.

- One commenter requested that if changes are necessary after implementation of CFC has begun, that CMS provide States sufficient time to incorporate any new core elements into their assessment process.
- One commenter cautioned against requiring additional elements to be included in the assessment beyond the statutory requirements, as they believed it would increase the assessment time for social attendant care providers.
- One commenter urged CMS to proceed with caution with regard to standardized assessments for States, as research on HCBS is in need of development and codification of assessment elements at this stage may be premature. The commenter added that some States have broader eligibility standards than others and indicated that they would want CMS to adopt a broad view of assessment at this stage to facilitate future expansion and experimentation. The commenter also suggested that to the extent CMS requires States to use a standardized set of data elements, we should consider additional individualized assessments of need that may not fit the standardized data elements.
- One commenter asked whether CMS will be including the determined universal core elements in the core standardized assessment in the State Balancing Incentive Payments Program.

Response: We appreciate the various points, concerns and recommendations made by these commenters. We will take these perspectives and recommendations into consideration during the development of universal core assessment elements as part of the Balancing Incentives Payment Program created under section 10202 of the Affordable Care Act, as well as future HCBS guidance. As noted above, we intend to share any finalized universal core elements that are developed with States as examples of elements that can be incorporated into the assessment of functional need for CFC and other HCBS assessments as determined by CMS. Future guidance will provide additional detail regarding the finalized set of universal core assessment elements.

After consideration of the public comments received, we are finalizing § 441.535 with revision, to refer to an ''assessment for functional need'', to indicate that the scope of the assessment is limited to CFC services and supports, to change ''or'' to ''and'' in paragraph (c), to add the ability for States to meet the face-to-face requirement through the use of telemedicine or other information technology medium if certain conditions are met, and to add a new paragraph (d) to indicate ''Other requirements as determined by the Secretary.''

J. Person-Centered Service Plan (§ 441.540)

We proposed to require a minimum set of criteria for a person-centered planning process, and proposed that the resulting person-centered service plan must reflect the services that are important for the individual to meet individual services and support needs as assessed through a person-centered functional assessment, as well as what is important to the person with regard to preferences for the delivery of such supports. We also proposed to require a minimum set of criteria for the person-centered service plan. Finally, we proposed additional requirements of the plan, including the timeframes for its review and revision.

Comment: Several commenters applauded CMS for recognizing the importance of person-centered planning and for seeking consistency in person-centered planning expectations across Medicaid authorities. The commenters noted that the person-centered planning process should be implemented in a customized fashion according to the unique needs and preferences of the individual. Two commenters agreed with our proposed language and one commenter added that the person-centered planning process should be comprehensive.

Response: We believe that our proposed approach will allow for the process to be incorporated with States' current approaches to maximize the strengths and preferences of the individual. As indicated earlier in the final rule, in an effort to streamline State requirements where possible across the programs, we proposed language in the CFC proposed rule that in some instances was consistent with other HCBS final rules, such as section 1915(j) of the Act, and in some instances was consistent with proposed language in a recently proposed rule for the section 1915(c) waiver program, which published in the April 15, 2011 **Federal Register**. Based on multiple comments and the acknowledgement that additional policy work is necessary to maximize the extent to which consistency can exist across Medicaid HCBS programs, we are revising the language in this section to clarify the requirements of this process and resulting service plan as it pertains to CFC. We are taking more time to consider all of the thoughtful comments from this rule, the comments received from the section 1915(c) proposed rule, and comments forthcoming from the section 1915(i) proposed rule to have additional policy discussions both internally and with stakeholders. We will be issuing subregulatory guidance to provide additional details and expectations as it pertains to the person-centered planning process and the elements that should be included in a person-centered service plan.

Comment: A few commenters stated that it is extremely important that the person-centered planning process not interfere with, or delay access to, services. One commenter added that at times extensive person-centered assessment and planning processes are so time consuming that individuals trying to avoid placement in a facility cannot access services in a timely manner and are forced into an unwanted institutional placement. A few commenters suggested that the regulation require States to include an expedited enrollment process for such situations so that individuals may receive basic attendant services and supports and avoid institutional placement while the complete person-centered service plan is being developed. One commenter suggested that CMS require States to complete the assessment and service plan within 30 days of application.

Response: We agree that the process should not interfere with or delay access to services. States currently conduct assessment processes and create service plans for HCBS programs. We do not believe that the proposed person-centered principles and service plan components for CFC should be overly burdensome or time consuming. In the Collection of Information Requirements for implementing CFC, we estimated that a total of 3.5 hours on average would be necessary per individual, including the assessment, the person-centered planning process, service plan development and providing an individual a copy of the service plan. In addition, as we indicated in the preamble of the proposed rule, States will need to have a minimum set of policies and procedures associated with the assessment and service plan. These policies and procedures should ensure that the process is timely. We expect

States to establish guidelines that support a timeframe that responds to the needs of the individual, thus allowing access to needed services as quickly as possible. We encourage States to implement policies and procedures that provide services as expeditiously as possible. In addition, we are incorporating language originally proposed at paragraph (c)(2) to indicate that the person-centered planning process must be timely, in addition to occurring at times and locations of convenience to the individual.

Comment: Another commenter suggested that while the statute uses the term person-centered, CMS should encourage States to use a consumer-directed process as consumer-directed planning puts the individual in charge of the planning process whereas the term person-centered has been used to allow others on a planning team to make all important decisions ''in their best interests.''

Response: We appreciate the commenter's perspective and the term consumer-directed, but do not agree that the language should be changed for this rule. To be consistent with other Medicaid programs, we will maintain the phrase ''person-centered'' in referring to this process. That said, CFC has a strong focus on individual choice and direction that is evidenced throughout the regulation. For the person-centered service plan, much effort was put into ensuring that an individual maintains a central role in both the planning process and finalizing the service plan. In addition, we are adding at § 441.540(a) that the person-centered planning process must be driven by the individual.

Comment: One commenter suggested that more guidelines be provided to States for the person-centered planning process as the proposed rule does not include qualifications for the entities responsible for the planning process and the entities States utilize may not have adequate training in self-determination/direction or any true person-centered planning training. The commenter suggested that § 441.540(c) include requirements for the States' policies and procedures including the qualifications, training and quality assurance of those conducting the person-centered plans. Another commenter indicated that it would be beneficial, particularly for individuals with mental illness, if the person-centered service planning process included a requirement for a facilitator who had more experience and information than family or other outside individuals chosen by the individual. The commenter noted that in mental health service planning, individuals need some support to fully understand their choices and explore their preferences, and to learn how to assess what support they may need to carry out the plan. The commenter indicated that peers trained to perform this facilitator role might be the best option and suggested that States could be encouraged to consider that option.

Response: States are responsible for determining the provider qualifications of the entities who will conduct the assessments and the 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 additional guidance should be provided to States and we intend to issue future guidance, as indicated above, regarding our vision of the person-centered process and how we intend to apply that philosophy across Medicaid HCBS programs.

Comment: One commenter asked if States can leverage existing single entry point entities currently under contract for section HCBS 1915(c) waiver assessments and planning processes to conduct the person-centered planning process outlined in § 441.540. Another commenter asked CMS to clarify whether the State can delegate its responsibilities to other entities, such as a managed long-term care plan, to develop service plans, budgets, etc.

Response: States have the flexibility to leverage existing entities to conduct various functions required in CFC, provided all requirements of the final regulation are met.

Comment: One commenter stated that the proposed rule implies that two separate meetings will be held, one to complete the assessment and one to develop the service plan through the person-centered planning process, and recommended, along with another commenter, that the rule reflect the ability to combine these meetings.

Response: We did not intend to require two separate and distinct meetings. While individuals and States may choose to conduct separate meetings, particularly depending on the length of the assessment and the availability of all parties involved, we believe that it is appropriate that the assessment of need and the person-centered planning process could be combined into one meeting. We have not revised the regulation, to maintain flexibility, based on individual circumstances.

Comment: Two commenters supported the identification of all of a person's needs (not just what is offered under CFC). One of the commenters also supported the identification of the individual's desired outcomes from services and suggested that the assessment cover the individual's broad life goals and desires as well. The other commenter added that CMS should require that all needs identified during the assessment be addressed in the service plan, ensuring that the needed service is actually being addressed either informally and/or by applying to other programs and benefits.

Response: While this comment references the assessment, the specifics of the comment relate to this section so we will address this comment here. It is our expectation that during the assessment process, and the subsequent person-centered service plan process, an individual's CFC service and supports needs, as well as what is important to the person with regard to preferences for the delivery of such services and supports, be identified and addressed. In States conducting a more comprehensive assessment that exceeds the scope of CFC services and supports, a determination would then need to be made as to which services and supports could be delivered under CFC and which are more appropriately delivered through another benefit or informal support. For the purposes of CFC, States would only be required to provide the services and supports required under CFC as indicated by the final rule. However, we encourage States to coordinate among all the services an individual is eligible for to determine how to best meet an individual's needs as identified during this assessment. As indicated above, we will issue additional guidance regarding our vision of the person-centered process and how we intend to apply that philosophy across Medicaid HCBS programs.

Comment: One commenter suggested that CMS add language that requires coordination with other government-funded health services that may also be providing personal care to consumers, stating that the absence of such clarity can threaten the continuity of care and risk care duplication.

Response: It is our expectation that during the assessment of functional need and the subsequent person-centered service planning process, all attendant/personal care needs and currently received services and supports in place to meet those needs would be identified. A determination would then need to be made as to which services and supports could be delivered under the CFC Option and which are more appropriately delivered through another benefit. States are familiar with this process and we do not agree that

additional regulatory language is necessary. States are expected to take every step to ensure that services are not being duplicated and individuals currently receiving attendant services and supports experience continuity of care during a transition to CFC.

Comment: One commenter noted that the criteria described including consumer direction, convenience to time and place, cultural considerations, conflict resolution, the ability to alter the plan and real choice are all good markers for a good process but indicated that these should be regarded as a minimum level of responsiveness and not a maximum. The commenter added that respecting a person's gender identification is also important.

Response: We appreciate the commenter's perspective regarding the criteria being regarded as a minimum level of responsiveness and not a maximum. We agree that respecting an individual's gender identification is important. We expect that all individuals will be treated with respect.

Comment: One commenter suggested that CMS offer guidance on how to provide necessary support to ensure the person with a disability has meaningful input in the planning process.

Response: We will consider this suggestion as we work on additional guidance regarding our vision of the person-centered process and how we intend to apply that philosophy across Medicaid HCBS programs. In the meantime, we will look to States to implement a person-centered planning process that ensures meaningful input from all individuals in the CFC program.

Comment: One commenter voiced concern over the requirement that the person-centered planning process must occur at ''times and locations of convenience to the individual'' as referenced in paragraph (a)(3), as they believed that this is overly restrictive and beyond the statutory requirement. The commenter stated that the process should be scheduled when it is mutually convenient for both the agency staff and individuals and added that it may be necessary to have the assessment conducted at the individual's home so that the staff can more accurately assess the client's needs in the context of their home environment and community. Another commenter urged CMS to include language that will allow States flexibility to put reasonable limits on the optional locations for these assessments/plans. One commenter indicated that to adequately assess for environmental as well as health and safety needs, States must be allowed to require the face-to-face meeting be held in the participant's place of residence and recommended deleting the words ''and locations'' from paragraph (a)(3).

Response: We appreciate the commenters' concerns and suggestions. The commenters appear to be talking about both the assessment of functional need, which was required in the proposed rule to be conducted face-to-face with the individual, and the person-centered service plan development, which is to occur at times and locations of convenience to the individual. While we do not prescribe the setting in which the assessment of functional need takes place, we encourage the assessment to be conducted in an individual's home in order for the entity conducting the assessment to get a more informed perspective of the individual's supports and needs in their residence. However, we are not mandating this as some individuals will use CFC to transition from an institutional setting, and therefore, would be assessed while still residing in the institution. With regard to the person-centered planning process, if this process takes place separate and apart from the assessment of functional need, we expect that this meeting be scheduled at a time and place that is convenient to all parties taking part in the process, but particularly to the individual. We recognize that there will be practical constraints for the professionals involved in the person-centered planning process and the assessment of functional need, such as availability being limited to certain business hours; however, we do not believe it is necessary to revise the regulation as suggested.

Comment: One commenter asked what the expectations/requirements are for States in terms of supports that address the needs identified by the assessment of expanded areas such as employment, school, income and savings, and social goals as referenced in paragraph (b)(3). The commenter indicated that providing this expanded assessment will result in additional costs to States and it is unclear what States would be required to address. The commenter asked if these requirements would be limited in scope to ''the provision of services'' as stated in § 441.535(a)(2) and the qualification at § 441.515 that States provide CFC ''in a manner that provides the supports that the individual requires to lead an independent life.'' The commenter asked CMS to confirm that a State would not be required to provide money-management support, and it would not have to have an outcome measured in the quality assurance system, if an individual had the goal to save money for their grandchild's college fund in their assessment/plan. The commenter wanted to know how this expands a State's responsibilities or liability.

Response: While this comment references aspects also covered in the assessment section, the main issue expressed in this comment relates to this section so we will address this comment here. As indicated above, we have revised the regulation to indicate that it is only the need for services and supports within the scope of CFC services that must be assessed. It is our expectation that during the assessment process, and the subsequent person-centered service plan process, an individual's CFC service and supports needs as well as what is important to the person with regard to preferences for the delivery of such services and supports be identified and addressed. In States conducting a more comprehensive assessment that exceeds the scope of CFC services and supports, a determination would then need to be made as to which services and supports could be delivered under the CFC and which are more appropriately delivered through another benefit or informal support. We believe that many States already have such a system in place. For the purposes of CFC, States would only be required to provide the services and supports required under CFC as indicated by the final rule. However, we encourage States to coordinate among all the services an individual is eligible for to determine how to best meet an individual's needs as identified during this assessment.

After considering the feedback received and the acknowledgement that additional policy work is necessary to maximize the extent to which consistency can exist across Medicaid HCBS programs, we are revising the language in this section to clarify what must be included in the plan as it pertains to CFC. As indicated above, we are taking more time to consider all of the thoughtful comments from the CFC proposed rule, the section 1915(c) proposed rule and the comments we will receive in response to the forthcoming section 1915(i) proposed rule to have additional policy discussions both internally and with stakeholders. We plan to issue additional guidance regarding our vision of the person-centered process and how we intend to apply that philosophy across Medicaid HCBS programs.

Comment: One commenter indicated that in § 441.540(a)(5), CMS describes the requirements for service plans

including a requirement that States have ''strategies for solving conflict or disagreement within the process, including clear conflict of interest guidelines for all planning participants'' and in § 441.555(b)(2)(xiv), CMS requires that participants be provided ''information about an advocate or advocacy systems * * * and how [they] can access [such] systems.'' The commenter then pointed out that CMS does not discuss CFC appeals processes in the proposed rule and recommended that CMS clarify the appeals processes and the relation to the provisions noted above. Another commenter asked if CMS plans to intend for an individual to have the right to appeal the service plan. A commenter suggested that CMS require that both the final written assessment and the service plan include information on the individual's right to appeal if she/he disagrees with the assessment or any parts of the service plan.

Response: An individual has the right to appeal the service plan. The person-centered service plan, which is based on the assessment of functional need, must be finalized and agreed to in writing by the individual. If the individual does not agree with the findings of the assessment or the proposed service plan based on these findings, an individual does not have to agree to or sign the service plan. The individual would have the right to disagree with the assessment and service plan at any time during the process. As such, States electing the CFC option are also required to have appeals for denials and reconsideration procedures of an individual service plan in place as part of their quality assurance system for the CFC.

Comment: Several commenters noted that it is not clear what components of the service plan proposed by CMS are ''required'' versus ''recommended'' and pointed out that there is also inconsistency in the use of terms (for example, Support Plan, Service Plan, and Plan of Care). The commenters recommended that, regardless of the term chosen, the term reflect the person-centered approach and participant-directed nature of CFC.

Response: As indicated in the proposed rule, the elements in § 441.540(b) are all required. This is evidenced by the use of the term ''must'' in the last sentence prior to the numbered list of elements. We are revising the regulation to ensure that all ''plan'' references throughout the rule indicate that it is the ''person-centered service plan.'' In addition, based on multiple comments regarding the requirements of the plan at § 441.540(c), we have removed the duplicative requirements that were already captured in § 441.540(b) and have moved the remaining requirements to the more appropriate Support System section at § 441.555.

Comment: One commenter stated that the person-centered service plan should reflect that the place where the individual resides is the least restrictive setting available based on the individual's need for a handicap accessible place of residence and affordability, as well as the consumer's freedom of choice to live in that particular place of residence. The commenter added that the person-centered service plan should determine the appropriate setting for an individual covered under CFC.

Response: While we agree that the service plan could reflect that an individual resides in the least restrictive setting of their choice, we do not agree that the service plan should determine the appropriate setting for an individual. We have revised the service plan process to add paragraph (a)(8) requiring States to record the alternative home and community-based settings that were considered by the individual. We also amended the person-centered service plan to require an assurance that the setting in which the individual resides is chosen by the individual. This will be reflected as a new paragraph (b)(1), and all existing text will be renumbered accordingly.

Comment: One commenter suggested that to protect the integrity of the program and to ensure adherence to service plans, that CMS allow for fiscal or other program intermediaries to validate service plans, issue rules for the training of attendants, and develop a process to ensure that services and supports are assessed for appropriateness.

Response: States may decide to have a mechanism by which a service plan is compared to the services provided to protect the integrity of the program, but we are not clear how allowing a fiscal or other program intermediary to issue rules for the training of attendants would protect program integrity. States have the discretion to determine provider training and qualifications as long as the requirements in the final rule are met. We believe the assessment of functional need, person-centered service planning process and finalizing of the service plan should result in appropriate services and supports being provided to the individual to meet their assessed needs.

Comment: One commenter asked CMS to clarify whether a State may use a prior authorization process to ensure services rendered and paid for match the service needs indentified through the service planning process.

Response: States have the flexibility to use various methods to ensure that services provided match the needs identified through the assessment and service plan. States will need to describe in their State plan amendment how they propose to utilize the prior authorization process.

Comment: Two commenters suggested that the development of the person-centered service plan, as spelled out in the proposed rule, should include health promotion and wellness components designed to mitigate health risks and maintain and support healthful behaviors.

Response: As indicated above, additional policy work is necessary to maximize the extent to which consistency can exist across Medicaid HCBS programs and we are taking more time to consider all of the thoughtful comments from this rule, comments received from the section 1915(c) proposed rule, and forthcoming comments from the section 1915(i) proposed rule to have additional policy discussions both internally and with stakeholders. We plan to issue additional guidance regarding how we intend to apply the person-centered philosophy across Medicaid HCBS programs. We will continue to consider this comment during that process. In the meantime, there is no prohibition against a State incorporating these elements into the development of the person-centered service plan. In addition, we are taking this opportunity to add an additional requirement that will allow for the incorporation of future person-centered planning requirements published by CMS.

Comment: A commenter noted that paragraph (b)(2) refers to the ''person-centered functional assessment'' and recommended that CMS change the language to: ''reflect clinical and support needs as identified through a functional assessment'' as they believe that § 441.540 needs to more clearly reflect the distinction between the assessment of functional need and the person-centered service plan.

Response: We are revising the regulation to say ''reflect clinical and support needs as identified through the assessment of functional need.'' This is now paragraph (b)(3).

Comment: Several commenters suggested that in paragraph (b)(3) CMS change the phrase ''individually identified goals'' to ''participant identified goals.''

Response: We do not agree with the commenters' suggestion. While an individual receiving services and

supports under CFC will be a ''participant'', we choose to maintain the term ''individual.'' This term is used throughout the regulation and we prefer to be consistent so as to not create any unnecessary confusion.

Comment: A commenter encouraged CMS to require in paragraph (b) that the standard assessment of need include the individual's assessment of their strengths and their goals regarding housing, services, education, transportation, employment, recreation and socialization, wellness and the supports needed to enable them to live independently in the community setting of their choice, in addition to a person's preferences.

Response: The proposed rule at § 441.540(b)(1) indicates that the person-centered service plan must reflect the individual's strengths and preferences. Section 441.540(b)(3) proposed language to address an individual's goals and desires and included the term ''may'' to suggest aspects that could be included in the person-centered service plan. Based on comments and further consideration we have decided not to specify particular aspects of an individual's strengths, preferences and goals that could be assessed or included in the person-centered plan as we do not want to create an unintended limit on the aspects that could be included in the service plan. Therefore, we are revising the regulation to read ''Include individually identified goals and desired outcomes'' at paragraph (b)(4).

Comment: Several commenters indicated that the proposed rule appropriately sets forth multiple factors to be considered in determining the need for and authorization/provision of services, but they, and multiple other commenters, voiced concern regarding the identification of informal supports. Other commenters supported the consideration of natural and informal supports but did not want it to be construed that the existence of family, natural and other informal supports could be used as a reason to reduce the level of services an individual would receive. Multiple commenters indicated that these supports can be considered as appropriate in determining the individual's needs, strengths, and preferences, but eligibility and supports covered for an individual by CFC should be based upon functional need, independent of the existence of family or other informal caregivers. Several commenters believed that reliance on family and other informal supports who may not be skilled/trained to care for certain conditions and may have limitations of their own could lead to additional strain on families and could put the consumer at risk. One commenter voiced concern that the regulation does not include the CMS Handbook definition of informal care (that which is capable, available and freely given) and that without emphasis on ''freely given'' States may assign the responsibility of this care to family members and other informal supports. Another commenter suggested that at a minimum, if family members or other informal supports are identified in the assessment/plan, the participant must indicate acceptance of the unpaid supports in lieu of provided services and the family members or other informal supports must indicate they are willing and able to perform the roles/tasks. The commenter added that the participant and family/informal supports must also have the ability to no longer accept or to withdraw their support without harming the beneficiary and the plan should be adjusted to reflect the lost support. Another commenter added that if the State includes family or other informal caregivers in the service plan, it should be a requirement that the needs of the family or other informal caregiver also be assessed and addressed, especially if crucial aspects of the service plan depend on these caregivers. The commenter added that such an assessment would identify the family caregiver's needs, strengths and preferences and connect such caregivers to critical supports such as respite, training or other assistance, as helping the caregiver to continue in their caregiving role could delay or prevent institutionalization of the care recipient. Another commenter indicated that the consideration of unpaid assistance needs to take into account the sometimes oppressive influence this has on family and personal relationships adding that these relationships should not be forced to become strictly defined as a caregiver/care-receiver relationships at their core level and that the provision of unpaid but necessary services can affect the ability of the consumer to control how his/her services are provided. Other commenters urged CMS to remove the language from the preamble.

Response: While these comments reference aspects also referenced in the preamble for assessment of need, the requirement referenced is included in § 441.540 so we will address this comment here. We appreciate the concerns regarding the potential that the identification of natural supports could result in the decrease of services provided under CFC, or these natural supports might be weakened as a result of the expectation that they be provided. We expect that the identification of these natural, unpaid supports be taken into consideration for the purpose of understanding the level of support an individual has, and should not be used to reduce the level of services provided to an individual unless the individual chooses to receive, and the identified person providing the support agrees to provide, these unpaid supports to the individual in lieu of a paid attendant. We have modified the regulation to incorporate this intention. We also expect that if an individual is receiving services and supports, either paid or unpaid, that if circumstances change, an individual has the right to request a reassessment of need and/or revision to the person-centered plan. For the concern regarding individuals providing supports having the skills or training to care for certain conditions or having their own limitations, having a full picture of the individual's paid and unpaid supports will assist the State and the individual in determining what level of support the individual requires and what services need to be accessed to meet the individual's needs and ensure their health and safety. With regard to the recommended requirement that the needs of the family or other informal caregiver also be assessed and addressed, we agree that it is important to consider these needs to encourage and preserve support for the individual, but we do not agree that this should be an additional requirement in the CFC final regulation. As noted above the order of the paragraphs has shifted and this requirement is now reflected at paragraph (b)(5).

Comment: One commenter indicated that the risk assessment portion of the planning process is a challenge, as many consumers are competent adults and need to be allowed the same level of freedom and personal control as a non-disabled person, and allowed to assume risk at the same levels as non-disabled persons. The commenter voiced concern that this section could potentially be used to impede a consumer's goals and desires and recommended that if there are disability-related conditions that impact the ability of the individual to assess risk, their plan should only impinge on their freedom commensurate with the need for reasonable safety. The commenters added that strategies for risk abatement should include voluntary participation in skills training and peer support to improve their ability to access and assume risk, and that the consumer's use of additional training for the

personal assistant related to risk avoidance may be another strategy. Another commenter asked that CMS clarify that a contingency plan should be part of the service plan, to ensure that individuals are prepared and have a backup attendant care provider if the regular attendant care provider is not able to provide services.

Response: We agree that individuals should have personal control and the opportunity to assume risk. We proposed at § 441.540(b)(5) that the person-centered service plan reflect risk factors and measures in place to minimize them, including backup strategies when needed. Service plans will need to reflect risk factors and measures in place to minimize them for each individual regardless of disability or level of need. Nothing in this section should be used to impede an individual's goals and desire outcomes or to impinge on an individual's freedom. As noted in response to comments received in the Definitions section, we are modifying the requirements of the person-centered service plan to remove the ''as needed'' language, to indicate that all individuals should have an individualized backup plan as specified in paragraph (b)(6). We would like to point out that for the purposes of CFC, this backup plan could include formal or informal backup supports as part of the plan.

Comment: A commenter voiced concern regarding the requirement that the individual sign the service plan as this may not always be possible due to disability or inability to write, and suggested that the regulation be amended by adding ''if possible.'' Another commenter suggested language in paragraph (b)(6) that would allow an individual's representative to sign the service plan when appropriate, and suggested the removal of a similar requirement in paragraph (d), as they felt the emphasis should be related to the individual and persons responsible for implementation. Another commenter indicated that the requirement for all individuals and providers to sign the plan may be onerous and logistically complicated as consumers can change providers frequently for a variety of reasons, and consumers should be able to obtain agreement from providers through formats other than the service plan. Other commenters added for clarification that the signature expectation is only for those involved with the actual assessment/planning process and not for the providers and others not present who are responsible for the implementation of the plan. Another commenter recommended that the language in paragraph (b)(6) be changed to: ''be distributed to all individuals and providers responsible for its implementation and signed by all parties within 30 days of the development date'' as they felt that requiring all provider signatures at the point of development would delay services.

Response: After consideration of these comments, we have revised the final regulation to indicate that the plan be finalized and agreed to in writing by the individual and signed by all individuals and providers responsible for its implementation. While we understand that some individuals may not be able to provide an actual signature, we believe that it is important to capture that the individual agrees to the service plan as finalized. Should an individual not be able to make any indication that they agree with the plan in writing or the individual does not have a representative who can do so on the individual's behalf, States will need to explain the methods they propose to use to indicate that the individual agrees with the service plan. While we do not specify the timeframe by which States must obtain the signature of the providers responsible for implementation of the plan, we expect that any provider that is responsible for implementing services or supports authorized in the service plan should receive and sign the individual's service plan, as this would be necessary to not only understand the level of CFC services and supports needed by an individual, but also the individual's strengths, preferences, goals and desired outcomes related to the provision of the services and supports. We are reflecting this change at a revised paragraph (b)(9) under § 441.540, and have removed this language from paragraph (b)(6) and paragraph (d).

Comment: One commenter suggested that CMS should clarify explicitly at paragraph (b)(7) that the plan must also be understandable to the individual's representative. A few commenters recommended that the regulations require the development of the service plan be conducted in a linguistically and culturally appropriate manner for the individual (and/or their appointed representative) as determined by the individual in a fully accessible way.

Response: We appreciate the commenters' suggestions. However, we do not agree that paragraph (b)(7) under § 441.540 needs to clarify explicitly that the plan must be understandable to the individual's representative as the language at paragraph (b)(7) encompasses a representative. We also believe that the requirement at § 441.540(a)(2), that the planning process provides necessary support to ensure the individual directs the process to the maximum extent possible, and the requirement at paragraph (a)(4), that the process and plan reflects cultural considerations of the individual, encompass the other commenters' suggestions.

Comment: With regard to the requirement to include a timeline for review, a commenter suggested that CMS add a requirement at paragraph (b)(8) that reviews of the service plan occur at least every 18 months to assure that not too much time will pass between reviews and does not place undue burden on the participant or service providers. Another commenter suggested that the person-centered plan of care be revised as needed to reflect the goal of providing the least restrictive setting. Another commenter strongly supported the periodic reassessment and revision of the care plan at least every 12 months. Another commenter suggested that CMS require timely review (within 1 week) when the individual believes that the plan needs to be revised. Multiple commenters recommended that paragraph (b)(8) be expanded to read ''include a timeline for review and implementation of changes.''

Response: While we proposed at paragraph (b)(8) that the person-centered service plan include a ''timeline for review'', we also proposed requirements at § 441.540(e) for reviewing the service plan. To clarify our expectation regarding review of the service plan, we are removing the language at paragraph (b)(8), as it is encompassed later in this section and have moved the language proposed at paragraph (e) to (c) with the exception of ''or the individual's representative, as applicable'' which we have removed.

Comment: One commenter stated that the ''agreement'' portion of the service plan, as required in paragraph (d), needs to be strengthened. The commenter indicated that ''agreement'' needs to be elevated to the level of a ''contract'' to avoid what they perceive to be the ''pitfalls'' of current HCBS waivers. The commenter indicated that in their State, the waiver service plan can be unilaterally altered by the State without the ability of clients to challenge the State's decision. The commenter believes this is a fundamental denial of a civil right, must not be extended into the new rule, and must be corrected within current HCBS waivers.

Response: We disagree with the commenter's suggestion that CMS change the service plan agreement language to a contract. We believe that the requirement proposed at

§ 441.540(d), now reflected in paragraph (b)(9), that the service plan must be agreed to in writing by the individual or their representative, as applicable, will ensure that the service plan is approved by the individual. States may not alter an individual's service plan without the individual's knowledge or approval. In addition, an individual has the right to appeal any State decision to decrease services. With regard to other HCBS programs including waivers, changes to their processes are not within the scope of this regulation.

Comment: With regard to distribution of the plan at § 441.540(b)(10), one commenter recommended that CMS should require that a copy of the service plan be placed in the hands of the consumer. Another commenter suggested that the phrase ''including the participant'' makes it look like providing the plan to the individual is an afterthought and that the consumer should be able to decide who else received a copy of the plan, as there may be services or goals identified in the plan that do not need to be shared with every provider.

Response: It is expected that each individual receiving services under CFC would receive a copy of the finalized service plan. We interpret the commenter's recommendation to mean that we should require States to hand-deliver the service plan to the individual. While we do not discourage a State from doing so, we do not require that the service plan be hand-delivered to each individual. The intent of the language ''including the participant'' was to emphasize that the individual must receive a copy of the plan. We have revised paragraph (b)(10) to make this clear. We appreciate the commenter's indication that individuals should determine with whom to share their person-centered service plan. While we do not believe it is necessary to include this requirement in the regulation, we expect an individual's preferences for the level of information in the plan that is shared with other providers to be respected.

Comment: One commenter indicated that the service plan should be composed to fully meet the needs of the individual regardless of the service delivery model and any shortcomings of a plan within the limitations of the Medicaid program or the delivery model should be referenced to the individual. The commenter added a person needs to be informed of their options, the risks of choosing particular options, the alternatives available, and the anticipated consequences of any alternatives. The commenter added that if a limitation in the State program puts an individual at risk of adverse consequences that could be mitigated in an alternative approach available under the State program, the service planning process should provide the individual with that information before the plan is finalized.

Response: It is our expectation that during the person-centered planning process and development of the service plan, the issues indicated above and options available will be articulated and discussed with the individual, regardless of the service delivery model. In addition, we are taking this opportunity to make clear that the service plan requirements for the self-directed model with service budget must be incorporated into the person-centered service plan when applicable.

Comment: Several commenters requested that CMS explain the rationale for service plan criteria related to the ''provision of unnecessary or inappropriate care.''

Response: This requirement was included to emphasize that the service plan should reflect and authorize only the services and supports necessary to meet the assessed needs of the individual.

Comment: One commenter asked who has final approval of the service plan. Several commenters stated that the preamble explains that the entire plan must be in writing and agreed to by the individual, but the regulation only requires ''signing off'' on the plan in writing. The commenters recommended that specific requirements be put in the plan itself, in writing, for the consumer to have adequate time to review the plan themselves or with others.

Response: The regulation does not indicate that an individual only needs to ''sign off'' on the service plan, but requires the service plan be ''finalized and agreed to by the individual.'' As the individual, and as appropriate the individual's representative, are included in the planning process and the development of the service plan, we believe that the individual should know what the plan includes throughout the process. Additionally, the service plan, as a whole, must be finalized and agreed to, in writing, by the individual. Therefore, we do not agree that revisions to the regulation are necessary.

Comment: One commenter indicated that the main conflict of interest in the care planning process emanates from the pressure on State agencies and their contractors to keep spending to certain levels, to promote or discourage the use of certain services based on cost and availability, or to enforce unwritten rules about levels of services which results in consumers previously determined eligible for services experiencing terminations either of particular services or of their HCBC eligibility all together. The commenter recommended that the conflict of interest provision at § 441.540(c)(4) address these conflicts as they are very real and limit consumer access to the services they need.

Response: The person-centered service plan is based on an assessment of functional need. If an individual requires a particular level or amount of attendant services to meet these needs, the services should not be decreased at any time unless an individual no longer requires that level of support. An individual must agree to and sign any service plan, and therefore, we do not believe that we need to issue any further guidance to States regarding the reduction of services absent a decrease in need. We do reiterate the ability of a State to implement limits on the amount, duration and scope of CFC services, as long as these limits are not based on an individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life, as prohibited in the statute.

The conflict of interest provisions proposed at § 441.540(c)(4) were intended to protect the individual and relate to similar protections at § 441.555. We are moving these protections to the more appropriate Support System (§ 441.555).

Comment: Two commenters indicated that there is potential for a significant conflict of interest resulting in public and private entities that authorize or pay for services and the individuals affiliated with them participating in the development of the person-centered service plan and suggested CMS include these entities at § 441.540(c)(4).

Response: We believe that this is already addressed in this section as paragraph (c)(4) indicates ''that apply to all individuals and entities, public or private.'' As indicated above, this section is being moved to the more appropriate Support System.

Comment: One commenter recommended that the conflict of interest provisions be clarified, as they may exclude a provider who conducts an assessment from providing one or more services to individuals under CFC, which the commenter believes would undermine their State's current delivery system. The commenter indicated that its State pioneered and predicated its core models of long term care and home care on the consolidation of the assessment, care management and

service delivery functions within, and at the provider level, which has been very successful in terms of cost efficiency, timely integration, and provision of services in accordance with the individuals needs. The commenter noted that the prohibition of this coordinated approach should not be part of CFC and stated that it was not required by the statute.

Response: As noted earlier, the conflict of interest provisions have been relocated to the more appropriate Support System, § 441.555. While we do not believe it is generally appropriate for an entity that would benefit financially from the assessed needs of the individual to also be the entity to perform the assessment of functional need or the person-centered planning process for the individual, we acknowledge that in some geographic areas there may be circumstances in which the only willing and qualified entity to perform the assessment of functional need and/or the development of the person-centered service plan also provides the HCBS services and supports in that area. Therefore, we are adding additional language to address this circumstance.

Comment: Multiple commenters expressed concern regarding the proposed conflict of interest standards included in § 441.540(c)(4). One commenter indicated that the proposed rule is contradictory with regard to the assessment of need in that section § 441.535 indicates that family members can support the individual, serve as representatives and be paid providers whereas paragraph (c)(4) excludes the family member from conducting the assessment/service plan. Another commenter suggested that there was a contradiction in the conflict provisions between the mandate that the individual be permitted to designate who may assist them with service plan development and who may provide the actual services. Multiple commenters indicated that the total prohibition of family members is too broad and may inappropriately undermine the preference of individuals to choose persons they wish to involve. Another commenter added that while the commenters agree that the assessment and planning process needs to be done by a neutral party, the regulation seems to include and exclude family/other participation. Several commenters urged CMS to develop a specific process by which the individual or authorized representative can make a written informed decision to waive the prohibition on family member involvement in development of the service plan that includes safeguards to facilitate an independent informed choice to waive the prohibition. Multiple commenters suggested that ''involved in'' at paragraph (c)(4) be changed to ''conducting'' as this conflict of interest provision should apply only to the team conducting that assessment and creating the plan, as a relative may be ''involved in'' the process to help the individual with any one of a number of functional limitations, assist with communication, or distribute and collect materials. Another commenter recommended that the words ''and service plan development process'' be removed from paragraph (c)(4) and that CMS change the language in the same paragraph to: ''at a minimum, these standards must ensure that the individuals or entities conducting that assessment of need are not.'' Multiple commenters objected to the conflict of interest provisions in paragraph (c)(4) altogether and suggested that CMS remove them, stating that service plan development should often include family members and service providers and that it is counterproductive, and potentially undermines a person's preference, to exclude them. Other commenters asked that CMS provide clarifying language to explain the intent of the provision. Other commenters asked CMS to provide guidance reconciling an individual's ability to choose participants with the requirement that certain individuals are not to be included in the planning process.

Response: These comments illustrate the need to clarify the intent of this provision. We acknowledge the confusion caused by use of the term ''involved in'' when describing the conflict of interest protections. To clarify our intent, we are revising this paragraph to state ''At a minimum, these standards must ensure that the individuals or entities conducting the assessment of functional need and person-centered service plan development are not * * *.'' As noted above, this new language will now be reflected in § 441.555, Support System.

Comment: A commenter suggested that at § 441.540(c)(4)(i), CMS change the language to ''family members, as defined by this section'' indicating that as written the language does not provide conflict of interest protections to Lesbian, Gay, Bisexual and Transgender individuals as there are different types of families that may not fall under the definition of ''related by blood and marriage.'' Another commenter asked for additional guidance on the exclusion of blood relatives, financially responsible relatives, paid caregivers and those with a financial interest in provided services from the assessment and service plan development processes.

Response: We do not believe that such revision is necessary, given the revision to the regulation text described above.

Comment: One commenter stated that physician input is necessary and indicated that it is not clear whether the proposed rules intend to exclude primary care providers (physicians, physician's assistants, etc) from the assessment and planning process.

Response: Nothing in this regulation excludes primary care providers from participating in the assessment of functional need or the development of the person-centered service plan, as long as the requirements of this section are met.

Comment: Multiple commenters recommended that subpart (e) be expanded to read ''the review and revision of the service plan must be conducted according to an established timeframe that is explained to the consumer.''

Response: We believe that a person-centered service plan, based on a reassessment of functional need, should be conducted at least every 12 months, at a minimum, to ensure that an individual's needs are commensurate to the services authorized in the service plan, as we understand that an individual's needs can change significantly over time and as a result of various circumstances. We include several provisions related to the reassessments and reviews to the service plan that we believe capture various circumstances necessitating a reassessment and updates to the service plan. Therefore, we do not agree that we need to revise the language. While we do not specify in regulation a particular timeframe for the review of the service plan based on each of the provisions, we expect States to respond to the requests for review in a timely manner as specified in paragraph (c).

Upon consideration of the public comments received, we are finalizing § 441.540 with the following revisions:

- We are adding a requirement that the person-centered planning process be driven by the individual;
- We are indicating that the scope of the person-centered service plan is only required to address the services and supports provided under CFC;
- We are consistently using the term ''person-centered service plan'' throughout the document;
- We are adding a requirement in paragraph (a) that the person-centered planning process must record the alternative home and community-based

settings that were considered by the individual;

• We are adding a requirement in paragraph (b) that the person-centered service plan must indicate that the setting in which the individual resides was chosen by the individual;

• Paragraph (b)(3) will now say ''reflect clinical and support needs as identified through the assessment of functional need;''

• We are modifying what is now paragraph (b)(4) to modify ''desires'' to ''desired outcomes'', to remove the specific examples of goals that could be addressed in the person-centered service plan;

• We are modifying what is now paragraph (b)(5) to indicate that natural supports should not supplant services and supports provided under CFC.

• We are modifying what is now paragraph (b)(6) to require all individuals to have an individualized backup plan specified in the person-centered service plan;

• We are removing the proposed language at paragraph (b)(8);

• We are modifying what is now paragraph (b)(9) to require that the person-centered service plan be finalized and agreed to in writing by the individual, and signed by all individuals and providers responsible for its implementation;

• We are modifying paragraph (b)(10) to indicate that the person-centered service plan must be distributed to the individual and others involved in the plan;

• We are revising § 441.540(b)(11) to incorporate the service plan requirements for the self-directed model with service budget at § 441.550, when applicable;

• We are adding § 441.540(b)(13) to state ''Other requirements as determined by the Secretary;''

• We have relocated the language from (c)(1) to the more appropriate Support System § 441.555, relocated ''is timely'' from proposed (c)(2) to the beginning of paragraph (a)(3), removed the duplicative requirements from the proposed paragraph (c)(3) that were already captured in § 441.540 (b), revised the language proposed at paragraph (c)(4) to state ''At a minimum, these standards must ensure that the individuals or entities conducting the assessment of functional need and person-centered service plan development are not'', and have moved this paragraph to the more appropriate Support System § 441.555.

• We have removed paragraph (d) as the requirements in the proposed (d) were incorporated in the revised paragraphs (b)(9) and (10).

• We have removed paragraph (e) as these requirements are now reflected at paragraph (c) with the exception of ''or the individual's representative, as applicable'' as this has been removed.

K. Service Models (§ 441.545)

We proposed that a State may choose one or more of the service delivery models defined in the statute. We categorized these models into two main groups, the Agency Model and the Self-directed Model with Service Budget. We proposed to further define the categories within the Self-directed Model with Service Budget to include the models specified in the statute, including financial management entity, direct cash, and vouchers.

Comment: Many commenters expressed support of the efforts to align CFC with Medicaid HCBS programs like section 1915(j) of the Act. Many other commenters offered support for the service models described in the proposed rule, including allowing States to use multiple service models. Many commenters strongly supported the direct cash option and the inclusion of financial management activities.

Response: We appreciate the commenters' support.

Comment: One commenter noted that in the definition section, § 441.505, the rule uses the term ''Agency-provider model'' and in § 441.545 the term ''Agency model'' is used.

Response: We have revised the rule at § 441.545(a) to make this technical correction.

Comment: One commenter recommended we include the statutory language regarding maximized consumer control found at section 1915(k)(1)(A)(iv)(II) of the Act in the opening language of this subpart. The commenter recognizes that it has been incorporated by definition into the term ''self-directed'' but considers it important here for clarity.

Response: We appreciate the commenter's perspective, but we do not believe such a revision is necessary, as the ''consumer controlled'' philosophy is inherent throughout this regulation.

Comment: One commenter requested that the regulation allow States to differentiate service models among populations serviced under CFC.

Response: Section 1915(k)(3)(B) of the Act requires that services must be provided without regard to the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports the individual requires to lead an independent life. When a State specifies what service delivery models will be provided under CFC, the model must be available to all individuals meeting the medical necessity for CFC services. Therefore, States may not target certain service delivery models to sub-populations of individuals eligible for CFC. However, States could give all individuals participating in CFC the ability to choose among more than one service model.

Comment: Many commenters expressed concern and disagreed with the fact that the regulation gives States a choice to provide one or more service models. Many commenters believe the proposed rules did not carry out the statutory intent that States must offer people with disabilities a full range of options (including choice of service model) for receiving home and community-based services. The commenters believe States should be required to offer both an agency with choice as well as a self-directed model with service budget. The commenters indicate that a ''choice'' does not exist if the State only offers one model. One commenter recommended the regulation require assurances that individuals, rather than the State, would have the ability to select the service model that is best suited for their specific needs. Additionally, the commenters expressed concern that States could choose to only provide services under a self-directed model with service budget, which would potentially prevent individuals without the capacity to self-direct from accessing these services. Similarly, States could choose to only select the agency model, which would potentially prevent individuals from stating control over the budget and prevent them from having control to the maximum extent possible. The commenters indicated that either of these alternatives alone is inconsistent with the statutory language. The commenters requested the regulation be revised to assure that individuals have the opportunity to select the service model that best meets their needs. Another commenter believed States should not be allowed to have one model of care because one model will not fit all participants. The commenter stated that limiting the service delivery model is counter to the purpose of section 1915(k) of the Act and would only serve to perpetuate discrimination against individuals who can safely live in their own homes.

Response: The commenters provided compelling arguments as to why a State should provide more than one service delivery model. However, section 1915(k)(A)(iii) of the Act requires that the State shall make available home and community-based attendant services and supports ''under an agency-provider

model or other model * * *.'' The use of the word ''or'' instead of ''and'' led us to interpret the requirement that States are given a choice of service model to offer. We agree that individuals should be given a choice of service model that best meets their needs and we encourage States to elect to provide more than one. However, based upon the statutory language, we do not believe we have the authority to mandate a State to offer both service models.

Comment: A few commenters indicated that it is not clear what models would be included in the agency-provider model. In addition to requiring States to offer more than one service delivery model, a few commenters also requested the regulation specify the additional delivery models to be provided, such as traditional agency model, agency with choice model and self-direction with a service budget.

Response: We would like to clarify that, for the purposes of CFC, the agency-provider model could include both the traditional model and the agency with choice model. States using the agency-provider model for CFC may choose one or both of these agency options. As noted in the response to comments received in the Definition section, we have modified the definition of agency-provider model. Therefore, we have also revised the language at § 441.545 to align this section with the revised definition.

Comment: One commenter believed that mandating all models would not only allow a wider range of eligible individuals the opportunity to access services, but could potentially be of benefit to the growing personal care workforce. The commenter acknowledged the value of self-directed models, but also expressed the belief that it can isolate attendant care providers and offer them little opportunity for advancement. If the person they care for passes away or is hospitalized, the attendant care providers have no assurance of continued work. Payment for travel costs and holidays, which is standard in agencies, is almost non-existent for attendant care providers participating in self-directed models. Working for an agency may guarantee continued work, ongoing professional training or support, and recourse for addressing employment problems.

Response: We appreciate the commenter's perspective, and as stated earlier, encourage States to offer more than one service delivery model. However, we do not believe the statute mandates the provision of more than one service delivery model. Additionally, the scope of this regulation does not extend to address advancement opportunities and the examples of employees benefits the commenter provided.

Comment: One commenter stated that attendant services and supports should be available to individuals whether or not the individual fully manages them. The commenter requested that we use the term ''consumer controlled'' instead of ''self-directed'' when talking about the agency-provider model.

Response: We agree that individuals should exercise the level of control they want to, and we believe the self-direction philosophy supports this flexibility. As indicated above, we have modified the definition of ''agency-provider model'' to remove the term ''self-directed'', to avoid confusion.

Comment: One commenter requested that we clarify how an agency-provider model can legally provide participants with ''hiring and firing authority'' of personal care attendants, if attendant care providers are employees of the agency. Another commenter requested we clarify the definition of agency model within the context of consumer direction.

Response: We would like to clarify that the hiring and firing authority in the agency-provider model grants individuals the choice of who will provide services to them. When an individual chooses to not continue to use a attendant care provider (that is, ''fire'' the attendant care provider), the attendant care provider is still employed by the agency and is available to provide services to someone else. As indicated in an earlier response we have replaced references to ''hire'' and ''fire'' with ''select'' and ''dismiss''.

Comment: One commenter wanted to know if an individual's representative assisting the individual to self-direct and manage their services can be paid as part of the service plan.

Response: The assistance provided to a participant by an authorized representative is not considered a CFC service, and therefore, there is no reimbursement available through CFC.

Comment: One commenter indicated that the services available through the CFC program are provided in most States as adult day, home care and PACE, under different authorities such as sections 1915(c), 1915(b), 1115, 1915(i), and 1905(a) of the Act. The commenter recommended the regulation be amended to allow these providers to participate in the CFC program. One commenter suggested that the final regulation indicate that voluntary participation by PACE programs as a provider under CFC is allowed under the agency model or under another model established by the State.

Response: We do not agree the regulation should specify the various provider types that may be allowed to provide CFC services. The State determines the provider qualifications for providers to provide CFC services under the agency provider model. If the provider types listed meet the State's qualifications, and the providers are willing to provide the service, they may do so.

Comment: We received many comments requesting clarification on the level of control individuals have under the agency service model. One commenter indicated the regulatory language pertaining to the agency service delivery model is ambiguous. Section 441.545(a)(2) provided that under the agency model for CFC, individuals maintain the ability to hire and fire the providers of their choice. The commenter indicated that this can be read to mean individuals under this model only have the ability to hire and fire providers and do not have maximum control over service delivery, as required by the statute in section 1915(k)(6)(B) of the Act. The commenter recommended that this regulation be amended to make the language in § 441.550, relating to the authority of the individual to control service delivery, compliant with their interpretation of the statute.

Response: We do not agree with the commenter. When services are provided under the agency-provider model, individuals have maximum control within that service delivery model to select and dismiss attendant care providers, provide input as to the provision of services, and the type of assistance the attendant care provider provides. The individual also retains the right to train attendant care providers to perform the needed assistance in a manner that comports with the individual's personal, cultural, or religious preferences.

Comment: A few commenters requested that the regulation require that under the agency model, the individual maintain the ability to do the following: Select providers of their choice for services identified in their person-centered service plan, train, supervise, schedule, determine duties, fire their attendants, manage their providers and control, to the maximum extent possible, the services identified in their person-centered service plan.

Response: We believe the regulations include these requirements.

Comment: One commenter indicated that it is not clear if ''provider'' means agent, attendant or something else.

Response: For purposes of CFC, provider means any individual or entity providing a CFC service and/or support.

Comment: One commenter indicated that the statute calls for ''consumer-controlled'' services, regardless of the model utilized. The methods for adhering to this philosophy are clear with the self-directed model, but less clear within the agency-provider model.

Response: We would like to clarify that the agency-provider model (which States could choose to implement through a traditional agency model and/or an agency-with-choice model) also adheres to the philosophy of ''consumer-controlled.'' Under this model, individuals retain the ability to select, dismiss, and manage their attendant care provider.

Comment: A few commenters recommended that the rule ensure that the scope and authority it provides for the consumer's ''hiring and firing'' of the attendant care provider are complementary, appropriate and in sync with the agency's business and employment model, all applicable agency regulations, and basic employee protections. The regulation should include a clear delineation of the roles and responsibilities of the consumer and the agency under this model.

Response: We do not believe it is necessary to include such specificity in the regulation, as it will vary by service delivery model and should be developed by the State. We believe there are sufficient requirements in the regulation to ensure all parties understand their basic roles and responsibilities. We also reaffirm that the individual's ability to ''fire'' their attendant care provider in no way affects the attendant care provider's employment status with the agency. We reiterate that we have replaced references to ''hire'' and ''fire'' with ''select'' and ''dismiss.''

Comment: One commenter indicated that the agency service model can ''muddy the water'' for self-direction. The commenter recommends a consulting system, where an individual can receive any assistance needed to perform employer duties, such as hiring, training, and paperwork.

Response: We agree with the commenter's suggestion that individuals receive assistance needed to perform employer duties and believe these protections are included in the Support System section. Therefore, we have revised the Support System requirements at § 441.555 to apply to all individuals receiving CFC regardless of the service delivery model. We describe these revisions further in § 441.555.

Comment: Many commenters supported the provision in the Person-Centered Service Plan section of CFC that required that the Plan ''be directly integrated into self-direction where individual budgets are used'', but noted that it was unclear why the use of service budgets across all models is not assumed, given the language proposed in the section, ''Service Budget Requirements'' (§ 441.560). The commenters supported the use of service budgets in all models (since such a process ensures transparency and allows participants to have meaningful control over their services). The commenters requested that CMS reconsider the proposal for a separate section, ''Service Plan Requirements for Self-Directed Model with Service Budget'' (§ 441.550), as the Person-Centered Service Plan section should address the requirements for assuring true participant direction, regardless of the model chosen. The commenters pointed out that this is consistent with the expectation set forth by the CFC statute requiring CFC be ''consumer-controlled,'' regardless of the models chosen. The commenters added that while they recognize that basic elements of the person-centered service plan may be implemented differently based on the model, there should be core expectations for assuring participant direction across the models, and that models should be chosen based on appropriateness for the State, not based on presumptions relative to cost associated with fewer or less requirements.

Response: Every individual participating in CFC is expected to have a person-centered service plan that is based on an assessment of functional need regardless of the service delivery model available in the State. The service plan requirements for the self-directed model with service budget include the additional requirements that must be met when an individual is directing services through this model. We do not agree that service budgets should be a component of every service delivery model, as service budgets are not used in the agency-provider model.

Comment: We received many comments requesting that the regulation specify the various types of service delivery models that may be included under the ''other'' category. One commenter requested the regulations not restrict the statute's open-ended ''other'' category to only those models that feature a service budget component. A few commenters requested the regulation clarify that a collective bargaining model, which provides consumers the ability to select, direct and dismiss their own caregiver, while giving States the ability establish work-force wide compensation standards is an acceptable ''other model.'' Many commenters requested the CFC rules be designed so that all States with public authorities can fully participate in all aspects of CFC without undermining their successful policy approaches for expanding and stabilizing the workforce available to these consumers. In particular, the commenters requested that the regulation clarify that compensation setting and other workforce-related activities by the State be consistent with all allowable service models under CFC. The commenters indicated that difficulties finding and retaining quality home care attendant care providers are among the significant impediments to the expansion of attendant care programs, and CMS should ensure that the CFC regulation does not undermine these State activities but encourages such activities.

Response: We do not believe it is necessary to specify in regulation every type of service delivery model that exists, as we do not believe we would be able to capture them all. States wishing to utilize ''other models'', as defined in § 441.505, would need to include a description of the proposed service delivery model in their CFC SPA. We will discuss these models with the State, and a determination will be made as to whether it is an appropriate service delivery model for CFC.

We are taking this opportunity to add a new paragraph (c), to indicate that States have the ability to propose an alternative service delivery model not envisioned in this regulation. Such a model would be described in the State's CFC SPA, and approved by CMS.

Comment: One commenter requested the regulation be amended to add a provision that enables States to take on responsibility for building a self-directed workforce sufficient to meet the goals of the program by ensuring adequate compensation for direct care attendant care providers, establishing a consumer workforce for direct care attendant care providers, and implementing data systems to monitor the direct care attendant care providers.

Response: We do not believe it is within the scope of this regulation to mandate such activities. We believe that States have the ability to implement such requirements and should discuss them with the Development and Implementation Council.

Comment: One commenter is very appreciative of the broad language allowing individuals to choose their

attendant, establish additional cultural competency requirements, and train attendants to their specific cultural competency requirements. The commenter expressed that this flexibility is particularly important to ensuring service provision to Lesbian, Gay, Bisexual and Transgender (LGBT) individuals, especially older LGBT adults and people of color.

Response: We appreciate the commenter's support.

Comment: One commenter requested we clarify whether CMS perceives self-direction delivery models approved under different Federal authorities to be vulnerable to allegations of inequitable access under provisions of the Americans with Disabilities Act.

Response: The Americans with Disabilities Act requires that individuals with disabilities be given the ability to receive their long-term care services and supports in the most integrated setting appropriate to their needs. We believe that Medicaid authorities allowing for self-direction of services and supports do not conflict with this mandate, as self-direction is a service delivery model, and does not prevent the provision of additional services, through Medicaid or other authorities, that may be necessary for a State to comply with the Americans with Disabilities Act.

Comment: One commenter requested that the regulation clarify whether a State may select a self-direction model under the authority of section 1915(k) of the Act that differs from the State's existing self-direction delivery models under HCBS 1915(c) waivers.

Response: While there are many similarities between the section 1915(k) authority and the self-direction delivery models under the section 1915(c) authority, these are separate authorities with different requirements. States may implement different self-direction models under sections 1915(c) and 1915(k) of the Act, as long as all program requirements are met.

Comment: One commenter indicated that it is unclear if the direct cash model is intended to be a stand-alone model or an option within the financial management entity.

Response: Section 441.545(b)(1) requires a State to make financial management services available to all individuals with a service budget. States can separately choose to allow cash disbursement to individuals self-directing CFC services. Individuals using the direct cash option have the choice of using the financial management entity for some or all of the relevant functions.

Comment: One commenter recommended the regulation specify when FFP is drawn down under the direct cash option and how unexpended portions of a cash disbursement should be treated.

Response: Cash disbursement is given prospectively. States would report expenditures for CFC services on the CMS 64 form based on this prospective disbursement. States may determine how to account for unexpended portions of cash disbursements. Based on past experience, we know that some States recoup unexpended funds; others allow beneficiaries to carry over unexpended funds into subsequent months.

Comment: One commenter requested clarification on the requirement to comply with Internal Revenue Service rules contained under each service model. The commenter also requested clarification on how these paragraphs relate to the requirements in the State assurance provisions in § 441.570. The commenter suggested the regulations be clarified to ensure that the requirements of § 441.570 apply to each of the service models listed in § 441.545, as required by the statute.

Response: While the language pertaining to meeting IRS requirements may seem duplicative, the entity responsible for ensuring the requirement is met differs depending on the service delivery model used, and whether an individual is utilizing financial management activities. We believe the regulation is clear that requirements under the State Assurance sections apply to all service delivery models.

Comment: We received several comments supporting the inclusion of a financial management entity and the specific requirements for the service.

Response: We appreciate the commenters' support.

Comment: One commenter indicated that given the participant direction requirement of CFC, it may be important for CMS to consider whether or not a financial management entity could also be used within an Agency with Choice and other agency-provider models. The commenter added that the regulation does not provide specificity as to whether the financial management entity would operate on behalf of an individual who would be the employer of his or her attendants, or if a financial management entity could be an Agency with Choice, wherein the agency is the official employer of attendant care providers who provide service to participants.

Response: It is unclear how a financial management entity would be utilized in an agency-provider model. However, we would be willing to discuss such a proposal with States.

Comment: Two commenters suggested the regulation require States to offer more than one choice of financial management entity, and recommended the term ''entity'' be changed to ''entities.''

Response: Section 1915(k) of the Act does not provide the authority to require States to provide more than one choice of financial management entity, as this is an administrative function that may be completed by the State or a vendor organization. However, the statute does not prohibit States from having more than one financial management entity if they choose to. We believe offering more than one entity is congruent with the philosophy of consumer choice and encourage States to consider allowing more than one financial management entity.

Comment: One commenter recommended that § 441.545(b)(1)(iii) be amended to say ''separately track budget funds and expenditures for each individual.'' The commenter believes this revision is necessary because States may interpret ''separate account'' to mean ''separate bank account'' which is an overly complex, costly and unnecessary approach to managing an individual budget.

Response: The intent of this provision is to eliminate the possibility of commingling of individuals' budget funds. We have revised the rule to incorporate the suggested language and also added the requirement for the financial management entity (FME) to separately maintain budget funds. Additionally, we have revised paragraph (b)(vi) to clarify that the FME is required to provide periodic reports of expenditures to the individual and State.

Comment: One commenter suggested revising § 441.545(b)(2)(I) to also require filing and reporting FICA, FUTA and State unemployment taxes.

Response: We believe the regulation already specifies these functions, as we interpret ''compliance with'' to encompass filing and reporting. However, we are taking this opportunity to add ''and State employment and taxation authorities'' after requiring compliance with all applicable requirements of the IRS.

Comment: One commenter recommended that communications between the FME and the individual occur at least monthly.

Response: We believe the frequency of communication between the FME and the individual should be established by the State and should be based upon the level of assistance needed and provided.

Comment: One commenter wanted clarification as to whether the cost of the FME is considered a service cost rather than an administrative cost. The commenter also wanted to know if this service may be included in an individual's service budget.

Response: Consistent with other authorities including services provided by a financial management entity, this is considered an administrative function and may not be included in the individual service budget.

Comment: One commenter suggested the regulation should recognize fiscal intermediaries and include language that those entities that have been approved to serve a similar role under a State program should be automatically approved or allowed a streamlined approval process to provide similar services under CFC.

Response: Section 441.545 sets forth the minimum mandatory functions that must be performed by the FME. We recognize that States may interpret ''fiscal intermediaries'' differently. Additionally, we do not believe that fiscal intermediaries are synonymous with fiscal management activities. Therefore, we do not believe it is appropriate to list fiscal intermediaries in the regulation; however, we note they could provide the functions set forth in § 441.545, as determined by the State.

Comment: One commenter recommended the regulation clarify whether FME activities must be provided if a State does not elect to offer direct cash, vouchers, or permissible purchases.

Response: Section 441.545(b)(1) requires a State to make financial management activities available to all individuals with a service budget, including when the direct cash option is used. We are modifying paragraph (b)(3) to clarify that the requirements at § 441.545(b)(2)(i) through (iv) also apply to vouchers. Accordingly, we are removing ''If the cash option is the only model offered by the State for Community First Choice'' and ''services under the cash option'' from paragraph (b)(2)(iv) as we want to be clear that this provision applies to both direct cash and vouchers. States only implementing CFC through an agency-provider model would not need to provide FME activities.

Comment: One commenter recommended that a financial management entity be available for all self-directed model options. In such cases, the role of the financial management entity within each of the models would need to be clarified.

Response: Section 441.545(b)(1) requires a State to make financial management activities available to all individuals with a service budget. States can separately choose to allow cash disbursement or vouchers to individuals self-directing CFC services. Individuals using the direct cash option have the choice of using the financial management entity for some or all of the relevant functions. We believe these requirements ensure sufficient access to financial management entities.

Comment: One commenter stated that education on the responsibilities of managing cash when an FME is not used is key. Specifically, States and individuals should be educated on the risks associated with not using a financial management entity and the consequences of mismanaging the duties required.

Response: We agree with the commenter and believe the requirements under § 441.555, Support System, will provide individuals with the necessary education.

Comment: One commenter recommended the regulatory citations for service models be reorganized so that all the information pertinent to the agency model is together and the self-direction requirements are all together.

Response: As indicated earlier, we have revised the Support System language at § 441.555 to indicate that it applies to all service delivery models. We believe this addresses this commenter's suggestion.

Upon consideration of public comments received, we are finalizing § 441.545 with revision, revising paragraph (a) to refer to the ''agency-provider model'', amending paragraph (a)(1) to align with the revised agency-provider model definition, amending paragraph (b)(1)(iii) to say ''separately track budget funds and expenditures for each individual'', amending paragraph (b)(1)(vi) to require the FME to provide periodic reports of expenditures to the individual and to the State, amending paragraph (b)(2)(i) to specify compliance with State employment and taxation authorities, removing ''If cash option is the only model offered by the State for Community First Choice'' and ''services under the cash option'' from (b)(2)(iv), modifying paragraph (b)(3) to make the requirements at § 441.545(b)(2)(i) through (iv) apply to vouchers, and adding a new paragraph (c) to permit States to propose other service delivery models.

L. Service Plan Requirements for Self-Directed Model With Service Budget (§ 441.550)

We proposed that the self-directed service plan requirements convey authority to the individual to recruit, hire (including specifying attendant care provider qualifications), fire, supervise, and manage attendant care providers in the provision of CFC services and supports. In addition, we proposed that the service plan describe the ability of the individual to determine the amount paid for a service, support, or item, as well as the ability to review and approve provider invoices.

Comment: Many commenters offered general support of the self-direction model with service budget. The commenters believe the intent of this section is to give people maximum control over their services, recognizing that giving individuals the authority to manage their service provider is integral for self direction.

Response: We appreciate the commenters' support.

Comment: One commenter requested more specificity regarding the requirement for individuals to evaluate an attendant care provider's performance found at § 441.550(d)(4). Specifically, the commenter suggests that we explain the purpose of the evaluation, who will deliver and receive the evaluations, and what actions are to be taken in response to the evaluations. This commenter also questioned whether evaluations are required if the recipient is the spouse of the provider, or a minor with a parent provider. Alternatively, one commenter offered support of the evaluation requirement, but requested the rule not allow States to impose formal or standard evaluation processes. The commenter believes that the method for evaluation should be the decision of the employer.

Response: Individuals receiving services under the self-directed model with service budget have the ability to supervise and manage attendant care providers providing services to them. We expect individuals to evaluate the quality and adequacy of services the attendant care provider provides as part of their supervision responsibilities. We do not expect that the evaluation has to be a formal process, nor is it the responsibility of the State to impose a standard evaluation process. The purpose of the evaluation is to provide the individual with the opportunity to provide feedback to the attendant care provider with regard to the provision of services. When the individual has a representative, the representative would be expected to conduct the evaluation.

Comment: Many commenters expressed support of the self-directed service plan requirements. The commenters believe the requirements are essential to meaningful self-directed models of care and encourage their inclusion in the final regulation.

Response: We appreciate the commenters' support.

Comment: One commenter requested we clarify whether the State is allowed to set parameters or limits on any of the following: Annual service budget amount, the number of paid attendant care hours received from any single family member within a time period (per week, month, etc), or minimum wages.

Response: CFC is an optional State plan service. As such, States may set limits on the amount duration and scope of CFC benefits, as long these limits comply with the CFC specific requirements set forth in statute and regulation. We will be reviewing all State proposals to implement CFC under the State plan. Our review includes a review of any proposed limitations.

Comment: Many commenters expressed concern with individuals determining the amount to pay for a service, support, or item. Many commenters indicated that States should be allowed to establish reimbursement rates and methodologies including the use of collective bargaining as a way to establish consistent reimbursement rates for services and supports, while still allowing the individual to determine the amount, duration, and scope of the services provided. One commenter recommended the regulation be amended to specify that when an individual is determining the amount to pay for a service, support or item, the individual's decision should be consistent with existing State laws and regulations governing compensation standards. Another commenter indicated that while individuals should appropriately review invoices, requiring that individuals determine payment for attendant services (hourly rate or wages) is not a necessary component of self-direction and could undermine States' efforts to build their long-term services attendant workforce through regulating compensation standards for attendants/direct care attendant care providers. Another commenter requests the elimination of the requirement that individuals in a self-directed model with service budget determine the amount paid for a service, support, or item.

Response: We understand the concern expressed by these commenters. The intent of CFC is to provide individuals with the opportunity to maximize their independence and control of the home and community-based attendant services and supports. An integral component of the self-directed model with service budget is the ability of the individual to determine the amount paid for services. However, this flexibility should not conflict with responsibilities for setting compensation according to State and Federal requirements. Therefore, we are modifying § 440.550(e) to specify that determining the amount to pay for services should be ''in accordance with State and Federal compensation requirements''.

Comment: One commenter expressed concern related to the requirement that ''the budget methodology include calculations of the expected costs of CFC services and supports if those services and supports were not self-directed.'' The commenter believes States will find this provision challenging since it asks them to compare two separate models that are not necessarily directly comparable.

Response: We do not agree with the commenter. We expect the State to obtain this information based on an analysis of historical costs and utilization and other factors that are likely to affect costs.

Comment: One commenter requested that we provide clarification around budgeting requirements, specifically whether individual budgeting is required.

Response: The service budgeting requirements are used when individuals are receiving services under the self-directed model with a service budget. The budget is developed based on an individual's assessment of functional need and the services specified in the person-centered service plan.

Comment: The commenter indicated that the proposed rule gives the appearance that the self-directed model is more costly and onerous to implement than agency-provider models.

Response: CMS encourages States to avail themselves of a variety of service models to implement CFC. We acknowledge that agency-provider models are more straightforward to implement, and likely are already in existence in most States. However, we fully recognize the merits of self-directed service models, and will work with any State interested in adopting a self-directed service model for CFC.

Comment: One commenter recommended that the rule be revised to add language stating that the attendant care provider's duties are identified in the approved self-directed service plan and within the scope of CFC services.

Response: It is the person-centered service plan, required for each individual receiving CFC services and supports, regardless of service delivery model, that would convey the duties of the attendant care provider in accordance with the scope of CFC. We do not believe that it is necessary to amend this section of the rule to additionally make these points.

Comment: One commenter stated that with regard to ''reviewing and approving provider invoices or timesheets'' attendant care providers must utilize timesheets per the Fair Labor Standards Act (rather than invoices). The commenter recommended revising the rule to say ''Reviewing and approving provider payment requests.''

Response: We agree with the commenter and have revised the rule at § 441.550(f) to say ''reviewing and approving provider payment requests.''

Upon consideration of the public comments received, we are finalizing § 441.550 with revision, modifying paragraph (e) to specify that determining the amount paid for services should be ''in accordance with State and Federal compensation requirements'', modifying paragraph (f) to specify ''reviewing and approving provider payment requests.'' As noted in the response to comments received in the Definitions section, we modified paragraphs (a) and (b) to use the terms ''dismiss'' and ''select.''

M. Support System (§ 441.555)

Based on our experience with self-direction programs, we are aware that the support system provided by the State is a critical element of the service delivery model. Therefore, to maintain consistency and to reflect our policy relating to self-direction, in § 441.555 we proposed the requirement that the State have in place a support system to facilitate successful self-direction by the individual. While we did not prescribe the way States are to design their support system, to allow flexibility, based on our experience, we included a minimum list of activities for which individuals may need information, counseling, training, or assistance, but States may offer additional activities. Generally, the activities requiring support include participant rights information and how the self-directed model of service delivery operates.

Comment: We received several comments providing overall support for the requirements set forth at § 451.555. One commenter strongly endorsed this section as a critical component to ensuring consumers achieve maximum independence.

Response: We appreciate the commenters' support.

Comment: A few commenters suggested that we extend paragraph (b)(1) to require communication in a linguistically and culturally appropriate

manner, with accommodations for all functional limitations, including the need for alternative formats.

Response: For a State to comply with this requirement, it is an expectation that the State will assure that information is provided to individuals in a manner that is culturally sensitive and at a level most appropriate for the individual to understand the information. This includes translator services as needed for non-English speaking participants and interpreter services and accommodations for individuals with sight or hearing impairments. We agree with the commenter's recommendation and have revised paragraph (b)(1) to include the following language: ''To ensure that the information is communicated in an accessible manner, information should be communicated in plain language and needed auxiliary aids and services should be provided.''

Comment: One commenter requested that we provide guidance on all conditions that are required for person-centered planning with a service budget to better determine the cost of participating.

Response: The requirements for person-centered planning are the same regardless of the service delivery model and are described at § 441.540. Additionally, the requirements set forth at § 441.560 must be met for individuals receiving services through the self-directed model with a service budget.

Comment: One commenter indicated that, with regard to risk management agreements required under paragraph § 441.555(b)(2)(xi), the regulation does not address whether criminal history record checks are permitted to help mitigate risk. The commenter questioned whether record or background checks would be allowed if the participant recruits, hires, trains and fires attendant care providers. The commenter requested CMS to clarify whether States are required to allow participants to hire someone who presents a risk of harm.

Response: Following the practice of other programs offering self-direction, we believe that criminal background checks of attendants should be left to the discretion of the States. However, we agree that this expectation was not clear in the proposed regulation.

While we will not prescribe the tools or instruments States should use when developing risk management agreements, we are revising § 441.555 to require States to specify any tools or instrument it uses to mitigate identified risks. In this section, we further add that if States make criminal or background checks a requirement, States would bear the expense of the background checks it performs on behalf of individuals participating in CFC.

Additionally, we believe that the individual must retain the authority to decide who to hire to provide personal attendant services, as this decision is inherent in self-direction, as long as the choice adheres to section 1903(i) of the Act that Medicaid payment shall not be made for items or services furnished by individuals or entities excluded from participating in the Medicaid Program.

Comment: One commenter requested that we consider giving States the option to make self-directed training mandatory to ensure that individuals have mastered the skills needed to manage the service budget.

Response: We do not agree with the commenter. Section 441.555(b) requires States to provide or arrange for the provision of appropriate information, counseling, training and assistance to ensure that an individual is able to manage the services and budget. These supports are to be available to the individual on a continuous basis until such time as it has been demonstrated that after additional counseling, information, training or assistance the individual cannot effectively manage self-direction responsibilities.

Furthermore, § 451.555(b)(2)(v) requires there to be a discussion about the risks and responsibilities of self-direction. We believe these protections are sufficient to facilitate successful provision of services and supports via a self-directed model with service budget.

Comment: One commenter asked if the entity providing the support system could also be the financial management entity.

Response: Such an arrangement would be appropriate, as long as the conflict of interest protections originally proposed in § 441.540(c)(4)(iv), and now relocated to this section, are met.

Comment: One commenter requested clarification as to whether the State's obligation is limited to providing information about existing advocacy systems or if there is an expectation that States actively invest in fostering development of advocacy systems for the CFC option.

Response: It is an expectation that States would provide information about existing advocacy systems. We are not mandating the establishment of additional systems specific to the CFC program.

Comment: One commenter recommends that paragraph (b)(2)(vii) be revised as ''Individual rights, including appeal rights.''

Response: We agree with the commenter and have revised the rule at § 441.555(b)(2)(vii) to say ''individual rights, including appeal rights.''

Comment: One commenter expressed concern that the regulatory language requiring States to provide assistance to define goals, needs and preferences in paragraph (b)(2)(ix) exceeds current program limits and could overpower existing systems. The commenter recommends States have the ability to define this within current program abilities and limits.

Response: We do not agree with the commenter that States be given the ability to define support activities within the States' current program abilities. While similar to existing authorities, CFC is not the same. We are clarifying that this requirement relates to the provision of CFC. Therefore we have revised the rule at § 441.555(b)(2)(ix) to say ''Defining goals, needs and preferences of Community First Choice services and supports.''

Comment: Several commenters expressed concern that the regulation only applies supports to the self-directed model population. The commenters indicated that some of these supports may also be relevant and important to individuals participating in the agency model. The commenter recommends extending the relevant support requirements to that population.

Response: We recognize that although participants may not control an individualized budget in the agency-provider model, participants may manage their services to the maximum extent possible. We agree with the commenters that the supports provided under this section apply to all service delivery models, not just the self-direction model with a service budget. Therefore, we have revised the rule to include language that applies this requirement to all service delivery models.

Comment: We received many comments suggesting States be encouraged to develop attendant care provider registries as part of the additional activities they undertake to support a self-directed model of service delivery. A few commenters expressed concern that individuals who do not choose to receive services through an agency may have difficulty locating direct-care attendant care providers outside of their immediate network of family members and contacts. The commenters indicated that a ''matching service registry'' is a labor market intermediary that creates a dynamic platform for matching supply and demand by allowing individuals to tap into an up-to-date bank of available

attendant care providers. The commenters also indicated that the attendant care providers can also alert participants of their availability for employment. These commenters recommended the regulatory language be revised to require States to establish a labor market intermediary such as a matching service registry to assist participants with identifying and accessing independent providers.

Response: We believe States should have the flexibility to design a system that would best address workforce issues and ensure access to providers in their States. We support State activity to implement systems that will improve an individual's access to attendants. However we believe it is beyond the scope of the regulation to mandate that States implement attendant care provider registries.

Comment: A few commenters suggest we add ''peer supports'' to the list of included support activities. Another commenter suggested that the regulation promote the use of local, peer-based and consumer controlled providers so beneficiaries have maximum access to their fiscal agent.

Response: We do not agree with the commenters that ''peer support'' services should be added to the list of support activities. For purposes of Medicaid, peer support services are an evidence-based mental health model of care that assists individuals with their recovery from mental illness and substance use disorders. We recognize that peer support is provided by specially trained individuals who are in recovery from mental illness and/or substance use services. As such, we believe it would create confusion to include ''peer supports'' as a CFC service.

Recognizing that individuals with experience in utilizing personal attendant services and supports could provide valuable assistance to individuals who desire to do the same, States could utilize individuals who were or are receiving such services in the implementation of the activities required under the Support System.

Comment: One commenter recommends deleting paragraph (b)(2)(xi), pertaining to risk management agreements. The commenter compares such agreements to managed risk agreements in assisted living facilities that are inappropriate and illegal to the extent that they purport to release a service provider from liability. The commenter indicated consumer law invalidates any agreement that would absolve a personal care provider from responsibility for his or her actions.

Response: We disagree with the commenter, as we do not believe the risk management agreement requirement absolves personal care providers from responsibility for his or her actions. We believe the purpose of the risk management agreement is to identify the risks that an individual is willing and able to assume, and the plan for how identified risks will be mitigated. The State must ensure that the risk management agreement is the result of discussion and negotiation among persons providing the support system functions, the individual, and others from whom the individual may seek guidance. This is a requirement under the person-centered service plan.

Comment: One commenter suggested that the regulation be revised at § 441.555(b)(2)(vi) to state ''The ability to freely choose from available home and community-based attendant providers, service delivery models and (if applicable) financial management entities.''

Response: We agree with the commenter, but must acknowledge that States have the choice of how many service delivery models to provide. Therefore we have revised § 441.555(b)(2)(vi) to state ''the ability to freely choose from available home and community-based attendant providers, available service delivery models and if applicable, financial management entities.''

Comment: One commenter requested that we clarify the vision for ensuring development of a conflict free support system, as alluded to in the preamble, in the service plan discussion. The commenter indicated the proposed rule contains no such language or guidance.

Response: The conflict free support system discussed in the preamble is operationalized by a State's adherence to the language proposed in § 441.540(c)(4), which has now been relocated to this section.

Comment: One commenter indicated that to avoid conflict with standard language referring to contracts, the word ''plan'' should be substituted for the word ''agreement'' in paragraph (b)(2)(xi): development of risk plans.

Response: We do not agree with the commenter's suggestion. We believe the use of the term ''agreement'' most accurately reflects that these strategies are the result of discussion and negotiation required under the person-centered plan development.

Comment: One commenter requested that the regulation include support system workforce competencies.

Response: We disagree with this suggestion, as we believe States should have the flexibility to determine the qualifications of the entities conducting the assessment of functional need and developing the person-centered service plan, provided all requirements of this regulation are met.

Comment: One commenter indicated that individuals may need ongoing education and guidance from the self-direction support system.

Response: We agree with the commenter, and believe that this ongoing support is provided for.

Upon consideration of the public comments received, we are finalizing § 441.555 with the following revisions:

- We are revising paragraph (b)(1) to include the following language: ''To ensure that the information is communicated in an accessible manner, information should be communicated in plain language and needed auxiliary aids and services should be provided.''
- We are adding a requirement at paragraph (b)(2)(xi) that States specify any tools or instruments it uses to mitigate identified risks, and adding that if States make criminal or background checks a requirement, States would bear the expense of the background checks it performs on behalf of individuals participating in CFC;
- We are revising paragraph (b)(2)(vii) to include ''individual rights, including appeal rights'';
- We are revising paragraph (b)(2)(ix) to state ''Defining goals, needs and preferences of CFC services'';
- We are revising the introduction to include language that applies this requirement to all service delivery models;
- We are revising paragraph (b)(2)(vi) to state ''the ability to freely choose from available home and community-based attendant providers, available service delivery models and if applicable, financial management entities.''
- We are adding a paragraph (c) to incorporate conflict of interest language proposed in § 441.540(c)(4).

N. Service Budget Requirements (§ 441.560)

We proposed to require that a service budget be developed and approved by the State and include specific items such as the specific dollar amount, how the individual is informed of the amount, and the procedures for how the individual may adjust the budget. We proposed that the budget methodology set forth by the State meet certain criteria, such as being objective and evidence based, be applied consistently to individuals in the program, and be included in the State plan. In addition, we proposed the budget methodology include calculations of the expected

costs of CFC services and supports if those services and supports were not self-directed. We proposed that States could place monetary or budgetary limits on self-directed CFC services and that if a State chose to do so, we proposed to require that the State have a process in place that describes the limits and the basis for the limits, any adjustments that will be allowed, and the basis for the adjustments, such as an individual's health and welfare. We proposed to require certain beneficiary safeguards in light of these possible limitations.

Comment: Many commenters offered their support for this requirement.

Response: We appreciate the commenters' support.

Comment: One commenter requested clarification around CMS' intent for anticipated safeguards, and whether it is limited to circumstances in which an individual's needs change.

Response: Our experience with self-direction indicated that at a minimum, a certain level of oversight by the State is necessary to help flag potential issues with the provision of services. We believe it is important that States have a system to oversee the expenditures being made by individuals self-directing their care. Premature depletion of the funds in a service budget could signal a health crisis which would require the State to immediately determine the health status of an individual and construct a new assessment. It could also signal misuse of funds, for which the State would need to take corrective action. Although there are general safeguard requirements outlined in the Support System section, the safeguard requirements in § 441.560 pertain specifically to resolving issues when the budgeted service amount is insufficient to meet the individual's needs.

Comment: One commenter requested more guidance in the regulation on the procedures the State must have in place to provide safeguards when the budgeted service amount is insufficient to meet the individual's needs.

Response: We appreciate the commenters' suggestions; however the specific safeguards are determined by the State. We will review the State's proposed safeguards during the review of their State plan amendment submitted to implement CFC.

Comment: One commenter suggested that the rule should require the State to explain and provide in writing the criteria used for determining an individual's service budget amount when the individual receives the final written service plan.

Response: Section 441.560(a)(2) requires the State to specify procedures for informing an individual of the amount of the service budget before the service plan is finalized. Additionally, paragraph (d) requires the State to have a method of notifying individuals of the amount of any limit that applies to CFC services and supports. To ensure individuals receive information in a manner in which they understand, we have revised § 441.560(d) to include the following language: ''Notice must be communicated in an accessible format, communicated in plain language, and needed auxiliary aids and services should be provided.''

Comment: One commenter wanted to know if a State must adhere to the required elements at § 441.560(a)(1), (a)(2), (a)(3)(i) and (a)(5) if the State does not elect to provide transition costs, direct cash, vouchers or permissible purchases.

Response: Any State allowing self-direction with a service budget must adhere to all requirements of the final regulation. To clarify the requirements as they relate to permissible services and supports, we are taking this opportunity to revise paragraph (a)(5) inserting ''other permissible services and supports as defined at § 441.520(b)'' after ''transition costs'' and removing the remaining language.

Comment: We received several comments requesting clarification with regard to a State's flexibility to establish service limits on the service budget. One commenter believes strongly that States should be allowed the flexibility to institute caps on hours of services in this section, especially in times of fiscal crisis or uncertainty. The commenter also believes States should not be required to provide all services relating to all needs identified through the needs assessment process as there are limited [financial] resources. Another commenter requested the regulation explicitly say if a State may set a per person service budget limit for the self-directed model.

Response: CFC is an optional State plan service and States have the flexibility to determine the amount, duration, and scope of the program, within the confines of statutory requirements. We provide clarification under the assessment of functional need section that although the assessment will identify all needs an individual has, the CFC program will only be responsible for the provision of services available under CFC. We believe it is necessary and appropriate for the individual to be referred to other Medicaid and non-Medicaid programs the individual may be eligible for, that will address the needs identified that are not available under CFC.

Comment: One commenter requested the provision of guidance to States on ensuring that when a budget is capped, there are methods to modify the budget allotment, especially in emergency situations.

Response: Section 441.560(b)(5) and (c) require States to have procedures to adjust limitations placed on CFC services and procedures to provide safeguards to individuals when the budgeted amount is insufficient to meet the individual's needs. These provisions allow States to modify the budget allotments in emergency situations.

Comment: One commenter recommends the regulation include appropriate safeguards to ensure that budgets are not arbitrarily reduced for an individual's self-directed services. Another commenter indicated it is not clear what ''safeguards'' are considered acceptable when the budgeted services amount is insufficient to meet the individual's needs. The service budget requirements should explicitly address what adjustments may be made, for example when the individual is at risk of an institutional placement because of budget limits. Another commenter indicated that individuals should be well-informed of the appeal process if they believe that a service budget cannot adequately meet their needs.

Response: Section 441.560(c) requires the State to have procedures in place that will provide safeguards to individuals when the budgeted service amount is insufficient to meet the individual's needs. The Support System set forth in § 441.555 requires individuals be informed of the process for changing the person-centered service plan. An individual is supposed to sign their plan only if they agree with it. If the individual does not agree with the service budget, it should be addressed at this time. Additionally, there are requirements for individuals to file an appeal, and as always, the standard Medicaid fair hearing appeal rights exist for individuals receiving CFC services.

Comment: One commenter indicated that the regulation should require that appeals be handled by entities not responsible for conducting the assessment or providing case management services.

Response: We agree appeals should be handled by an independent entity. Reconsiderations may be handled by the individuals responsible for conducting an assessment and facilitating the person-centered plan of care. However, if an individual is not satisfied with the service plan developed, including the amount of hours identified on the plan, an individual has the right to file an appeal. The individuals should file an

appeal following the State's appeal process.

Comment: One commenter requested the rule clarify the applicability of ''evidence based'' to a service budget allocation methodology, as referenced in paragraph (b)(1). Additionally, the commenter requests clarification as to whether the ''cost data'' invokes a relationship to historical Medicaid rates and corresponding expenditure costs, or if it CMS' expectation that ''cost'' is related to audited costs for providing services unrelated to historical reimbursement rates.

Response: By this, we mean that the method used by the State is based on an analysis of historical costs and utilization and other factors that are likely to affect costs.

Comment: One commenter requested that CMS clarify the test against which we will measure service budget allocation methodology to determine approval. This commenter asked if there is an expectation of actuarial soundness or some other rate setting standard against which the methodology will be judged.

Response: Verification of actuarial soundness will not be required. States are expected to provide a description of the methodology used to determine the individual's service budget amount. The methodology must take into account the cost of services if they were not self-directed. We would like to further clarify that we use the term ''cost'' to mean what it will cost the beneficiary to purchase the services, at either the fee-for-service rate or a beneficiary negotiated rate. We recognize the confusion the use of the terms ''allocation'' and ''cost'' in § 441.560(b)(1) have created, and therefore, we have revised the rule to remove the terms. Additionally, we have revised this section to remove redundant language.

Comment: One commenter requested clarification as to whether a State may set participation parameters, such that individuals may be prohibited from participating if the individual's choices around wage limits result in the service budget being insufficient to cover the assessed needs.

Response: Section 441.545(b)(2)(iii) requires that States make available a financial management entity to an individual who has demonstrated, after additional counseling information, training or assistance, that the individual cannot effectively manage the responsibilities of receiving a cash payment.

Comment: A few commenters noted an incorrect regulatory citation for the Medicaid fair hearing process.

Response: We have revised the rule to make this technical correction.

Comment: A few commenters suggested the regulation be revised at paragraph (b)(1) to require individuals to follow a compensation standard developed by the State under § 441.570. The commenters believe the States should include labor market data in their methodology for developing a participant service budget as a basis for setting adequate compensation standards for direct care services to support recruiting and retaining qualified providers.

Response: We do not agree with the commenter's suggestion because it would not support the requirement at § 441.550(e) granting individuals the authority to determine the amount paid for a service, support, or item.

Comment: Several commenters expressed support for the requirement § 441.560(e) that the service budget not restrict access to other medically necessary care and services furnished under the State plan.

Response: We appreciate the commenter's support.

Comment: One commenter requested that the service budget criterion be clear regarding what is permitted and prohibited. With regard to what is permitted, flexibility due to changing needs, priorities, or goals needs to be recognized.

Response: States must ensure the method of determining the budget allocation is objective and evidence based utilizing valid and reliable cost data. Additionally, the regulation requires that States have a process for adjusting any limits placed on the provision of CFC services.

Comment: One commenter indicated that safeguards for individuals to address budgeted amounts insufficient to meet consumer needs must be robust and timely.

Response: We agree with the commenter and will review the description of the State's safeguards through the State plan amendment process.

Comment: One commenter requests the regulation clarify if a State may set self-directed budgets at a level which assures that those using the self-directed service option will not exceed the amount of funding which would be spent under an agency-directed mode. The commenter indicated the necessity for fiscal neutrality, indicating that self-directed services in the State has led to budgets being reduced by a specific percentage to account for the fact that flexibility is likely to mean a person uses more of the funding allowed to care for them during the year. The commenter urges that any reductions or discounts be based on data and a transparent methodology.

Response: States determine the methodology through which the service budgets are developed. As required in paragraph (b)(1), this methodology must be objective and evidence-based, using valid, reliable cost data.

Comment: One commenter recommends revising paragraph (a)(3)(i) to indicate that ''the procedure for an individual to freely adjust amounts allocated to specific services and supports within the approved service budget.''

Response: We acknowledge the clarity this revision brings, and are revising the regulation to incorporate it.

Comment: One commenter recommends health and safety be added to paragraph (c).

Response: We do not believe that such a clarification is necessary, as the term ''safeguards'' is sufficiently broad to encompass health and safety protections.

Upon consideration of public comments received, we are finalizing § 441.560 with revision to paragraph (a)(5) inserting ''other permissible services and supports as defined at § 441.520(b)'' after ''transition costs'' and removing the remaining language, correcting the citation of the fair hearings process in paragraph (a)(6), incorporating the commenter's suggested revision to paragraph (a)(3)(i), removing the terms ''allocation'' and ''cost'' from paragraph (b)(1), revising paragraph (d) to inserting ''Notice must be communicated in an accessible format, communicated in plain language, and needed auxiliary aids and services should be provided'' and removing redundant language.

O. Provider Qualifications (§ 441.565)

We proposed to require that States provide assurances that necessary safeguards have been taken to protect the health and welfare of CFC recipients. States must define qualifications for providers of attendant services and supports under the agency-provider model. We proposed that an individual has the option to permit family members, or any other individuals to provide CFC services and supports identified in service plan as long as they meet the qualifications to provide such services and supports. We also proposed that individuals retain the right to train their attendant care providers in the specific areas of attendant services and supports needed by the individual, and that individuals also retain the right to establish

additional staff qualifications based on their needs and preferences.

Comment: One commenter supported the requirement that States take necessary safeguards to protect the ''health and welfare'' of enrollees.

Response: We recognize that the protection of health and safety requires program-wide consideration and oversight; we are therefore taking this opportunity to move this assurance from the Provider Qualifications section to the State Assurances section. Additionally, we are adding language to the State Assurance section to make it clear that this includes assuring the State's adherence to section 1903(i)(2) of the Act that Medicaid payment shall not be made for items or services furnished by individuals or entities excluded from participating in the Medicaid Program.

Comment: One commenter expressed concern that the regulatory language at § 441.565(c) does not state the statutory requirement that services be provided by an individual who is qualified. The commenter recommended the regulatory language be revised to explicitly state this.

Response: The requirements at § 441.565(b) requiring the development of provider qualifications includes the requirement that providers must be qualified. Therefore, we are not revising the regulatory language to explicitly state this.

Comment: One commenter requested that we define the term ''qualified.'' A few commenters requested that the regulation go beyond requiring States to define provider qualifications, by also establishing core qualifications for States to build around. The commenters believe the core qualifications should be applied uniformly to home care agencies, as well as the self-directed model with service budget. The commenters indicated that at a minimum, attendant care providers should be subject to criminal background checks, a minimum set of basic caregiver training standards, and training on mandated ''abuse and neglect'' reporting. Several commenters requested that the regulation require States to adopt national credentialing standards for personal assistance attendant care providers. One commenter requested that we confirm that the individual's right to establish additional staff qualifications does not interfere with a State's ability to set provider qualifications including those necessary to ensure the individual's health and welfare. A few commenters expressed concern that the State would not define the qualifications of providers who are not part of an agency, such as family members and friends. These commenters believed that there should be minimum safeguards that States must meet in establishing provider qualifications for services provided under both an agency model and self-directed model. These standards should include caregiver training and competencies, health assessments, quality assurance systems and others.

Response: Consistent with other Medicaid authorities providing personal assistant services, States have the flexibility to establish the minimum provider qualifications for providers of services provided under the agency-provider model. A description of provider qualifications will be reviewed with each State's proposal to implement CFC. Additionally, individuals receiving services under the agency-provider model retain the right to establish additional staff qualifications based on the individual's needs and preferences. We agree that these additional qualifications should not interfere with the State's ability to protect the health and welfare of individuals receiving CFC services and supports.

We appreciate the commenters' suggestions for possible safeguards States could employ to protect the health and welfare of participants receiving CFC services. While we agree with the suggestions, we believe that mandating specific safeguards will not allow States the flexibility to utilize procedures that have proven successful. In addition, we do not believe it is necessary or appropriate to establish at the Federal or State level provider qualifications for individuals delivering services via the self-directed model with service budget. A hallmark of self-directed models is the ability of the individual receiving services to define the qualifications of those furnishing services. The only exceptions in CFC is the need to adhere to requirements of State Practice Acts when determining the ability of ''health-related tasks'' to be delegated by licensed healthcare professionals and adherence to section 1903(i) of the Act prohibiting payment for items or services furnished by individuals or entities excluded from participating in the Medicaid Program.

We believe requiring State assurance of the provision of necessary safeguards is sufficient; however, as indicated above, we are moving this required assurance and adding language requiring adherence to section 1903(i) of the Act to § 441.570, State Assurances.

Comment: One commenter expressed concern that providers with a history of defrauding government programs need to be avoided in the selection process.

Response: We agree with the commenters' concerns and expect States to implement safeguards to prevent such individuals or entities from providing CFC services.

Comment: Several commenters requested the regulation require that all employers comply with basic attendant care providers rights such as minimum wage, tax withholding and provision of attendant care providers compensation.

Response: Except for the mandatory flexibility within the self-directed model with service budget for individuals to retain the authority to determine the amount to be paid for a service, we believe the commenters' suggestions are addressed in the requirements set forth in §§ 441.545 and 441.570. Additionally, we have modified § 441.570 State Assurances to add a paragraph (d)(5) to say ''any other employment or tax related requirements.''

Comment: One commenter asked if the personal care attendant is considered to be the provider. If the personal care attendants are considered to be providers, the commenter wanted to know if the providers are subject to the screening requirements under § 455.000.

Response: Based on the commenter's statement we are unable to determine if the commenter is referencing the program integrity requirements found at 42 CFR Part 455 or if this is an error as the proposed rule for CFC did not contain a § 455.000. However, we note that § 400.203(1) defines provider as either of the following: (1) For the fee-for-service program, any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency; or (2) For the managed care program, any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services. To the extent personal care attendants meet one of the above definitions, they would be considered Medicaid providers and subject the program integrity requirements found at 42 CFR part 455. We acknowledge that the inherent flexibility of who can provide services under a self-directed service model, may result in a personal care attendant not meeting the definition of providers found in § 400.203. We believe the program safeguards included throughout this regulation, such as the activities required under the support system, provider qualifications, State assurances, and establishing a quality assurance system that evaluates quality of care and develops and implements mechanisms for discovery and

remediation and quality improvement activities, will ensure individuals receiving services under this benefit are afforded protections of health, safety and program integrity in circumstances in which the personal care attendant does not fall within the regulatory definition of a provider. Additionally, a State must adhere to the provisions of section 1902(a)(27) of the Act, and Federal regulations § 431.107, governing provider agreements.

Comment: We received many comments supporting the requirement that individuals have the option to permit family members or other individuals of their choosing to provide attendant services and supports. We also received many comments supporting the requirement that individuals set their own qualifications for family members or individuals they recruit.

Response: We appreciate the commenter's support.

Comment: One commenter believes services are best provided by public or not-for-profit entities. The commenter believes that if for-profit driven entities are used, the contracts should specify the profit and make sure the rest is spent for the consumers' benefit. The commenter also expressed concern that services may be cut to boost profits.

Response: The statute does not include language to exclude for-profit entities from providing CFC services if they are qualified to do so. We believe the regulation provides sufficient safeguards to thwart inappropriate behavior that could occur with any provider.

Comment: One commenter stated consumer voices need to be heard regarding the selection for providers.

Response: We believe that self-direction and consumer choice are supported throughout the rule. Regardless of the service delivery model, the individuals have control over who is providing services to them. As specified in the statute, and implemented in provisions of the rule, individuals have control to select and manage services. The Development and Implementation Council, which requires its membership composition include a majority of elderly individuals, individuals with disabilities, and their representatives, is an excellent forum to discuss important issues such as service delivery options and provider types to be included in the State's CFC program.

Comment: We received many comments requesting clarification regarding whether individuals are allowed to hire family members to provide CFC services. The commenters requested that participants be allowed maximum flexibility to hire any individual capable of providing services and supports, including legally responsible relatives. Many commenters requested that the regulatory language at § 441.565(b) state that individuals have the option to have family members provide services and supports whether the State allows family members to be a attendant care provider or not.

Response: Section 1915(k)(1)(A)(iv)(III) of the Act requires that services are provided by any individual who is qualified to provide such services, including family members. We interpret this to mean that under the self-directed model with service budget, States must allow individuals to hire family members qualified to provide any service identified on the person-centered service plan. Recognizing States have the option of only offering the agency-provider model, we expect that this model would allow an individual to exercise maximum control over who provides services to them. While we cannot mandate agencies to employ individuals' family members for the purpose of providing CFC services, we strongly encourage agencies to consider employing such individuals if they meet the established qualifications.

Comment: Many commenters requested the regulatory language at § 441.565(c) be revised to state that individuals or their representatives have the right to train attendant care providers to perform any tasks within an approved service plan without regard to State licensure or certification requirements.

Response: We interpret this provision to allow individuals to train providers to perform non-skilled activities tailored to the specific needs of the individual; therefore, we are not revising the regulatory language. However, for reimbursement to be made for services that meet the definition of a health-related task, those services must be delegated within the State's Practice Act for the practitioner delegating the service.

Comment: One commenter asked for confirmation on the applicability of 42 CFR 440.167 that prohibits FFP for payments to legally responsible individuals for the provision of State plan personal care services, unless those services meet the criteria as being ''extraordinary'' care.

Response: The regulatory requirements for State Plan personal care services do not apply to CFC, which has its own statutory and regulatory requirements. We acknowledge the confusion created by including in the same section State flexibilities in determining provider qualifications under agency-provider models and individual flexibilities in determining provider qualifications under self-directed models with service budgets. Such confusion was evident in many comments received. To that end, we are revising this section to indicate that paragraph (a) applies to all service delivery models, and paragraph (b) applies only to agency models and paragraph (c) applies only to self-directed models with a service budget. Paragraph (d) applies to ''other'' models defined by the State.

Comment: Many commenters expressed concern that the provider qualifications established by the State could threaten the ability of individuals to staff their support needs. The commenters suggested there be an exception process if there is no satisfactory attendant care provider available and the consumer makes a voluntary affirmative choice to waive the provider qualifications requirement. The commenters suggested that the regulation define ''voluntary affirmative choice'' in a way that will allow informed and sophisticated consumers to have the default requirement for a provider qualifications waiver, while not allowing this authority to be abused. For example, an agency should not be able to offer an unsuspecting consumer a waiver to ''get a faster attendant placement.'' Lastly, the commenter recommended that the administrative burdens of ascertaining and evaluating provider qualifications should not fall so heavily on an individual as to prevent hiring.

Response: As noted above, we have restructured this paragraph to clarify the requirements that apply under the various service delivery models. We believe this should alleviate any confusion. However, we disagree with the commenters' recommendation to add an exception process for individuals if there is no satisfactory attendant care provider available. For the purposes of ensuring health and welfare of individuals receiving CFC services, we believe that providers must meet either the qualification standards established by the State when services are delivered through the agency-provider model, or by the individual, when services are delivered through the self-directed model with service budget.

Comment: One commenter requested clarification as to whether a State, in accordance with State law, may prohibit family members from serving as the client's representative while also providing paid attendant services.

Response: We are clarifying here that an individual's representative may not

also serve as the individual's paid attendant. This arrangement was prohibited in the section 1915(j) program, and we are modifying the definition of ''individual's representative'' to continue that prohibition for CFC.

Comment: One commenter requested that the regulation give States the authority to determine which family members may act as providers of care.

Response: We do not believe it is appropriate for the regulation to authorize States to determine which family members may act as providers of care under the self-directed model with service budget. Consistent with the philosophy of self-direction, we believe individuals receiving CFC services must have the opportunity to exercise maximum control in deciding who can provide services.

Comment: One commenter indicated that when services are provided in a traditional agency model, the regulation should mandate that States establish a qualification standard that includes establishing a specific set of patient rights, including the right to immediate access to a supervisor to request a change in attendant, or hours, or duties.

Response: We do not agree that the regulation should mandate that States establish qualifications above and beyond what is already required for CFC. We believe that these important individual rights are included as requirements under the person-centered planning requirements at § 441.540 and the support system requirements at § 441.555.

Comment: One commenter suggested that the regulation should set the expectation that fraud, waste and abuse will not be tolerated and should be prevented, punished and prosecuted.

Response: A major tenet of the Medicaid program is maintaining program integrity. This requirement applies not only the section 1915(k) authority, but to all Medicaid authorities. In addition, the CFC regulation specifically requires services furnished to be based on the assessment of functional need, and indicates that the person-centered service plan should prevent the provision of unnecessary or inappropriate care. To promote the integrity of the Medicaid program, we have modified § 441.570(a), State assurances, to explicitly require a State's adherence to section 1903(i) of the Act, which stipulates that Medicaid payment shall not be made for items or services furnished by individuals or entities excluded from participating in the Medicaid Program, when implementing the CFC State plan option.

Comment: One commenter believes mandatory attendant training should be required. Another commenter believes the State should make available training programs or individualized coaching for those participants who prefer their attendant care provider receive such training. Alternatively, many commenters support the right of individuals to train attendant care providers in the specific areas of attendant care needed. The commenters suggested CMS clarify the interaction of this individual right with State laws mandating training requirements governing all attendant care providers.

Response: We disagree with the commenters' suggestion to require States to have mandatory trainings for providers of attendant services, as this would remove the authority vested in the individuals to train their providers. However, to support the requirement at § 441.565 that individuals retain the right to train attendant care providers in specific areas, and to be consistent with related requirements under section 1915(j) of the Act, we expect States to allow individuals to have access to additional attendant care provider training if needed or desired by the individual and related to needs identified in the person-centered plan. We have revised the rule at § 441.565 (a)(1) to reflect this change.

Comment: One commenter requests that cultural competency provisions explicitly include lesbian, gay, bisexual, and transgender populations.

Response: We do not believe that language specific to lesbian, gay, bisexual, and transgender populations is necessary, as the requirement applies for all individuals receiving CFC services.

Comment: A few commenters believe that there should be certain safeguards and oversight to ensure that services have been provided appropriately and at the level that is authorized.

Response: We believe that the regulation provides sufficient individual protections to detect whether needed services are provided appropriately. It is our expectation that an individual's services will be monitored by the entity providing support system services, and any irregularities in the provision of services will be detected and addressed. Additionally, the State Medicaid agency will exercise ongoing oversight and monitoring of the provision of services through review of the person-centered service plans, and through the Quality Assurance and Improvement Plan.

Comment: One commenter requested clarification regarding whether a State may set limits on the number of hours an individual may receive from any single family member, such as 40 hours per week.

Response: We do not believe it is appropriate for States to apply limitations to a certain classification of providers.

Upon consideration of public comments received, we are finalizing § 441.565 with revision, moving the requirement in paragraph (a) that requires States to assure the necessary safeguards that will be taken to protect the health and welfare of enrollees in CFC to § 441.570. ''State Assurances'' and modifying paragraph (c) to include the phrase ''including through the use of training programs offered by the State.'' We are also modifying this section to specify which requirements apply in various service delivery models.

P. State Assurances (§ 441.570)

We proposed to reflect the requirements at section 1915(k)(3)(C) of the Act that, for the first full fiscal year in which the State plan amendment is implemented, the State must maintain or exceed the level of expenditures for services provided under sections 1905(a), 1915, or 1115 of the Act, or otherwise, to individuals with disabilities or elderly individuals attributable to the preceding fiscal year. We also proposed to interpret this requirement to be limited to personal care attendant services. In addition we proposed to reflect requirements at section 1915(k)(4) of the Act that States electing this option must comply with certain laws in the provision of CFC regardless of which service delivery model the State elects to provide. Specifically, the statute requires that services and supports are provided in accordance with the Fair Labor Standards Act of 1938 and applicable Federal and State laws regarding withholding and payment of Federal and State income and payroll taxes; provision of unemployment and workers compensation insurance for attendant care workers; maintenance of general liability insurance; and occupational health and safety. We proposed to include these assurances as specified in the statute at § 441.570(b).

Comment: Multiple commenters supported limiting the application of the State maintenance of expenditure requirement to a defined set of services rather than to all Medicaid expenditures for older people and individuals with disabilities. Multiple commenters agreed that there is a need to develop a standard which more accurately reflects the legislative intent of CFC, as applying the maintenance of expenditure to all services is overly broad and would render the provision ''nearly pointless'',

but indicated that limiting it only to personal care services is overly narrow. Multiple commenters added that the maintenance of expenditure requirement should include all home and community-based services, not just personal care and indicated that this would be consistent with the intent of the law. Other commenters asked CMS to clarify in the regulation that CMS interpreted this requirement to only apply to personal care attendant services under sections 1905(a), 1915, and 1115 of the Act for the first year.

Response: We interpreted section 1915(k)(3)(C) of the Act to mean that, for the first full calendar year in which the State chooses to offer CFC in the State plan, the State's share of Medicaid personal care attendant expenditures for individuals with disabilities or elderly individuals must remain at the same level or be greater than State expenditures from the previous 12 month period year. As CFC is an attendant services and supports benefit, we believe it is appropriate to apply this maintenance of expenditure requirement only to comparable expenditures authorized under sections 1905(a), 1915, 1115 or other sections of the Act. We articulated this interpretation in the preamble of the proposed rule. To increase the clarity of this requirement, we are modifying the regulatory provision to specify the scope of services required under the requirement, to indicate that the clause ''or otherwise'' also applies to home and community-based attendant services authorized under other provisions of the Social Security Act, clarify that this requirement applied to State expenditures and to clarify we interpret the fiscal year to be a 12 month period. The new language will say ''For the first full 12 month period in which the State plan amendment is implemented, the State must maintain or exceed the level of State expenditures for home and community-based attendant services and supports provided under sections 1115, 1905(a), 1915, or otherwise, under the Act, to individuals with disabilities or elderly individuals attributable to the preceding 12 month period.''

Comment: A commenter indicated a 1-year maintenance of expenditure requirement is not sufficient, given that demographics will drive an increasing need and suggested that the requirement should be at a baseline for the first full fiscal year and then increase based on factors such as population demographics or indicators of need or demand such as waiting lists, applications for services, etc. Another commenter recommended that the requirement include gradual increases each year in access to personal care services.

Response: We believe that section 1915(k)(3)(C) of the Act was clear in terms of the timeframe for which States are required to maintain or exceed the level of expenditures.

Comment: Multiple commenters indicated that while States should have the flexibility to move beneficiaries from other programs into CFC, they recommended that safeguards be in place to ensure that beneficiaries do not experience any disruptions or loss of benefits, and that they are able to retain their providers from the initial program if they previously directed their own supports. Multiple commenters added that the shift should be seamless for consumers. Another commenter added that if States substitute personal care services under CFC for otherwise available personal care services, the qualifications and availability of the services should be maintained so that no currently eligible person or group loses care, and pointed out that the level of expenditures could be maintained in several ways including the expansion of eligibility for personal care services under section 1915(c) programs or State plan personal care.

Response: We believe the maintenance of expenditures provision will serve as a safeguard in that these expenditures cannot decrease for the first year of implementation; however, we acknowledge the commenters' concerns and expect States to ensure that services will not be disrupted, decreased, or lost as a result of a State choosing to elect CFC. We do not foresee there being an issue with individuals retaining their current providers if they choose to receive their attendant services and supports through CFC.

Comment: Multiple commenters stated that it was their belief that the legislative intent of the maintenance of expenditure provision was to ensure that States implemented the CFC to expand access to services, and not as a way to constrict existing services while securing higher matching funds. The commenters suggested that there be extra scrutiny of State reductions in services that are related to taking up CFC, in particular, where the State makes no effort to grandfather in existing services for affected consumers. The commenters explained that if a State were to take up the CFC option and apply an institutional level of care eligibility requirement, the State might be tempted to eliminate its personal care option to get higher match for those services through CFC. The commenter added that the large majority of States do not have an institutional level of care requirement for the personal care option and thus many individuals who were in the personal care option would not be able to transition to CFC. While the commenter noted that the State would likely not be in technical violation of the maintenance of expenditure requirement, based on the broader CFC spending obligations, it might violate the spirit of the CFC for thousands of consumers to find themselves without personal care services. The commenter cautioned that HHS should be careful to avoid helping States evade the purpose of the requirement.

Response: We do not believe that this regulation promotes the constriction of existing services to secure higher matching funds. We appreciate the suggestions regarding the potential reduction of services. The CFC State plan option provides individuals requiring an institutional level of care the opportunity to receive personal attendant services and supports (PAS) in the community instead of in an institution. We anticipate States will use this State plan option to improve access to non-institutional long term care services and supports. Additionally, § 441.570 requires States, for the first 12 months of implementing this State plan option, to maintain or exceed the level of State expenditures for similar services provided under other benefit authorities under the Act.

Comment: One commenter advised that if the maintenance of expenditure requirements for CFC pertain only to personal care attendant services, it should be clarified in the regulatory language in paragraph (a) to include HCBS waiver services as well. The commenter also expressed concern regarding the interaction between the Affordable Care Act Maintenance of Effort (MOE) for home and community-based waiver services and the maintenance of expenditure requirement for CFC purposes, as the commenter anticipated that persons may move from a waiver to CFC, and indicated that States should not risk noncompliance with the MOE under the Affordable Care Act if persons move from HCBS to CFC. Another commenter indicated that States need clarification as to whether they are required to maintain the same number of waiver slots, as would be required by the Affordable Care Act MOE if a State takes up CFC, as States may be unwilling to take up the option if they cannot realize savings from directing people away from waivers and towards less expensive State plan services.

Response: This set of comments addressed two aspects of the

maintenance of expenditure requirement of CFC. First, the spending covered by the maintenance of expenditure requirements are for home and community-based attendant care services in the State as authorized under sections 1905(a), 1915, 1115, or otherwise, under the Act. The final rule reflects that this requirement pertains to these services and these provisions of statute.

Secondly, the comments raised questions regarding the relationship of the maintenance of expenditure requirements as set forth in section 1915(k) of the Act to the MOE requirements established through Affordable Care Act as such requirements apply to long term services and supports, including HCBS waiver programs. The Affordable Care Act MOE pertains to Medicaid eligibility standards, methodologies, and procedures. Because institutional care and HCBS waivers can serve as a doorway to eligibility for certain individuals, changes impacting access to those benefits may raise MOE questions.

While changes to the section 1915(c) waiver eligibility and capacity may have implications for the Affordable Care Act requirements regarding MOE, a State currently has great flexibility to modify benefits to manage waiver costs. As a result, a State may elect to provide attendant care services and supports through CFC that are currently provided through other Medicaid authorities. States seeking to reduce waiver capacity (''slots'') or otherwise adjust the eligibility requirements for HCBS waivers should consult with CMS to ensure continued compliance with the MOE requirements, and to receive guidance on alternatives available to them in this regard. For additional information on the MOE requirements of the Affordable Care Act and its relationship to HCBS waivers, please see the State Medicaid Director letter issued on this matter at *http://www.cms.gov/SMDL/SMD/list.asp#TopOfPage.*

However, we do encourage States to evaluate what it offers under existing programs and consider the opportunities offered through CFC and the corresponding reporting and quality requirements to determine what is best for each State and its beneficiaries. We note that the additional 6 percentage point increase in FMAP would apply only to CFC, and would not apply to any currently approved program authorizing personal attendant services and supports.

Comment: A commenter recommended that CMS require States to formulate a plan to reduce existing waiver waiting lists for personal attendant care services.

Response: While we appreciate the commenter's suggestion, we do not plan to add a requirement to CFC for States to formulate such a plan as it is outside the scope of this benefit.

Comment: Another commenter requested further clarification on the section 1915(k)(4) requirement that waiver services meet FLSA and payroll tax requirements. Currently the State in which this commenter resides does not pay payroll taxes. The State shifts its payroll obligations to Medicaid recipients and also imposes unpaid care on the providers forcing them to ''volunteer'' for their employers. The commenter would like clarification as to whether or not CMS is attempting to remedy these abuses for CFC Option, as well as existing waivers.

Response: We reiterate that CFC is not a waiver program, but is a new, optional State plan benefit. Any State implementing CFC must adhere to the requirements in the authorizing legislation. By submitting a SPA to implement this program, the State will be assuring adherence to these requirements. States have the ability to contract with entities for the provision of activities such as the withholding of payroll taxes, etc., but retain ultimate responsibility for ensuring they are done appropriately.

Comment: A commenter asked for details regarding the applicable Federal laws regarding the requirement to maintain ''general liability insurance'' as their State's current personal care services program does not require this insurance for any party, and their current program is in compliance with all other provisions of this section. The commenter requested that this language be removed. Another commenter asked that CMS clarify which entity is expected to maintain general liability insurance as it is unclear whether it is the individual self directing care, the attendant providing services, or the financial management entity. The commenter also asked CMS to clarify whether the attendant's employer must provide attendant care providers with health insurance coverage.

Response: These details are best left to State Medicaid Agencies as they implement the program, so as to allow for State flexibility.

Comment: Another commenter suggested that CMS require States to set forth in detail how they intend to comply with/meet the various employment-related laws.

Response: States electing CFC must submit a State plan amendment that assures their adherence to this requirement. The specifics of how this happens are left to the States to determine.

Comment: A commenter stated that at paragraph (c)(4), CMS indicates that a State must assure that all applicable provisions of Federal and State law are met including those related to ''occupational health and safety'' and added that since the majority of CFC services will be delivered under person-centered plans and primarily in persons' residences, CMS should clarify how they envision States ensuring compliance with OSHA requirements, if that is the intent. The commenter stated that if compliance with OSHA requirements is not the intent, CMS needs to clarify what is meant by ''occupational health and safety.''

Response: These assurances were set forth in statute at section 1915(k)(4) of the Act. We will look to the State Medicaid Agencies to implement any policies they believe are necessary to ensure compliance.

Comment: Two commenters proposed an additional assurance at a new paragraph (c)(5) that States ensure that fiscal agents who will be cutting checks to attendant care providers on behalf of beneficiaries have sufficient cash reserves to be able to pay attendant care providers timely, notwithstanding delays in reimbursement due to bank holidays, etc.

Response: It is the responsibility of a State to ensure that the fiscal agents with whom the State chooses to work are capable of compensating providers of services and supports.

Comment: Several commenters recommended the following language: ''A State must assure that fair hearing processes for individuals are met in accordance with 42 CFR Part 431 Subpart E.''

Response: State Medicaid programs must adhere to the fair hearing requirements at 42 CFR part 431 Subpart E for all Medicaid programs. Therefore, we do not agree with the commenters that it is necessary to add an additional State assurance to the regulations for CFC.

Comment: A commenter suggested that the regulation promote the use of local, peer-based and consumer-controlled providers so beneficiaries have maximum access to their fiscal agent.

Response: This regulation includes extensive flexibility for States to establish provider qualifications in a way that encompasses a broad pool of experience. Individuals participating in a self-directed model will have ultimate

flexibility for selecting providers of services.

Upon consideration of public comments received, we are finalizing § 441.570 with revision, to clarify the intent of the maintenance of expenditures requirements proposed in paragraph (a), now paragraph (b). In addition, as indicated above, we are adding a new paragraph to reflect the movement of the requirement that States assure the provision of necessary safeguards to protect the health and welfare of CFC enrollees including adherence to section 1903(i) of the Act which stipulates that Medicaid payment shall not be made for items or services furnished by individuals or entities excluded from participating in the Medicaid Program. This will be a new paragraph (a), with the existing language being adjusted accordingly. As indicated in § 441.565, Provider Qualifications, we are adding a new paragraph (d)(5) to state ''any other employment or tax related requirements.''

Q. Development and Implementation Council (§ 441.575)

We proposed that States must establish a Development and Implementation Council that is primarily comprised of individuals with disabilities, elderly individuals and their representatives. We also proposed to require that States must consult and collaborate with this Council during the development and implementation of a State plan amendment to provide home and community-based attendant services and supports under CFC.

Comment: Many commenters had positive comments regarding the Development and Implementation Council. Many commenters stated the Development and Implementation Council is an excellent idea and a positive step forward for States, as well as a mechanism to ensure consumer input and implementation monitoring. Many of the commenters were pleased that CMS is soliciting comments on ways to design the Implementation Council, as it provides for robust stakeholder collaboration.

Response: We agree that the Council will provide additional opportunities for stakeholder input and collaboration.

Comment: Many commenters weighed in on the makeup of the Development and Implementation Council. Many commenters requested that a diverse population from advocacy organizations, disability rights groups, private agency representatives, stakeholders, direct support professionals, and direct service attendant care providers or their representatives be included in the Council's membership.

Many commenters requested that the final rule ensure that a majority of the Council is made up of individuals with disabilities, elderly individuals, and their representatives. The commenters further recommended that the Council should be comprised of members that reflect the diverse populations who use or could use CFC services and supports. One commenter requested that the following sentence be added to the end of § 441.575(a): ''This Council must also include home and community-based attendants or their selected representatives.'' Another commenter requested that the rule should require that 51 percent of the Council be made up of elderly or disabled individuals.

Response: Section 1915(k)(3)(A) of the Act requires that this Council include a majority of members with disabilities, elderly individuals and their representatives. This was reflected in the proposed rule at § 441.575 and is a requirement of the program. We believe that this membership will reflect the populations who will participate in CFC. We acknowledge that various advocacy organizations, disability rights groups, private agency representatives, stakeholders, direct support professionals and direct service attendant care providers and representatives could have a voice on the Council as long as the Council meets the requirements set forth in the final regulation. We do not agree that the regulation should add an additional requirement that attendants or their selected representatives be included in the membership of the Council or that the Council be broken down into a specific percentage of individuals. The statute specifically requires a ''majority'' of members with disabilities, elderly individuals and their representatives and this language will be maintained in our final rule. However, we acknowledge that the regulatory language proposed in the proposed rule used the phrase ''primarily comprised'' rather than a ''majority.'' We are revising the regulation to more closely align with the statute.

Comment: One commenter requested that consumers with the highest needs have a significant presence on the Development and Implementation Council.

Response: We believe that a having an array of individuals with varying needs on the Council will provide a broad representation of the individuals for whom CFC was created.

Comment: One commenter requested further definition of an ''aging or disability'' consumer. The commenter requested clarification on whether an older adult, who is not Medicaid eligible or low income, could hold a position on the Council under the current definition.

Response: Section 1915(k)(3)(A) of the Act requires that the Development and Implementation Council include a majority of members with disabilities, elderly individuals and their representatives. The statute did not set forth any additional qualifier or specifications these individuals must meet to participate on the Council. Therefore, we do not believe an older adult who is not on Medicaid or is not low-income would be prohibited from participating on the Council.

Comment: One commenter requested that the regulation suggest agencies and advocacy groups from which the Council could recruit.

Response: We disagree with providing specific agencies and advocacy groups from which to recruit, as this would unfairly advantage certain groups. States have the flexibility to determine how to best meet this requirement.

Comment: Many commenters requested that the Council's meetings and other functions be accessible and that supports be provided to individuals, as needed, to facilitate their full participation. The commenters indicated that these supports could include the use of modern technological devices. Several commenters requested that the Development and Implementation Council should hold their meetings publically and provide opportunities for public input, which would allow for transparency.

Response: We agree that the Council's meetings and other functions should be accessible to individuals to facilitate their full participation. With regard to the commenters' suggestion to require that these meetings be held publicly to allow for transparency, while we appreciate the suggestion, States have the flexibility to decide how to meet these requirements. A State's proposal for operating the Council will need to be described in their State plan amendment and approved by CMS for implementation. We do encourage these meetings to be held in a way that facilitates participation by a broad range of individuals.

Comment: Several commenters requested clarification of what ''transparency in the selection process'' means, as mentioned in the preamble to this section, and suggested using rules for implementing section 10201(i) of the Affordable Care Act as a means of providing transparency.

Response: In the proposed rule, we invited comments regarding how States

could achieve robust stakeholder input including transparency in the selection process and activities of the Council. The intent of this request was to gather ideas regarding what processes States might use to select members of the Council. States have the flexibility to determine how to meet the requirements of the final rule and we encourage States to be transparent in their selection processes.

Comment: One commenter requested that States be required to provide public notice on how they will establish the Development and Implementation Council.

Response: While we encourage States to provide public notice regarding how they will establish the Council, as this is a matter of interest to individuals and may be a direct way to solicit members, we do not agree that this should be an additional requirement that is added to this regulation. States maintain the flexibility to determine how to best meet the requirements to implement CFC.

Comment: Many commenters provided input related to how the Development and Implementation Council should be structured and the duties associated with it. Many commenters requested that baseline definitions and minimum participation standards for the Council be included in the final rule.

Response: We disagree with further defining the role of the Council or with setting minimum participation standards for the Council in this regulation.

Comment: One commenter provided models and examples of committees and councils formed to address issues related to home health care.

Response: We appreciate the commenter's efforts and contribution, but again emphasize that, outside of the specific mandates of the regulation, States will have the discretion to design their councils.

Comment: One commenter requested that the regulation require the Council to be in place, and to provide recommendations on CFC prior to October 2011, or whenever the State implements the program.

Response: We agree with the commenter that the Council will need to be in place prior to implementation, as the State is required to consult and collaborate with the Council to develop a State plan amendment for CFC, as set forth in section 1915(k)(3)(A) of the Act and reflected at § 441.575. We do not agree that revisions to the regulation are necessary.

Comment: One commenter requested that Council members be trained on what it means to be a Council member, including what the expectations are with regard to their role representing a larger constituency group. Council members should be supported in the acquisition of knowledge necessary to be active members and provided support to ensure meeting attendance.

Response: We agree that members of the Council should understand their role in the Council and the responsibilities that the Council has with regard to CFC. States may want to take this into consideration when determining how to best meet the requirements of this Council. It is important for the Council membership to understand their role and the purpose of the Council as a whole. Training requirements for the Council are beyond the scope of this regulation and we do not agree with the commenter that these should be added to the regulation. With regard to the commenter's point about support for meeting attendance, as we indicated above, States should make every effort to ensure that the meetings are held at times and locations that are accessible to the members of the Council.

Comment: One commenter requested that financial and personnel resources be dedicated solely to the work of the Council. The commenter added that States should recognize that the frequency of meetings will impact the success of the Council and suggested that they occur at least quarterly.

Response: States have the flexibility to implement the Council, and to determine the frequency at which meetings of the Council will occur, as long as all the requirements in the final regulation are met. Therefore, we do not agree that the regulation should add specific requirements pertaining to these issues.

Comment: Many commenters weighed in on the level of influence that the Development and Implementation Council has on the State. One commenter requested that the recommendations made by the Development and Implementation Council be incorporated into the State plan. One commenter expressed concern regarding the role of Council as it relates to the independent decision making authority of the State in developing and implementing a State plan amendment for CFC. The commenter would like clarification that the Council should in no way be empowered to impede a State's authority.

Response: As noted above, section 1915(k)(3)(A) of the Act sets forth the requirement that a State establish the Development and Implementation Council. This provision also requires a State to consult and collaborate with this Council to develop and implement the State plan amendment for CFC. While States must describe in their State plan amendment how this collaboration and consultation occurred, this does not mean that the State's ability to make decisions is compromised. States need to consider the Council's input and should make every effort to incorporate the feedback of the Council in these decisions. However, we are not interpreting ''collaboration'' as total concurrence.

Comment: Another commenter requested that the life of the Development and Implementation Council be extended beyond implementation to include a role in the ongoing improvement of the State's CFC program.

Response: Section 1915(k)(3) of the Act requires consultation and collaboration with the Council ''in order for a State plan amendment to be approved under this paragraph.'' We encourage States to continue operations of the Council even after implementation of CFC. A strict interpretation of the statute would require consultation and collaboration with the Council prior to submitting any type of CFC SPA to CMS, which would encompass amendments to an already approved CFC SPA. We recognize that requiring such consultation and collaboration prior to submitting a SPA to implement a minor or administrative change would be overly burdensome to both the State and Council members. But we are taking this opportunity to specify that any substantive changes to the operation of an approved CFC program would require the prior consultation and collaboration of the Council. We would define a substantive change to include revisions to the amount, duration, and scope of services provided under CFC, revisions to the service delivery model, revisions to payment methodologies, etc.

Comment: Another commenter requested that the Development and Implementation Council identify specific data to help better advise the State on the program and recommended that the proposed rules should also assure that States are responsive to the Council's request for such data.

Response: Section 441.575 reflects the requirements in the statute for this Council and we do not agree that additional requirements are necessary in regulation.

Comment: Many commenters requested further guidance from CMS regarding the Development and Implementation Council. A number of commenters requested confirmation that

a State may use an existing self directed care advisory committee or whether the requirement is for a dedicated advisory Council limited to self direction pursued under the section 1915(k) authority. Many commenters believe States should ensure that the Council coordinates with other stakeholder bodies that have related missions such as *Olmstead* implementation councils and long-term service and support commissions.

Response: States may utilize existing advisory bodies in the implementation of CFC, as long as the statutory requirements for the Development and Implementation Council are met. We acknowledge the benefits of the Council coordinating with related stakeholder councils and commissions and strongly encourage States to do so. States may also choose to leverage these councils and/or incorporate members from these councils to meet the requirements for CFC.

Comment: Many commenters requested amending the current proposed language to include more specific Development and Implementation Council criteria regarding what groups should be included in the Council membership and additional roles that the Council should assume. Several commenters requested adding a reference to ''direct-care attendant care providers'' after ''elderly individuals.'' The rationale behind the commenters' request is that direct care attendant care providers' contributions will enhance the work of the Council by providing regular, direct communication with the State on core service delivery issues. Furthermore the commenters recommend the following language be included, ''(c) The Council should develop a plan that ensures the adequacy of provider rates and compensation; makes attendant care provider training available; establishes a central mechanism to help program participants find providers; and develops an approach to collecting essential workforce data elements.''

Response: As indicated above, the statute was very specific in both the requirements for the membership and the functions and responsibilities of the Council. The final regulations reflect the statutory requirement and we do not agree with creating additional requirements that States must meet in addition to what is clear in the statute.

Comment: One commenter requested clarification regarding whether the activities of the Development and Implementation Council will be eligible for Federal funds because the Council is mandated both by statute and regulation.

Response: Activities required by CFC that are done for the operation of the program, such as implementation of the Development and Implementation Council will not receive an additional 6 percentage point FMAP increase, as they are administrative activities and are only eligible for the standard Federal administrative matching rate of 50 percent available at § 433.15(b)(7).

Comment: Several commenters requested a timeline for the creation of this Council.

Response: We believe that the Council should be in place prior to the submittal of a SPA requesting CFC, as States are required to consult and collaborate with the Council regarding the development and implementation of a SPA for CFC.

Comment: One commenter requested changing the rule to state: ''(a) States must establish a Development and Implementation Council comprised primarily of individuals with disabilities, elderly individuals, their representatives, and disability rights advocates. The Development and Implementation Council must be cross-disability and cross-age and must include representation of all categories identified in this paragraph; (b) The Council must include individuals who are eligible for and, when applicable, in receipt of CFC services; (c) States must consult and collaborate with the Council when developing and implementing a State plan amendment to provide home and community-based attendant services and supports or when contemplating any changes; and (d) To maintain quality assurance, States must continue to regularly consult with the Council and incorporate their recommendations into the operation of the Community First Choice Option.''

Response: We appreciate these suggestions, but do not agree that these additional requirements need to be incorporated into the regulation.

Comment: Another commenter requested changing the Development and Implementation Council language as follows: ''(a) States must establish a Development and Implementation Council which includes providers and individuals with disabilities including elderly individuals, and their representatives; and (b) States must consult the Council when developing and implementing a State plan amendment to provide home and community-based attendant services and supports.''

Response: We disagree with adding ''providers'' to § 441.575(a). The statute only directs that the majority of the Council must consist of elderly or disabled individuals, and their representatives. We do not believe it is appropriate to require other representation. We believe that § 441.575(b) closely mirrors the commenter's change in language and does not require change.

Comment: One commenter requested clarification of the term ''representative'' in reference to individuals who are elderly, have disabilities, or are the representatives of individuals with disabilities. Another commenter requested clarification of the term ''consumer representative'' as it is ambiguous and could be interpreted as an individual representing a consumer or an employee of an advocacy organization.

Response: We are interpreting ''representative'' broadly in the context of the Council, including both the individual's representative, as defined in § 441.505, and other representatives of elderly individuals or individuals with disabilities in general. The phrase ''consumer representative'' is not used in this regulation.

Comment: One commenter recommended that the proposed rule expressly state that section 1915(k)(3) of the Act, pertaining to State collaboration with a Development and Implementation Council, does not negate the State responsibility to solicit advice from Indian health programs and urban Indian organizations as required by section 5006(e) of the ARRA.

Response: We acknowledge the commenter's concern. Nothing in the CFC regulation should be construed as superseding current requirements for States in regard to Indian health organizations and programs.

Upon consideration of public comments received, we are finalizing § 441.575 with revision, to align with the statutory requirement that a majority of the Council be comprised of individuals with disabilities, elderly individuals, and their representatives.

R. Data Collection (§ 441.580)

We proposed to require that States must provide information regarding the provision of home and community-based attendant services and supports under CFC for each fiscal year for which the services and supports are provided. We also proposed a number of specific data elements that must be collected and reported.

Comment: One commenter commended the inclusion of subpart (c) regarding the collecting of information about individuals served under CFC and indicated that this data will be an essential tool to identify deficiencies in the provision of the benefit.

Response: We appreciate the commenter's support.

Comment: A few commenters asked what is meant by ''type of disability'', as indicated in paragraph (c).

Response: We interpret ''type of disability'' as set forth in section 1915(k)(5)(B)(iii) to include developmental disability, physical disability, traumatic brain injury, etc.

Comment: One commenter stated that in section § 441.535(a)(5) States are required to obtain information about an individual's ''school.'' This commenter asked if ''school'' is synonymous with ''education level'' as specified in § 441.580(c).

Response: Based on comments, we revised the text at § 441.535(a) and school is no longer a specified element of the assessment of functional need for the implementation of CFC. Therefore, there is no need to clarify further as the data collection requirement at § 441.580(c) is clear regarding ''education level.''

Comment: One commenter asked for a clarification of ''previous fiscal year'' with regard to data collection timeframes.

Response: We interpret ''fiscal year'' to mean ''Federal fiscal year.'' We plan to issue additional guidance to States regarding maintenance of expenditure requirements.

Comment: Several commenters asked for clarification regarding the data collection requirements at § 441.580(e) in terms of what CMS meant by ''data regarding how the State provides CFC and other home and community-based services.''

Response: We interpret this requirement to mean the methods in which the State delivers home and community-based services under CFC, through other State Plan authorities, through section 1915(c) waivers, or through section 1115 demonstrations. For CFC, this could include which service models are offered in the State, the permissible services and supports that a State has chosen to make available, any limits the State has set on services and supports, and a number of other factors as determined by the State. We anticipate being able to collect much of the information related to this requirement from the State Plan as the State Plan must describe how the State is providing CFC. We anticipate releasing additional guidance in the future, providing more detail on data collection and how it relates to the CFC evaluation required in the legislation.

Comment: One commenter stated that the language in paragraph (g) appears to be a request for a description and not data collection activity.

Response: We do not understand the commenter's concerns based on this comment, but while the requirement at § 441.580(g) could include a description of how the State provides individuals the choice to receive home and community-based services in lieu of institutional care, it could also include information regarding the methods used to offer this choice, the strategies involved in making this choice available, and the number of individuals that have made that choice.

Comment: One commenter asked CMS to clarify any expectations to reconcile estimated number of individuals anticipated to receive services against actual utilization. This commenter asked if there will be an expected accuracy standard and further stated that since this is a new option there is potential for significant discrepancy.

Response: We are clarifying that States may report on the actual number of individuals that received CFC services and supports in the prior fiscal year, when reporting on the estimate of individuals expected to receive them in the upcoming fiscal year. We understand that there will be discrepancies in the number of individuals estimated vs. actually served.

Comment: One commenter sought clarification on the respective roles the State and Federal government will play in regard to the evaluation.

Response: Section 1915(k)(5) of the Act sets forth the requirements that States provide data to the Secretary for an evaluation and reports to Congress. The States and the Federal government will partner to accomplish an evaluation of CFC. The States can evaluate their individual programs based on data collected throughout the fiscal year. The Federal government will be evaluating CFC on a nationwide basis based on each State's data. We anticipate releasing additional guidance in the future, providing more detail on data collection and how it relates to the CFC evaluation required in the legislation.

Comment: One commenter asked whether a self-report is an acceptable standard for type of disability, education level and employment status. Additionally, this commenter asked that CMS clarify the acceptability of retaining the original data with updates if there are changes rather than collecting it each year. This commenter also asked for clarification of the expectations for linking the data collected and asked whether a State could begin with data unlinked and phase in those capabilities over time.

Response: We are deferring answering this question until such time as we release additional guidance in the future, providing more detail on data collection and how it relates to the CFC evaluation required in the legislation.

Comment: One commenter asked what the Department hopes to collect.

Response: Through the data collection process, the Department hopes to determine the effectiveness of the provision of CFC services and supports in allowing the individuals receiving such services and supports to lead an independent life to the maximum extent possible; the impact on the physical and emotional health of the individuals who receive such services; and an comparative analysis of the costs of services provided under the State plan amendment under this paragraph and those provided under institutional care in a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded. As such, we are modifying the regulation to include a data collection requirement for States to capture data on the impact of CFC services and supports on the physical and emotional health of individuals, and other data as determined by the Secretary.

Comment: One commenter requested specificity of the exact data comparison expected for CFC and other home and community-based services.

Response: We are deferring answering this question until such time as we release additional guidance in the future, providing more detail on data collection and how it relates to the CFC evaluation required in the legislation.

Comment: One commenter suggested that the data collection section should begin with what questions CMS wants answered, some of which are in the preamble. This commenter further asked what the data at § 441.580 are supposed to illuminate. In conclusion, this commenter suggested considering convening an expert group to help draw up data points.

Response: The data collected from States will be used to complete the statutorily required evaluation of the effectiveness of CFC services and supports. We anticipate releasing additional guidance in the future, providing more detail on data collection and how it relates to the CFC evaluation required in the legislation.

Comment: One commenter asked for clarification regarding reporting the number of individuals that received services and supports during the preceding fiscal year. This commenter asked if after CFC has been in place the second and following years, if States report the number of persons in CFC from the preceding year(s).

Response: In accordance with section 1915(k)(5)(B) of the Act, States should

report the number of individuals that have received CFC services and supports during the preceding fiscal year. This means that after CFC has been in place the second and following years, States should report the number of persons in CFC for the preceding year (that is, reporting the number of individuals served under CFC in year one after the program has been in place for 2 years).

Comment: Two commenters asked for clarification pertaining to the requirement to report the specific number of individuals who were previously served under other authorities or State Plan options.

Response: To clarify, with regard to individuals receiving CFC services and supports, the State should report the number of these individuals who were previously receiving supports under sections 1115, 1915(c) and (i) of the Act, or the personal care State plan option.

Comment: One commenter asked whether a State may limit the number of individuals reported to those who received attendant support services under the specified authorities rather than all individuals served under the waivers, with regard to the requirement in paragraph (d).

Response: A State may not limit the number of individuals reported in this way. As stated in § 441.580(d), States are required to report the specific number of CFC individuals who were previously served under another authority regardless of what services and supports were received under that authority.

Comment: One commenter asked whether the requirement to report the specific number of individuals who have been previously served under sections 1115, 1915(c) and (i) of the Act is intended to include those individuals who are served concurrently or just those who are no longer accessing personal care services under those authorities and are now accessing only CFC services.

Response: States are required to report the number of individuals who were previously served under the authorities stated above, meaning that these individuals are now accessing attendant care services and supports through the CFC Option. It is possible that individuals receiving attendant services and supports through CFC could also be receiving other services, particularly via a section 1115 demonstration or section 1915(c) waiver.

Comment: One commenter stated that it is imperative that data collection is not a barrier to the provision of timely, high quality services.

Response: We agree that data collection should not be a barrier to the provision of services. Our intention is to place as little burden as possible on States and individuals in terms of data collection while ensuring that data is available to comply with the statutory requirements for evaluation and reporting.

Comment: Many commenters provided suggestions for additional data collection options. One commenter recommended the regulation require recording the number of individuals served, both in terms of the number of individuals eligible to receive CFC, and in terms of individuals receiving all of the various CFC services. Another commenter stated that it would be helpful if the data could show whether individuals who transferred to CFC from another home and community-based option experienced any loss of service subsequent to the transfer. This same commenter recommended that the regulation provide for the collection of data in such a way as to tell whether individuals receiving CFC services and supports were previously receiving home and community-based services through waivers or other options, or if individuals receiving CFC services are newly eligible for home and community-based services. Two commenters suggested collecting data specific to the service models utilized. One of these commenters further suggested including what services and items are used by those choosing the agency model versus those who choose the self-directed model with a service budget. Several commenters suggested including data pertaining to the number of people who were previously receiving services in institutions or nursing facilities. One of these commenters suggested collecting data on Medicaid costs of this option vs. Medicaid costs in institutional settings. Two commenters suggested that data should be made available to the public. One of these commenters also suggested that CMS should collect the data quarterly. Several commenters also suggested including data with additional demographic break-down of individuals. Two commenters suggested collecting data pertaining to race. One of these commenters suggested also including ethnicity, limited English proficiency, and type of residence. One commenter suggested that States include optional sexual orientation and gender identity questions to break down utilization rates. One commenter suggested requiring States to provide data on an individual's veteran status. Many commenters recommended that States be urged to provide data on the staff providing services including: attendant care provider availability, turnover and retention rates, and compensation. One commenter suggested also collecting data pertaining to training and credentialing of staff. Additionally, many commenters stated that in a self-directed delivery system, program participants will be the most likely source of data pertaining to staff, and urged for identification of collection methods that will be feasible for participants. One commenter suggested adding an ''other as determined by the Secretary'' element to this section.

Response: We appreciate the ideas and suggestions that commenters proposed. States continue to have the flexibility to design their data collection requirements as long as all of the requirements included in the regulation for CFC are met. States may adopt additional data collection requirements for their own purposes. As indicated above, we are adding data collection requirements for States to capture data on the impact of CFC services and supports on the physical and emotional health of individuals, and other data as determined by the Secretary.

Comment: One commenter stated that data collection requirements are excessive in comparison to reporting on section 1915(c) waivers and the section 1915(j) State Plan option. The commenter also stated that some of the requirements do not appear to provide CMS or the States with any additional information that is useful in the operation of multiple home and community-based services programs, quality assurance, or customer satisfaction. This commenter also stated that the requirements at paragraphs (a), (b), (d), and (f) are similar to existing reporting.

Response: We have implemented data collection requirements as they were specified in the statute. We do not agree that the data collection requirements are excessive. We believe that these requirements are an essential tool needed to evaluate CFC.

Comment: One commenter asked for CMS to clarify anticipated mechanisms to report annual estimates, and asked whether CMS will make changes to existing reporting mechanisms. Another commenter suggested that CMS provide States with flexibility in data reporting until existing State automated systems can be updated to accommodate new reporting requirements. Another commenter stated that mechanisms chosen need to include consumer input and consumer satisfaction surveys as well as outcome measures.

Response: As we noted, we will provide future guidance on the format of this reporting requirement. We will consider the commenters' perspectives as we develop our guidance and will try to impose as little burden on the States and individuals as possible. However, with regard to State flexibility in reporting, States must provide the information specified in § 441.580 in a timely manner regardless of the State's systems and potential system modifications needed. States may leverage existing data collection and reporting vehicles to meet the requirements of CFC.

Upon consideration of the public comments received, we are finalizing § 441.580 with revision, adding data collection requirements for States to capture data on the impact of CFC services and supports on the physical and emotional health of individuals, and other data as determined by the Secretary.

S. Quality Assurance System (§ 441.585)

We proposed to require that States must establish and maintain a comprehensive, continuous quality assurance system, detailed in the State plan amendment, that includes a quality improvement strategy and employs measures for program performance and quality of care, standards for delivery models, mechanisms for discovery and remediation, and quality improvements proportionate to the benefit and number of individuals served. We proposed that the quality assurance system must include program performance measures, quality of care measures, standards for delivery models and methods that maximize consumer choice and control. We also required that States elicit and incorporate feedback from key stakeholders to improve the quality of the CFC benefit and that States must collect and report on monitoring, remediation, and quality improvements related to information defined in the State's quality improvement strategy.

Comment: Several commenters commended the requirement that the quality assurance system be detailed in the CFC SPA.

Response: We appreciate the support of this requirement.

Comment: Several commenters noted that it is crucial that the quality management system utilized for CFC reflect the participant direction philosophy and recommended that the quality system resemble what is seen in sections 1915(i) and 1915(j) of the Act. The commenter indicated that special attention and/or assistance may be needed to ensure agencies administering CFC implement quality assurance and measurement techniques that build upon the participant direction paradigm.

Response: We appreciate the commenters' views and agree that the perspective of the individuals receiving CFC attendant services and supports is an important aspect to consider. We believe the requirement to incorporate stakeholder feedback will complement the other elements of the participant direction philosophy included in CFC. While certain aspects of the CFC quality assurance system were set forth in the statute, similar measures are required for other Medicaid programs including sections 1915(c), 1915(i) and 1915(j) of the Act, and we anticipate that States will leverage their current systems to meet the requirements for CFC where possible.

Comment: Multiple commenters suggested additional requirements for the quality assurance system including the following:

- Modification of the program performance measures to capture achievement of individuals' outcomes and goals identified in the service plan;
- Indication of the choice of location where the services are provided such as home, school, work or other;
- Collection of type of living situation such as group home, family home, individual's home or other in § 441.585(a)(1)(iii);
- Specification of the choice of institution or community;
- Collection of a core set of functional indicators which are representative of the full range of functional limitations for the CFC population;
- Implementation of measures of consumer satisfaction and consumer experience;
- Measurement and reporting of barriers to achievement of individual outcomes and goals and how the State intends to address and remove any identified barriers;
- Collection and monitoring of the difference between the number of personal attendant care hours scheduled or authorized in each qualified individual's service plan and the hours of the scheduled type of service that are actually delivered to the qualified individual;
- Implementation of a program performance measure called ''gaps in service'' which they believe would allow States to document, gauge and address service gaps;
- Implementation of standards for services and supports;
- Measurement of the numbers individuals served both in terms of the number of individuals eligible to receive CFC, and in terms of the individuals receiving all of the various CFC services;
- Measurement of the numbers of shifts that went unstaffed;
- Measurement of the general availability, turnover and retention of attendant staffing;
- Measurement of access to services on the basis of fields identified in § 441.580(c);
- Measurement of race, ethnicity, limited English proficiency, and type of residence;
- Evaluation of whether the payment methodologies for attendant services and supports are sufficient for developing and sustaining an adequate workforce;
- Measurement of the impact direct care workforce wages have on the access consumers have to a wide range of reliable, timely home and community-based services;
- Analysis of workforce quality and stability; and
- Development and implementation of program integrity measures to evaluate the validity of individual eligibility, appropriateness of the care plan, and propriety of payments to caregivers.

Response: We appreciate the commenters' suggestions regarding additional requirements to be included in States' quality assurance systems for CFC. As noted in previous sections, we are working to streamline the various HCBS requirements and expectations where possible across Medicaid HCBS programs. We are presently working with stakeholders to better understand the most effective and efficient method to assure the health and welfare of individuals with long term services and support needs, and to maximize quality across Medicaid HCBS authorities. We are considering the feedback from stakeholders, including the feedback received regarding the proposed language for CFC and forthcoming section 1915(i) comments, and analyzing current statutory and regulatory guidance across applicable Medicaid authorities. Additional guidance will be provided to States regarding any streamlined approaches that are developed for utilization across Medicaid HCBS. For the purposes of this regulation and the implementation of CFC, we have revised the quality assurance system requirements to more closely align with requirements included in statute. We will consider these commenters' suggestions as the work continues to better understand the most effective and efficient method to assure the health and welfare of individuals with long term services and

support needs, and to maximize quality across Medicaid HCBS authorities.

Comment: One commenter indicated that it is critical in a quality improvement framework to examine participant outcomes and suggested that CMS be more prescriptive in the assessment elements which will result in comparable data on which to monitor quality and compare outcomes across States over time. The commenter suggested that CMS consider identifying a standard set of measures that would be implemented across States as they believed that this would allow CMS to identify exemplary States that could serve as best practice examples, as well as identify those States that may require support to improve the provision of services to CFC participants. Another commenter recommended that CMS include a set of minimum measures in the regulation, stating that this will both ensure States are collecting core meaningful quality measures and also allow for comparison of different programs to help identify best practices. Several commenters indicated that States' continuous quality assurance systems must be designed to measure and report on achievement of individual outcomes and goals expressed by beneficiaries in their person-centered services and supports plans.

Response: We agree with the commenters that individual outcomes are an important component to consider in terms of quality improvement and quality assurance, particularly as they relate to specific services. We expect that States' quality assurance systems will utilize the information present in service plans to inform how needs are being met across the program and to see where improvements need to be made. As noted earlier, we have modified the Person-Centered Service Plan section to include individually identified goals and desired outcomes. States have the flexibility to incorporate additional measures above what is required through this regulation. Also, as mentioned in the assessment section, we are currently working to determine universal core elements to include in an assessment for consistency across Medicaid HCBS programs. Based on multiple comments and the acknowledgement that additional policy work is necessary to maximize the extent to which consistency can exist across the Medicaid programs as it relates to assessments for HCBS programs, we revised the assessment requirements to reflect the broad requirements in statute. Our intent is to require any finalized universal core elements that are developed to be incorporated into the assessment of functional need for CFC and other HCBS assessments as determined by CMS.

We also appreciate the commenters' suggestions regarding standard sets of quality measures. As noted, we are presently working with stakeholders to better understand the most effective and efficient method to assure the health and welfare of individuals with long term services and support needs, and to maximize quality across Medicaid HCBS authorities. For the purposes of this regulation and the implementation of CFC, we have revised the quality assurance system requirements to more closely reflect the requirements included in statute.

Comment: One commenter asked what the expectation is for measuring individuals' outcomes associated with the receipt of community-based attendant services and supports, particularly for the health and welfare of recipients of the service as stated at § 441.585(a)(2). The commenter asked if this is a major evaluation element or if it could be satisfied with a survey. The commenter voiced concern that a broad-based assessment of need that includes elements over and above what is offered in the personal care program's purview may negatively impact the ability of States to develop and measure individual outcomes.

Response: As noted above, individual outcomes are an important component to consider in terms of quality improvement and quality assurance, particularly as they relate to the services and supports provided under CFC. For these outcome measures being tied to assessment elements or the achievement of individual outcomes and goals expressed in the service plan, we expect that States' quality assurance systems will utilize the information present in service plans to inform how needs are being met across the program and to see where improvements need to be made. This information will also be a major component in the evaluation of CFC. States will need to describe how they plan to capture these outcomes in their quality assurance system. With regard to the commenter's concern regarding the assessment of need including elements over and above what is offered under CFC, as mentioned earlier, the assessment portion of the regulation has also been revised, as has the person-centered planning section, to remove the specified elements that went beyond the services and supports available under CFC. However, it is important to reiterate that our intent is to require any finalized universal core assessment elements that are developed to be incorporated into the assessment of functional need for CFC and other HCBS assessments as determined by CMS.

Comment: One commenter indicated that the proposed rule deferred too much to States, was too vague to provide adequate protection for Medicaid beneficiaries, and did not incorporate the monitoring function that section 2401 of the Affordable Care Act included as a requirement for a State's quality assurance system. The commenter recommended more prescriptive requirements for this function.

Response: We believe that the monitoring function was incorporated. Several protections for individuals are required under the quality assurance system, and the system as a whole must continuously monitor the quality of the program and incorporate feedback from key stakeholders. However, as mentioned above, we are continuing the work to determine quality approaches for utilization across Medicaid HCBS authorities. Therefore, for the purposes of this regulation and the implementation of CFC, we have revised the quality assurance system requirements to more closely reflect the requirements included in statute. Section 441.585(a)(2) now indicates that the quality assurance system must monitor the health and welfare of each individual who received CFC home and community-based attendant services and supports, including a process for the mandatory reporting, investigation, and resolution of allegations of neglect, abuse, or exploitation in connection with the provision of community-based attendant services and supports.

Comment: One commenter noted that the data collection and quality assurance system should not be burdensome on consumers and they should not be surveyed every month with a lot of questions that get into unnecessary detail or invade the person's privacy.

Response: We agree with the commenter.

Comment: Several commenters commended the inclusion of the examples of measures in the preamble, including functional indicators and individual satisfaction. One commenter added that the perspective of service recipients and advocates will be critically important in making determinations as to ''quality,'' particularly as it pertains to personal goal and outcome achievement.

Response: We believe that individual outcomes are an important component to consider in terms of quality improvement and quality assurance, particularly as they relate to the services and supports provided under CFC. With

regard to the perspective of individuals and advocates as referenced in the comment, States' quality assurance systems must also incorporate stakeholder feedback to improve the quality of the services offered under CFC. These aspects of CFC, along with the Development and Implementation Council, demonstrates the importance of the individual's perspective as it relates to services and supports provided under the program.

Comment: One commenter asked CMS to clarify whether a State can delegate its quality assurance responsibilities to an outside entity while retaining ultimate responsibility, or if the State is required to facilitate these functions.

Response: States continue to have the flexibility to design their quality assurance programs as long as all of the requirements included in the regulation for CFC are met. A State will need to determine whether they want an entity outside the State to be responsible for meeting this requirement.

Comment: A few commenters voiced concern about the complexity of the proposed quality assurance system, pointed out that it is very similar to that for the section HCBS 1915(c) waiver programs, and referenced a previous letter they had sent to CMS that stated: ''The growing demands on States to implement increasingly complex quality management systems and improvement strategies are problematic because they: (a) Deviate significantly from the original intent of the quality initiative, that is, that CMS would review State systems of quality rather than monitor activities at the level of the individual beneficiary, (b) extend beyond the expectation specific in the HCBS Waiver Application Version 3.5 and related guidance, and (c) are being placed on States at a time when their fiscal and human resources are diminishing.'' Another commenter referenced this letter and asked that CMS clarify expectations regarding how section 1915(k) quality assurance is similar or dissimilar to section 1915(c) quality improvement, with specific attention paid to individual outcome measures and remediation activity level of detail.

Response: As noted earlier, based on the feedback received during this process and the direction of ongoing work at CMS to develop a quality strategy that can be utilized to the extent possible across the Medicaid programs, we are revising this portion of the regulation to more closely align with the quality assurance system requirements included in statute.

Comment: One commenter indicated that the proposed language is similar to quality assurance in HCBS waivers, which they believe is unsatisfactory because it has few, if any, quality of care standards, and is based on quality indicators that may or may not be meaningful and do not give guidance to consumers when there is a dispute about how services are to be provided. The commenter added that the quality assurance process seems to be hidden from consumers and that the data seems to be almost exclusively viewed by the State and CMS, with little or no involvement from consumers. The commenter recommended that information from the quality assurance process be shared with stakeholders, including but not limited to consumers and their representatives.

Response: As mentioned above, we have revised the quality assurance system requirements to more closely align with the quality assurance system requirements included in statute. We have maintained the language that requires outcome measures associated with the receipt of community-based attendant services and supports, particularly for the health and welfare of recipients of this service. States may use a number of quality of care measures to meet that requirement. We also point the commenter to the final rule at § 441.585(b), which requires that the quality assurance system employ methods that maximize consumer independence and control and will provide information about the provisions of quality improvement and assurance to each individual receiving such services and supports, and § 441.585(c), which requires that the State elicit and incorporate feedback from individuals and their representatives, disability organizations, providers, families of disabled or elderly individuals, members of the community, and others to improve the quality of CFC.

Comment: One commenter indicated that the quality improvement strategy needs to involve consumer and stakeholder input, and that measurements and remediation needs to consider the convenience to the consumer and their ability to understand the process, and not impinge unduly on consumer direction while improving service delivery. The commenter added that the Development and Implementation Council needs to be directly involved in monitoring and making program changes to implement quality improvement strategies. Several other commenters indicated that in addition to stakeholder feedback received through the Council, feedback from consumer satisfaction surveys and other means should be included in the quality assurance system and should be included in the rule. Another commenter urged CMS to clarify that feedback from aging organizations should also be incorporated in the quality assurance system.

Response: We point the commenter to the final rule at § 441.585(b), which requires that the quality assurance system employ methods that maximize consumer independence and control, and will provide information about the provisions of quality improvement and assurance to each individual receiving such services and supports, and § 441.585(c), which requires that the State elicit and incorporate feedback from individuals and their representatives, disability organizations, providers, families of disabled or elderly individuals, members of the community, and others to improve the quality of CFC. We expect that States will include the feedback of the Development and Implementation Council as part of this requirement as the membership of the Council will include many of the individuals specified at § 441.585(c). We agree with the commenter that consideration should be given to the methods that involve individuals' feedback. We agree that surveys may be a useful component with which to gain feedback, but caution that this process not be overly complicated or burdensome for individuals.

Comment: One commenter asked that CMS clarify expectations for incorporating stakeholder feedback that may conflict with Federal regulations or State policy direction as defined in State statute, or drive increased expenditures for which a State lacks funding appropriation.

Response: The requirement at section 1915(k)(3)(D)(ii) of the Act, which we proposed to implement at § 441.585(b), requires that the quality assurance system incorporate feedback from consumers and their representatives, disability organizations, providers, families of disabled or elderly individuals, members of the community, and others. We are interpreting the use of the word ''incorporate'' to mean that feedback from these key stakeholders must be considered, but we do not expect that States must make changes based on each and every suggestion received. Should feedback received be in conflict with Federal regulations, States would not be expected to incorporate that feedback, in terms of making changes to the program, as Federal regulations must be adhered to for a State to be in compliance with such regulations. If feedback received was in conflict with

State policy direction, as defined in State statute, or would drive increased expenditures for which a State lacks funding appropriation, the State would need to make a choice as to whether to consider it.

Comment: One commenter asked to what extent a State must ''maximize consumer independence and control'' as described at § 441.585(a)(4), asked for an example of what this means and what CMS' intent is with this language. The commenter asked for confirmation that this is all within the confines of the individual's health needs and requested that if this is the case that CMS include additional language to make this clear.

Response: The statute and this regulation facilitate the ability for States to maximize individual independence and control throughout the CFC benefit, as illustrated by the inclusion of the language related to self-direction and person-centered planning, the Development and Implementation Council, and the stakeholder feedback requirements for the quality assurance system. While we do not set a minimum or maximum threshold that States must meet in terms of maximizing consumer independence and control, we expect that States make every effort to meet these requirements.

Comment: Multiple commenters recommended that the language at section 1915(k)(3)(D)(ii) of the Act be used at paragraph (b) Stakeholder feedback, instead of the term ''key stakeholders.''

Response: We appreciate the commenters' suggestion and have revised the language to include each entity specified in the statute.

Comment: Several commenters stated that at paragraph (a)(2), the regulation applies the statutory requirement regarding reporting and investigation of abuse and neglect. The commenters commended the connection of abuse and neglect reporting to quality of care measures, but believed that the statute (at section 1915(k)(3)(D)(iii) of the Act) applies the requirement more broadly than to the more limited subpart of ''Quality of care measures'' specified in paragraph (a)(2). The commenters recommended that it be more broadly set forth as an independent requirement under the quality assurance system.

Response: As mentioned above, we have revised the quality assurance system requirements to more closely align with the quality assurance system requirements included in statute. As such, § 441.585 of the final rule is clear that this function applies more broadly than to the proposed limited subpart of ''quality of care measures.''

Upon consideration of the public comments received, we are finalizing § 441.585 with revision, to more closely mirror the quality assurance requirements specified in statute.

T. Increased Federal Financial Participation (§ 441.590)

We proposed that beginning October 1, 2011, the FMAP applicable to the State will be increased by 6 percentage points for the provision of CFC home and community-based attendant services, under an approved State plan amendment.

Comment: One commenter expressed concern that since States will receive 6 percentage point increase in FMAP for costs associated to the program, it would seem shortsighted for a State not to take advantage of this opportunity to expand community-based services which will decrease the amount of money needed for institutional care.

Response: We appreciate the commenter's perspective.

Comment: Many commenters indicated that States should be permitted to receive the enhanced FMAP provided in CFC concurrently with receiving other HCBS enhanced match rates such as those authorized by the Money Follows the Person Rebalancing Demonstration and the Balancing Incentive Payments Program.

Response: We acknowledge the potential for States to receive enhanced FMAP under more than one program, and are willing to provide technical assistance to States interested in doing so.

Comment: One commenter requested clarification regarding how CFC services would work in conjunction with similar efforts already under way to transition individuals from skilled nursing facilities to a home and community-based setting, such as section 1915(c) waivers and MFP. The commenter asked if waiver participants would be able to access CFC services and if so, whether the additional FMAP would apply to MFP or waiver services.

Response: The enhanced FMAP applies to services authorized under the CFC program, but there is no prohibition on individuals receiving services through a section 1915(c) waiver or MFP program also receiving services through CFC.

Comment: One commenter stated that this provision needs to be strong enough to encourage State participation and should be seen as an incentive for States to comply with the Olmstead Integration Mandate. The commenter indicated that it should not preclude other forms of enforcement of the law.

Response: We agree with the commenter, and believe that the 6 percentage point increase in Federal match provides incentives to the States to provide CFC to eligible individuals. This provision does not preclude other forms of enforcement of the *Olmstead* decision.

Comment: Several commenters asked for clarification pertaining to what services and expenditures would be eligible for increased FMAP. One of these commenters requested that CMS clarify whether increased FFP is available for activities that support the delivery of ''home and community-based attendant services'' in context of CFC requirements. Two commenters requested that the enhanced reimbursement rate also be applied to assessments. One of these commenters further requested that CMS cover the coordination of the person-centered plan at the enhanced FMAP rate. Another commenter stated that their understanding is that attendant care would be eligible for the enhanced FMAP, and inquired whether additional services such as necessary case management or support brokerage services, administrative costs related to implementation of a fiscal agent structure, voluntary training for service participants, and the implementation of quality improvement mechanisms would be covered. One commenter requested clarification of the range of services eligible for the enhanced FMAP rate other than attendant services, such as case management, training, or personal agents. One commenter requested that CMS clarify that the additional 6 percent FMAP would be applied to all services qualifying under CFC. This same commenter encouraged CMS to clarify that the 6 percent additional FMAP applies to the entire package of services to anyone qualified to receive them, not just those who are newly in receipt of attendant care services and supports provided under CFC. This commenter also asked whether a Personal Emergency Response System (PERS) would also qualify for enhanced reimbursement.

Response: The authorizing legislation indicates that the additional 6 percentage points in FMAP applies to CFC services and supports. We are interpreting ''services and supports'' broadly in this context, to include not only the services referenced at § 441.520 (''Included services''), but also some of the activities referenced in the comments described above. Specifically, activities required by CFC that are performed for specific individuals, such as assessments, person-centered planning, support system and Financial

Management Services will receive an additional 6 percentage points to the State's service match rate. Activities required by CFC that are done for the operation of the program in general, such as quality management, data collection, implementation of the Development and Implementation Council, and administrative costs related to implementation of a fiscal agent structure will not receive an additional 6 percentage points as they are administrative activities and are only eligible for the standard federal administrative matching rate of 50 percent available at § 433.15(b)(7).

Comment: One commenter stated that CMS should ensure that the ''and supports'' is added to the end of ''home and community-based attendant services'' to be consistent with the terminology in the statute.

Response: We agree with this commenter and will add ''and supports'' to the end of ''home and community-based attendant care services'' in § 441.590.

Comment: One commenter requested that CMS clarify its expectations on how these services and expenditures are to be tracked to appropriately draw the higher FMAP. The commenter asked whether CMS will revise the CMS–64 form to reflect this State plan option.

Response: The CMS–64 form has been modified to include a new CFC line item.

Comment: Two commenters supported the 6 percent increase in FMAP, hoping that this will encourage States to select this option.

Response: We appreciate the perspectives these commenters had in support of this provision of the rule.

Comment: Two commenters requested confirmation of the duration of the 6 percent FMAP increase.

Response: There is no time limit attached to the FMAP increase. The 6 percentage point increase in FMAP is available to States for as long as States choose to provide services and supports under CFC.

Comment: One commenter asked if the enhanced Federal match is available if a State decides to implement later than October, 2011 to coordinate implementation efforts with other efforts connected to Affordable Care Act.

Response: The enhanced FMAP becomes available to a State upon the effective implementation date of their approved SPA for CFC, regardless of whether this date occurs after October 1, 2011.

Comment: One commenter suggested that a portion of the increased Federal financial assistance that States receive be invested in workforce compensation, and investment that has been shown to improve recruitment and retention and thus quality of care.

Response: States will continue to have flexibility with determining how they utilize the increased Federal funds that they will receive with the 6 percentage point enhanced match.

Upon consideration of the public comments received, we are finalizing § 441.590 with revision, to reflect that the enhanced match is available for CFC ''home and community-based attendant services and supports.''

III. Provisions of the Final Regulations

Generally, this final regulation incorporates the February 25, 2011 provisions of the proposed rule. We have outlined in section II of this preamble the revisions in response to the public comments. The provisions of this final regulation that differ from the proposed rule are as follows:

- At § 441.505 we have revised the following definitions: Agency-provider model, backup systems and supports, individual representative, other models, Self-directed. This section has also been revised to add two new definitions: Individual, Self-directed model with service budget.
- We have revised § 441.510 to set forth the requirement that all individuals that meet an institutional level of care, allow for State administering agencies to permanently waive the annual level of care recertification if certain conditions are met and clarify income requirements
- We have revised § 441.515 to combine (b) and (c) to more directly align with the statute.
- We have revised § 441.520 to rename it ''Included services'' to align with the statute. We have revised § 441.520(b) to clarify that (b)(1) and (2) that follow are both at the State's option, and to add the language from proposed 441.520(b)(3) ''linked to an assessed need or goal identified in the individual's person-centered service plan'' into the introductory section so that it is clear it applies to both (b)(1) and (2).
- We have revised § 441.530 to remove the proposed home and community-based settings criteria. This section is now reserved for future use.
- We have revised § 441.535 to add the ability for States to meet the face-to-face requirement through the use of telemedicine or other information technology medium if the certain conditions are met. We also added a new requirement at § 441.535(d) indicating ''Other requirements as determined by the Secretary.''
- We have revised § 441.540 to add a new requirement that the service plan require an assurance that the setting in which the individual resides is chosen by the individual, and to require a description of the setting alternatives available to the individual from which to choose. The proposed text at § 441.540(b)(1) through (5) all shifted down by one number. We added requirements for administering the person-centered service plan. We also relocated some of the proposed rule language to the Support System section at § 441.555.
- We have revised § 441.545 to expand the types of arrangements that may exist under the Agency provider model, to clarify the authority individuals have in the selection and dismissal of their service providers, to clarify the responsibilities of the Financial management entity and to add ''Other service delivery model'' as an additional service delivery model to allow States the option of proposing alternate delivery models for consideration.
- We have revised § 441.550(e) to specify that determining the amount paid for services should be ''in accordance with State and Federal compensation requirements''.
- We have revised § 441.555 to specify that support system activities must be available to all individuals regardless of the service delivery model; We also revised the requirements under this section to add additional beneficiary protections.
- We have revised § 441.560(a)(3)(i), replacing the phrase ''change the budget'' with ''adjust amounts allocated to specific services and supports within the approved service budget.''
- We have revised § 441.560 to make technical corrections.
- We have revised § 441.565 to clarify which requirements apply to which service delivery model.
- We have revised § 441.570 to clarify that this includes assuring the State's adherence to section 1903(i) of the Act that Medicaid payment shall not be made for items or services furnished by individuals or entities excluded from participating in the Medicaid Program. We also clarified that the Maintenance of Existing Expenditures requirements described at § 441.570(b) pertains to the first full 12 months in which the CFC State plan amendment is implemented, and is limited to the expenditures for home and community-based attendant services and supports provided under sections 1115, 1905(a), 1915, or otherwise, under the Act, to individuals with disabilities or elderly individuals

attributable to the preceding 12-month period.

- We have revised § 441.575 to align with the statutory requirement that a majority of the Council be comprised of individuals with disabilities, elderly individuals, and their representatives.
- We have revised § 441.580 adding additional requirements for States to capture data on the impact of CFC services and supports on the physical and emotional health of individuals and other data as determined by the Secretary.
- We have revised § 441.585 to more closely align with requirements set forth in statute.

V. Collection of Information Requirements

We solicited public comment on each of the issues for the following sections of this document that contain information collection requirements (ICRs). We received several public comments on specific sections contained in the ICRs. The comments and our responses follow:

A. Assessment of Functional Need (§ 441.535)

Section 441.535 requires States to conduct a face-to-face assessment of the individual's needs, strengths, preferences, and goals for the services and supports under CFC. States may use one or more processes and techniques to obtain this information about an individual. In § 441.535(a)(1), the State must define the provider qualifications for health care professionals to use telemedicine or other information technology mediums for the assessment. In § 441.535(a)(3), the State must obtain informed consent from the individual to use telemedicine or other information technology mediums for the assessment. In addition to the initial assessment, States are required to conduct reassessments at least every 12 months (§ 441.535(c)).

The burden associated with the requirements under § 441.535 is the time and effort it would take to conduct a face-to-face assessment of each individual's needs, strengths, preferences and goals for the services and supports under CFC. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The one-time burden associated with the requirements under § 441.535(a)(1) is the time and effort it would take the respondents to define the provider qualifications for health care professionals. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The burden associated with the requirements under § 441.535(a)(3) is the time and effort it would take the respondents to obtain informed consent from the individual to use telemedicine or other information technology mediums for the assessment. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The burden associated with the requirements under § 441.535(c) is the time and effort it would take the respondents to conduct reassessments at least every 12 months. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Comment: Several commenters recommended that CMS revisit the time estimates for the assessment of functional need and reassessment of need. The commenters had concerns regarding the one hour estimate provided in the proposed rule stating that an assessment could take up to three hours. The commenters added that this estimate also does not include travel time or the time necessary to analyze the information. It was also noted that while a reassessment may take less time than an initial assessment, it still would take up to two hours to perform.

Response: Our estimates are based on the average time it may take for States to complete the assessment. This average would take into account the fact that some assessments may take less than one hour while some may take more than 1 hour. We do not believe the estimate of 1 hour to complete a face-to-face interview to be unreasonable and did not receive overwhelming public comment to indicate otherwise. Therefore, we have not revised the collection of information estimate.

B. Person-Centered Service Plan (§ 441.540)

Section 441.540 requires the State to conduct a person-centered planning process resulting in a person-centered service plan (§ 441.540(b)), based on the assessment of functional need (§ 441.535), in collaboration with the individual and the individual's authorized representative, if applicable. This service plan must be agreed to in writing by the individual and signed by all individuals and providers responsible for its implementation. In addition, States must provide a copy of the plan to the individual and anyone else responsible for the plan. In addition to the initial plan, States are required to review the plan at least every 12 months (§ 441.540(c)).

The burden associated with the requirements under § 441.540(b) is the time and effort it would take to develop and finalize a written person-centered service plan for each individual, and to provide each individual and anyone else responsible for the plan a copy of that plan. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The burden associated with the requirements under § 441.540(c) is the time and effort it would take respondents to review each person-centered service plan at least every 12 months and revise, when necessary. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Comment: Several commenters recommended that CMS revisit the time estimates for development of the service plan. Several commenters stated that the CMS estimate of 2 hours to develop and finalize a service plan was too short. The commenters indicated that 2 hours is needed to develop the plan with an additional 2 hours, at minimum, to finish the plan. They added that the overall development of a person-centered plan, including administrative tasks, could take up to 5 hours.

Response: Our estimates are based on the average time it may take for States to complete the requirements related to § 441.540—Person-centered Service plan. This average would take into account the fact that some of these components may take less than the estimated time while some may take more than we estimated. We estimated a total of 3.5 hours on average. We do not believe that this estimate is unreasonable and did not receive overwhelming public comment to indicate otherwise. Therefore, we have not revised the collection of information estimate.

C. Service Models (§ 441.545)

Section 441.545 requires the State to choose one or more service delivery models for providing home and community-based attendant services and supports.

Under the agency-provider model for CFC, in § 441.545(a)(1), the State Medicaid agency or delegated entity, must enter into a contract or provider agreement with the entity providing the services and supports.

Under the self-directed model with service budget, in § 441.545(b), the individual must be provided with a service budget based on the assessment of functional need.

States must provide additional counseling, information, training, or assistance to individuals who have demonstrated that they cannot effectively manage the cash option described in § 441.545(b)(2)(iii). They must also provide the individual with the conditions under which the State would require an individual to use a financial management entity (§ 441.545(b)(2)(iv)).

In § 441.545(c), States have the option of proposing other service delivery models which must be defined by the State and approved by CMS.

The burden associated with the requirements under § 441.545(a)(1) is the time and effort it would take to enter into a contract or provider agreement with the entity providing the services and supports. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The burden associated with the requirements under § 441.545(b) is the time and effort it would take the respondents to develop person-centered service plans and service budgets. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The burden associated with the requirements under § 441.545(b)(2) is the time and effort it would take the respondents to provide additional counseling, information, training, or assistance to individuals who have demonstrated that they cannot effectively manage the cash option and provide that individual with the conditions under which the State would require an individual to use a financial management entity. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Comment: One commenter was concerned that the State burden will vary depending on the service model. The commenter indicated that implementing the ''self directed model with service budget'' would create additional burden for the State and that a State would view the complexity of managing self-directed service budgets with new service features such as direct cash, vouchers, and training to support consumers with the full employer responsibility, as a significant additional burden.

Response: We appreciate the commenter's perspective. It is difficult to accurately estimate the total burden associated with any one of these models, as it would depend on the number of models a State chose to offer. While we acknowledge the additional burden that a State may have if they do not already offer such a model that could be leveraged to meet the requirements of CFC, we did not receive any estimates or additional comments that provide any compelling information to modify this section. Therefore, we will not be revising this collection of information estimate.

D. Support System (§ 441.555)

For each service delivery model described under § 441.545, States must provide or arrange for the provision of a support system to: Appropriately assess and counsel an individual or the individual's representative, if applicable, before enrollment (§ 441.535); provide appropriate information, counseling, training and assistance to ensure that an individual is able to manage the services and budgets (if applicable) (§ 441.545); establish conflict of interest standards for the assessments of functional need and the person-centered service plan development process that apply to all individuals and entities, public or private (§ 441.540); and ensure that the responsibilities for assessment of functional need and person-centered service plan development are identified (§§ 441.535 and 441.540).

In § 441.555(b), States must specify in their State plan any tools or instruments used to mitigate identified risks. The one-time burden associated with the requirements under § 441.555(b) is the time and effort it would take to amend their State plan by specifying any tools or instruments used to mitigate any identified risks. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Comment: One commenter indicated that designing and implementing a support system that appropriately assesses and counsels an individual before an assessment, as well as providing information counseling, training, and assistance to the individual will require significant effort.

Response: We appreciate the commenter's perspective and agree that the requirements will require State effort. We did not receive any estimates or additional comments that provide any compelling information to modify this section. Therefore, we will not be revising this collection of information estimate.

E. Service Budget Requirements (§ 441.560)

For the self-directed model with a service budget, the State is required to develop and approve a service budget that is based on the assessment of functional need and person-centered service plan and must include all of the requirements in § 441.560(a)(1) through (a)(6). In addition to developing a service budget, the methodology used to determine an individual's service budget amount must meet the requirements in § 441.560(b) and must be included in the State plan (§ 441.560(b)(3)).

In § 441.560(c), the State must have procedures in place that will provide safeguards to individuals when the budgeted service amount is insufficient to meet the individual's needs. In § 441.560(d), the State must have a

method of notifying individuals of the amount of any limit that applies to an individual's CFC services and supports. In § 441.560(f), the State must have a procedure to adjust a budget when a reassessment indicates a change in an individual's medical condition, functional status, or living situation.

The burden associated with the requirements under § 441.560(a) is the time and effort it would take to develop and approve each service budget. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The one-time burden associated with the requirements under § 441.560(b) is the time and effort it would take the respondents to develop a methodology used to determine an individual's service budget amount and include that methodology in the State plan. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The one-time burden associated with the requirements under § 441.560(c), (d), and (f) is the time and effort it would take the respondents to develop: Procedures that will provide safeguards to individuals when the budgeted service amount is insufficient to meet the individual's needs, a method for notifying individuals of the amount of any limit that applies to an individual's CFC services and supports, and a procedure to adjust a budget when a reassessment indicates a change in an individual's medical condition, functional status, or living situation. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

An additional burden associated with the requirements under § 441.560(d) is the time and effort it would take the respondents to develop and distribute each notice that specifies the amount of any limit for the individual's CFC services and supports. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Comment: One commenter believed that is would take far more than 16 hours to develop communicate, test, and finalize budget procedures with input from interested parties and intradepartmental reviews.

Response: We acknowledge the commenter's concern, however, the development requirement imposed is a onetime burden that will vary by State. We believe that the 16-hour estimate is an accurate reflection of the average time a State would take to develop their procedures. We did not receive any estimates or additional comments that provide any compelling information to modify this section. Therefore, we will not be revising this collection of information estimate.

F. Provider Qualifications (§ 441.565)

For the agency provider model of CFC services and supports, States must develop system safeguards that include written adequacy qualifications for providers. In certain circumstances, this requirement may apply to other models.

The one-time burden associated with the requirements under § 441.565(b) is the time and effort it would take to develop written adequacy qualifications for providers. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Comment: One commenter believed that 16 hours to develop system safeguards, including written adequacy qualifications for providers, was significantly insufficient. The commenter noted that the identification, analysis, and development of provider qualifications together with executing regulator or contractual mechanisms to control and/or oversee the risk in the individual's environment will require more than 16 hours to complete.

Response: We disagree that 16 hours to develop system safeguards is insufficient. Our estimates are based on the average time it may take for States to fulfill these requirements. This would include States who may only have to slightly modify qualifications that are already in place and States who would have to create new qualifications. We did not receive any estimates or additional comments that provide any compelling information to modify this section. Therefore, we will not be revising this collection of information estimate.

G. Development and Implementation Council (§ 441.575(b))

States are required to establish a Development and Implementation Council, and must consult and collaborate with the Council when developing and implementing a State plan amendment to provide home and community-based attendant services and supports.

The burden associated with the requirements under § 441.575(b) is the time and effort it would take to consult and collaborate with the Council when developing and implementing a State plan amendment to provide home and community-based attendant services and supports. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

H. Data Collection (§ 441.580)

Section 441.580 requires States to provide specified information regarding the provision of home and community-based attendant services and supports under CFC for each Federal fiscal year for which such services and supports are provided.

The burden associated with the requirements under § 441.580 is the time and effort it would take to provide specified information regarding the provision of home and community-based attendant services and supports for each fiscal year for which such services are provided. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Comment: Many commenters expressed concerns pertaining to the estimated annual burden associated with the data collection requirement.

Response: We have implemented data collection requirements as they were specified in the statute. We disagree that the annual burden will be significantly

more than estimated. While some States may need to revise their data collection systems, we do not believe that this will affect all States. Additionally, since much of this data collection is also a requirement under other authorities, we believe that States have the mechanisms in place to gather the requested information for reporting without excessive additional burden.

Comment: One commenter believed that the data collection requirements set forth in the proposed regulations are reasonable. However, the commenter believed that the burden of the requirement to estimate the number of individuals served by type of disability, education level, and employment status in their State prior to the first fiscal year will be significant because it will likely require a manual effort from disparate sources. The commenter stated that once other major projects involving automation are implemented, the requirement for reporting in future years will become far less burdensome.

Response: We appreciate this comment and the time that it may initially take States to set up systems to capture the required information. We agree that the initial data collection effort could be significant; however, as systems are put in place to capture this data we are confident that the time associated with data collection will be significantly reduced.

Comment: One commenter believed that the requirement to report whether specific individuals were previously served in other programs or waivers is significant because it requires the development of ad-hoc reporting and report validation system which is not currently produced. The commenter stated that the estimated annual burden associated with this requirement will be significantly more than 24 hours or $576 per State for the initial year.

Response: We appreciate this commenter's perspective. Our estimates are based on the average time it may take for States to fulfill these requirements. This would include States who may only have to slightly modify or determine how to leverage current data collection methods and States that would have to create new methods or systems. We also believe that some of the data required could be retrieved by a State's MMIS. We did not receive any estimates or additional comments that provide any compelling information to modify this section. Therefore we will not be revising this collection of information estimate.

I. Quality Assurance System (§ 441.585)

Section 441.585(a) requires each State to establish and maintain a comprehensive, continuous quality assurance system, detailed in the State plan amendment. In § 441.585(b), States must provide information about the provisions of quality improvement and assurance to each individual receiving such services and supports. In § 441.585(c), States must elicit and incorporate feedback from individuals and their representatives, disability organizations, providers, families of disabled or elderly individuals, members of the community and others to improve the quality of the community-based attendant services and supports benefit.

The burden associated with the requirements under § 441.585(a) is the time and effort it would take to establish and maintain a comprehensive, continuous quality assurance system, detailed in the State plan amendment. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The burden associated with the requirements under § 441.585(b) is the time and effort it would take the respondents to provide information about the provisions of quality improvement and assurance to each individual receiving such services and supports. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

The burden associated with the requirements under § 441.585(c) is the time and effort it would take the respondents to elicit and incorporate feedback from individuals and their representatives, disability organizations, providers, families of disabled or elderly individuals, members of the community and others to improve the quality of the community-based attendant services and supports benefit. While this requirement is subject to the PRA, only a few States have expressed potential interest. Therefore, based on our informal discussions with States after the publication of the proposed rule, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Comment: One commenter believed that establishing and maintaining a comprehensive quality assurance system that includes a continuous quality assurance system, quality improvement strategy, and measures for program performance will exceed 100 hours for development. The cost will also be more than $2,400 annually.

Response: We appreciate this commenter's perspective. Our estimates are based on the average time it may take for States to fulfill these requirements. This would include States who may only have to slightly modify or determine how to leverage current quality assurance systems and States that would have to create new systems. We did not receive any estimates or additional comments that provide any compelling information to modify this section. Therefore, we will not be revising this collection of information estimate.

This document imposed information collection and recordkeeping requirements. Consequently, it was reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule implements section 2401 of the Affordable Care Act. The Secretary is to establish a new State plan option to provide home and community-based attendant services and supports at a 6 percentage point increase in Federal matching payments for expenditures related to the provision of services under this option. Section 2401 of the Affordable Care Act, entitled ''Community First Choice Option,'' adds a new section 1915(k) of the Act that allows States, at their option, to provide home and community-based attendant services and supports under their State plan beginning October 1, 2011.

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), 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 (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. This final rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately $139 million. Because this rule does not mandate State participation in section 1915(k) of the Act, there is no obligation for the State to make any change to their Medicaid program. Therefore, we estimate this final rule will not mandate expenditures in the threshold amount of $139 million in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As stated above, this final rule does not have a substantial effect on State and local governments.

This final rule is estimated to have an economic impact of $1.3 billion in fiscal year 2012, with the Federal and State shares reflecting $820 million and $480 million, respectively. The economic impact estimates presented in this final rule differ from those originally presented in the proposed rule, primarily due to the final rule revising § 441.510 to require, that in order to receive CFC services, all individuals, regardless of income, must be determined annually to meet an institutional level of care.

TABLE 1—MEDICAID COSTS FOR THE COMMUNITY FIRST CHOICE OPTION

[In $ millions] [1]

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016 [2]
Federal Medicaid	$820	$1,060	$1,815	$2,585	$3,520
State Medicaid	480	620	1,061	1,511	2,058

[1] Figures are rounded to the nearest $1 million and assume increased State participation per fiscal year.
[2] The proposed rule included cost estimates for FY 2012 through FY 2015. The cost estimates in this final rule are for FY 2012 through FY 2016.

This final rule provides States with additional flexibility to finance home and community-based services by establishing a new CFC Option at an increased FMAP for attendant services and supports. Because of this enhanced flexibility, and the fact that a majority of States may already provide attendant services and supports through optional medical assistance services in its Medicaid State plan, HCBS waiver programs or both, we anticipate that each State will likely compare and decide which vehicle provides greater benefits and stability to their overall Medicaid program. As such, at this time it is very difficult to accurately predict how many States will choose to adopt the CFC Option, and how a State's election to exercise this option will influence other parts of its Medicaid program. However, for purposes of this RIA, we assume a gradual growth in the number of States adopting this option, so that, by FY 2016, 30 percent of eligible persons who would want this coverage would reside in States that offer it.

C. Anticipated Effects

1. Effects on Medicaid Recipients

We anticipate that a large number of Medicaid recipients will be affected. We believe the additional option to provide attendant care services and supports at the increased FMAP will likely have significant positive effects on Medicaid recipients, particularly on their demand for these services. We anticipate that the provisions of the final rule will likely increase State and local accessibility to services that augment the quality of life for individuals through a person-centered plan of service and various quality assurances, all at a potentially lower per capita cost relative to alternative care-settings.

2. Effects on Other Providers

We anticipate that this final rule will increase the demand for attendant care services and supports. We believe this effect will be beneficial to providers, particularly providers of attendant care services and supports. Additionally, if the increase in demand for such services is sufficient, the number of providers of such services may increase.

3. Impact on Small Entities

The RFA 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 health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business and having revenues of less than $7 million to $34.5 million in any 1 year. (For details, see the Small Business Administration's Table of Size Standards at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf*.) Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the Secretary has determined that this final rule does not have a significant 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. We are not preparing an analysis for section 1102(b) of the Act because 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.

4. Effects on the Medicaid Program Expenditures

Varying State definitions of personal care services and rules concerning who may furnish them make it difficult to estimate accurately the potential increases in expenditures for States that choose to adopt CFC under section 1915(k) of the Act. While we specifically solicited comments on the number of States that were likely to participate in CFC, we received none.

Table 1 above provides estimates of the anticipated Medicaid program expenditures associated with furnishing attendant care services and supports. The estimates were made using various assumptions about increases in service utilization and costs, as well as assumptions about the induced utilization that may result from the CFC option. We have allowed for possible State incentives due to the increased FMAP rate, as well as for the possibility of savings due to beneficiaries being diverted from nursing facility use.

D. Alternatives Considered

In finalizing the policies set forth in this rule, we reviewed all public comments submitted within the allowed time.

We received a large number of comments on the proposed definition of home and community-based settings. We met with Federal partners to discuss the concerns raised by public commenters. We also reviewed several documents and policy papers prepared by advocacy groups, independent policy groups, and other stakeholders for information on the types of settings personal attendant services are provided in. Additionally, we looked to the *Olmstead* Decision and the ADA as the framework onto which we built our definition.

After much discussion and consideration of the impact of each option discussed, we concluded that further discussion and consideration on this issue is necessary. Therefore, we are not finalizing the language proposed at § 441.530. Rather, we will issue a new proposed regulation that will establish setting criteria for CFC developed as a result of the comments received.

E. Accounting Statement

As required by OMB Circular A–4 (available at: *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*), we have prepared an accounting statement showing the classification of estimated transfers, benefits and costs associated with section 1915(k) services offered by qualified providers in the Medicaid program, as a result of this final rule.

TABLE 2—ACCOUNTING STATEMENT: ESTIMATED TRANSFERS, BENEFITS, AND COSTS

[FYs 2012 to 2016] [3]

Category		Transfers		
Annualized monetized transfers	Year dollar	Discount rate		Period covered
	2012	7%	3%	
	Primary Estimate	$1.87 Billion	$1.92 Billion	FYs 2012–2016
From/To	Federal Government to Medicaid Qualified Providers.			
Category	Transfers			
Annualized monetized transfers	Year dollar	Discount rate		Period covered
	2012	7%	3%	
	Primary Estimate	$1.09 Billion	$1.12 Billion	FYs 2012–2016
From/To	State Governments to Medicaid Qualified Providers.			
Category	Benefits			
Qualitative Benefits	The CFC option will increase State and local accessibility to services which in turn improves, through a person-centered plan of service with various quality assurances, the quality of life for individuals, and reduces the financial strain on States and Medicaid participants.			
Category	Costs			
Administrative Burden Costs	The administrative burden costs are presented in the Paperwork Reduction Act section of this final rule.			

[3] The proposed rule included cost estimates for FY 2012 through FY 2015. The cost estimates in this final rule are for FY 2012 through FY 2016.

List of Subjects in 42 CFR Part 441

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

The Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

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

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

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

■ 2. Part 441 is amended by adding subpart K to read as follows:

Subpart K—Home and Community-Based Attendant Services and Supports State Plan Option (Community First Choice)

Sec.

441.500 Basis and scope.
441.505 Definitions.
441.510 Eligibility.
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Subpart K—Home and Community-Based Attendant Services and Supports State Plan Option (Community First Choice)

§ 441.500 Basis and scope.

(a) *Basis.* This subpart implements section 1915(k) of the Act, referred to as the Community First Choice option (hereafter Community First Choice), to provide home and community-based attendant services and supports through a State plan.

(b) *Scope.* Community First Choice is designed to make available home and community-based attendant services and supports to eligible individuals, as needed, to assist in accomplishing activities of daily living (ADLs), instrumental activities of daily living (IADLs), and health-related tasks through hands-on assistance, supervision, or cueing.

§ 441.505 Definitions.

As used in this subpart:

Activities of daily living (ADLs) means basic personal everyday activities including, but not limited to, tasks such as eating, toileting, grooming, dressing, bathing, and transferring.

Agency-provider model means a method of providing Community First Choice services and supports under which entities contract for or provide through their own employees, the provision of such services and supports, or act as the employer of record for attendant care providers selected by the individual enrolled in Community First Choice.

Backup systems and supports means electronic devices used to ensure continuity of services and supports. These items may include an array of available technology, personal emergency response systems, and other mobile communication devices. Persons identified by an individual can also be included as backup supports.

Health-related tasks means specific tasks related to the needs of an individual, which can be delegated or assigned by licensed health-care professionals under State law to be performed by an attendant.

Individual means the eligible individual and, if applicable, the individual's representative.

Individual's representative means a parent, family member, guardian, advocate, or other person authorized by the individual to serve as a representative in connection with the provision of CFC services and supports. This authorization should be in writing, when feasible, or by another method that clearly indicates the individual's free choice. An individual's representative may not also be a paid caregiver of an individual receiving services and supports under this subpart.

Instrumental activities of daily living (IADLs) means activities related to living independently in the community, including but not limited to, meal planning and preparation, managing finances, shopping for food, clothing, and other essential items, performing essential household chores, communicating by phone or other media, and traveling around and participating in the community.

Other models means methods, other than an agency-provider model or the self-directed model with service budget, for the provision of self-directed services and supports, as approved by CMS.

Self-directed means a consumer controlled method of selecting and providing services and supports that allows the individual maximum control of the home and community–based attendant services and supports, with the individual acting as the employer of record with necessary supports to perform that function, or the individual having a significant and meaningful role in the management of a provider of service when the agency-provider model is utilized. Individuals exercise as much control as desired to select, train, supervise, schedule, determine duties, and dismiss the attendant care provider.

Self-directed model with service budget means methods of providing self-directed services and supports using an individualized service budget. These methods may include the provision of vouchers, direct cash payments, and/or use of a fiscal agent to assist in obtaining services.

§ 441.510 Eligibility.

To receive Community First Choice services and supports under this section, an individual must meet the following requirements:

(a) Be eligible for medical assistance under the State plan;

(b) As determined annually—

(1) Be in an eligibility group under the State plan that includes nursing facility services; or

(2) If in an eligibility group under the State plan that does not include such nursing facility services, have an income that is at or below 150 percent of the Federal poverty level (FPL). In determining whether the 150 percent of the FPL requirement is met, States must apply the same methodologies as would apply under their Medicaid State plan, including the same income disregards in accordance with section 1902(r)(2) of the Act; and,

(c) Receive a determination, at least annually, that in the absence of the home and community-based attendant services and supports provided under this subpart, the individual would otherwise require the level of care furnished in a hospital, a nursing facility, an intermediate care facility for the mentally retarded, an institution providing psychiatric services for individuals under age 21, or an institution for mental diseases for individuals age 65 or over, if the cost could be reimbursed under the State plan. The State administering agency may permanently waive the annual recertification requirement for an individual if:

(1) It is determined that there is no reasonable expectation of improvement or significant change in the individual's condition because of the severity of a chronic condition or the degree of impairment of functional capacity; and

(2) The State administering agency, or designee, retains documentation of the reason for waiving the annual recertification requirement.

(d) For purposes of meeting the criterion under paragraph (b) of this section, individuals who qualify for medical assistance under the special home and community-based waiver eligibility group defined at section 1902(a)(10)(A)(ii)(VI) of the Act must meet all section 1915(c) requirements and receive at least one home and community-based waiver service per month.

(e) Individuals receiving services through Community First Choice will not be precluded from receiving other home and community-based long-term care services and supports through other Medicaid State plan, waiver, grant or demonstration authorities.

§ 441.515 Statewideness.

States must provide Community First Choice to individuals:

(a) On a statewide basis.

(b) In a manner that provides such services and supports in the most integrated setting appropriate to the

individual's needs, and without regard to the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life.

§ 441.520 Included services.

(a) If a State elects to provide Community First Choice, the State must provide all of the following services:

(1) Assistance with ADLs, IADLs, and health-related tasks through hands-on assistance, supervision, and/or cueing.

(2) Acquisition, maintenance, and enhancement of skills necessary for the individual to accomplish ADLs, IADLs, and health-related tasks.

(3) Backup systems or mechanisms to ensure continuity of services and supports, as defined in § 441.505 of this subpart.

(4) Voluntary training on how to select, manage and dismiss attendants.

(b) At the State's option, the State may provide permissible services and supports that are linked to an assessed need or goal in the individual's person-centered service plan. Permissible services and supports may include, but are not limited to, the following:

(1) Expenditures for transition costs such as rent and utility deposits, first month's rent and utilities, bedding, basic kitchen supplies, and other necessities linked to an assessed need for an individual to transition from a nursing facility, institution for mental diseases, or intermediate care facility for the mentally retarded to a home and community-based setting where the individual resides;

(2) Expenditures relating to a need identified in an individual's person-centered service plan that increases an individual's independence or substitutes for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

§ 441.525 Excluded services.

Community First Choice may not include the following:

(a) Room and board costs for the individual, except for allowable transition services described in § 441.520(b)(1) of this subpart.

(b) Special education and related services provided under the Individuals with Disabilities Education Act that are related to education only, and vocational rehabilitation services provided under the Rehabilitation Act of 1973.

(c) Assistive devices and assistive technology services, other than those defined in § 441.520(a)(3) of this subpart, or those that meet the requirements at § 441.520(b)(2) of this subpart.

(d) Medical supplies and medical equipment, other than those that meet the requirements at § 441.520(b)(2) of this subpart.

(e) Home modifications, other than those that meet the requirements at § 441.520(b) of this subpart.

§ 441.530 [Reserved]

§ 441.535 Assessment of functional need.

States must conduct a face-to-face assessment of the individual's needs, strengths, preferences, and goals for the services and supports provided under Community First Choice in accordance with the following:

(a) States may use one or more processes and techniques to obtain information, including telemedicine, or other information technology medium, in lieu of a face-to-face assessment if the following conditions apply:

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

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

(3) The individual is provided the opportunity for an in-person assessment in lieu of one performed via telemedicine.

(b) Assessment information supports the determination that an individual requires Community First Choice and also supports the development of the person-centered service plan and, if applicable, service budget.

(c) The assessment of functional need must be conducted at least every 12 months, as needed when the individual's support needs or circumstances change significantly necessitating revisions to the person-centered service plan, and at the request of the individual.

(d) Other requirements as determined by the Secretary.

§ 441.540 Person-centered service plan.

(a) *Person-centered planning process.* The person-centered planning process is driven by the individual. The process—

(1) Includes people chosen by the individual.

(2) Provides necessary information and support to ensure that the individual directs the process to the maximum extent possible, and is enabled to make informed choices and decisions.

(3) Is timely and occurs at times and locations of convenience to the individual.

(4) Reflects cultural considerations of the individual.

(5) Includes strategies for solving conflict or disagreement within the process, including clear conflict-of-interest guidelines for all planning participants.

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

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

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

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

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

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

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

(4) Include individually identified goals and desired outcomes.

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

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

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

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

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

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

(11) Incorporate the service plan requirements for the self-directed model

with service budget at § 441.550, when applicable.

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

(13) Other requirements as determined by the Secretary.

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

§ 441.545 Service models.

A State may choose one or more of the following as the service delivery model to provide self-directed home and community-based attendant services and supports:

(a) *Agency-provider model.* (1) The agency-provider model is a delivery method in which the services and supports are provided by entities, under a contract or provider agreement with the State Medicaid agency or delegated entity to provide services. Under this model, the entity either provides the services directly through their employees or arranges for the provision of services under the direction of the individual receiving services.

(2) Under the agency-provider model for Community First Choice, individuals maintain the ability to have a significant role in the selection and dismissal of the providers of their choice, for the delivery of their specific care, and for the services and supports identified in their person-centered service plan.

(b) *Self-directed model with service budget.* A self-directed model with a service budget is one in which the individual has both a person-centered service plan and a service budget based on the assessment of functional need.

(1) *Financial management entity.* States must make available financial management activities to all individuals with a service budget. The financial management entity performs functions including, but not limited to, the following activities:

(i) Collect and process timesheets of the individual's attendant care providers.

(ii) Process payroll, withholding, filing, and payment of applicable Federal, State, and local employment related taxes and insurance.

(iii) Separately track budget funds and expenditures for each individual.

(iv) Track and report disbursements and balances of each individual's funds.

(v) Process and pay invoices for services in the person-centered service plan.

(vi) Provide individual periodic reports of expenditures and the status of the approved service budget to the individual and to the State.

(vii) States may perform the functions of a financial management entity internally or use a vendor organization that has the capabilities to perform the required tasks in accordance with all applicable requirements of the Internal Revenue Service.

(2) *Direct cash.* States may disburse cash prospectively to individuals self-directing their Community First Choice services and supports, and must meet the following requirements:

(i) Ensure compliance with all applicable requirements of the Internal Revenue Service, and State employment and taxation authorities, including but not limited to, retaining required forms and payment of FICA, FUTA and State unemployment taxes.

(ii) Permit individuals using the cash option to choose to use the financial management entity for some or all of the functions described in paragraph (b)(1)(ii) of this section.

(iii) Make available a financial management entity to an individual who has demonstrated, after additional counseling, information, training, or assistance that the individual cannot effectively manage the cash option described in this section.

(iv) The State may require an individual to use a financial management entity, but must provide the individual with the conditions under which this option would be enforced.

(3) *Vouchers.* States have the option to issue vouchers to individuals who self-direct their Community First Choice services and supports as long as the requirements in paragraphs (b)(2)(i) through (iv) of this paragraph are met.

(c) *Other service delivery models.* States have the option of proposing other service delivery models. Such models are defined by the State and approved by CMS.

§ 441.550 Service plan requirements for self-directed model with service budget.

The person-centered service plan under the self-directed model with service budget conveys authority to the individual to perform, at a minimum, the following tasks:

(a) Recruit and hire or select attendant care providers to provide self-directed Community First Choice services and supports, including specifying attendant care provider qualifications.

(b) Dismiss specific attendant care providers of Community First Choice services and supports.

(c) Supervise attendant care providers in the provision of Community First Choice services and supports.

(d) Manage attendant care providers in the provision of Community First Choice services and supports, which includes the following functions:

(1) Determining attendant care provider duties.

(2) Scheduling attendant care providers.

(3) Training attendant care providers in assigned tasks.

(4) Evaluating attendant care providers' performance.

(e) Determining the amount paid for a service, support, or item, in accordance with State and Federal compensation requirements.

(f) Reviewing and approving provider payment requests.

§ 441.555 Support system.

For each service delivery model available, States must provide, or arrange for the provision of, a support system that meets all of the following conditions:

(a) Appropriately assesses and counsels an individual before enrollment.

(b) Provides appropriate information, counseling, training, and assistance to ensure that an individual is able to manage the services and budgets if applicable.

(1) This information must be communicated to the individual in a manner and language understandable by the individual. To ensure that the information is communicated in an accessible manner, information should be communicated in plain language and needed auxiliary aids and services should be provided.

(2) The support activities must include at least the following:

(i) Person-centered planning and how it is applied.

(ii) Range and scope of individual choices and options.

(iii) Process for changing the person-centered service plan and, if applicable, service budget.

(iv) Grievance process.

(v) Information on the risks and responsibilities of self-direction.

(vi) The ability to freely choose from available home and community-based attendant providers, available service delivery models and if applicable, financial management entities.

(vii) Individual rights, including appeal rights.

(viii) Reassessment and review schedules.

(ix) Defining goals, needs, and preferences of Community First Choice services and supports.

(x) Identifying and accessing services, supports, and resources.

(xi) Development of risk management agreements.

(A) The State must specify in the State Plan amendment any tools or instruments used to mitigate identified risks.

(B) States utilizing criminal or background checks as part of their risk management agreement will bear the costs of such activities.

(xii) Development of a personalized backup plan.

(xiii) Recognizing and reporting critical events.

(xiv) Information about an advocate or advocacy systems available in the State and how an individual can access the advocate or advocacy systems.

(c) Establishes conflict of interest standards for the assessments of functional need and the person-centered service plan development process that apply to all individuals and entities, public or private. At a minimum, these standards must ensure that the individuals or entities conducting the assessment of functional need and person-centered service plan development process are not:

(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) Individuals who would benefit financially from the provision of assessed needs and services.

(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 entity/entities to perform assessments of functional need and develop person-centered service plans in a geographic area also provides HCBS, and the State devises conflict of interest protections including separation of assessment/planning and HCBS provider functions within provider entities, which are described in the State plan, and individuals are provided with a clear and accessible alternative dispute resolution process.

(d) Ensures the responsibilities for assessment of functional need and person-centered service plan development are identified.

§ 441.560 Service budget requirements.

(a) For the self-directed model with a service budget, a service budget must be developed and approved by the State based on the assessment of functional need and person-centered service plan and must include all of the following requirements:

(1) The specific dollar amount an individual may use for Community First Choice services and supports.

(2) The procedures for informing an individual of the amount of the service budget before the person-centered service plan is finalized.

(3) The procedures for how an individual may adjust the budget including the following:

(i) The procedures for an individual to freely adjust amounts allocated to specific services and supports within the approved service budget.

(ii) The circumstances, if any, that may require prior approval by the State before a budget adjustment is made.

(4) The circumstances, if any, that may require a change in the person-centered service plan.

(5) The procedures that govern the determination of transition costs and other permissible services and supports as defined at § 441.520(b).

(6) The procedures for an individual to request a fair hearing under Subpart E of this title if an individual's request for a budget adjustment is denied or the amount of the budget is reduced.

(b) The budget methodology set forth by the State to determine an individual's service budget amount must:

(1) Be objective and evidence-based utilizing valid, reliable cost data.

(2) Be applied consistently to individuals.

(3) Be included in the State plan.

(4) Include a calculation of the expected cost of Community First Choice services and supports, if those services and supports are not self-directed.

(5) Have a process in place that describes the following:

(i) Any limits the State places on Community First Choice services and supports, and the basis for the limits.

(ii) Any adjustments that are allowed and the basis for the adjustments.

(c) The State must have procedures in place that will provide safeguards to individuals when the budgeted service amount is insufficient to meet the individual's needs.

(d) The State must have a method of notifying individuals of the amount of any limit that applies to an individual's Community First Choice services and supports. Notice must be communicated in an accessible format, communicated in plain language, and needed auxiliary aids and services should be provided.

(e) The budget may not restrict access to other medically necessary care and services furnished under the State plan and approved by the State but which are not included in the budget.

(f) The State must have a procedure to adjust a budget when a reassessment indicates a change in an individual's medical condition, functional status, or living situation.

§ 441.565 Provider qualifications.

(a) For all service delivery models:

(1) An individual retains the right to train attendant care providers in the specific areas of attendant care needed by the individual, and to have the attendant care provider perform the needed assistance in a manner that comports with the individual's personal, cultural, and/or religious preferences.

(2) An individual retains the right to establish additional staff qualifications based on the individual's needs and preferences.

(3) Individuals also have the right to access other training provided by or through the State so that their attendant care provider(s) can meet any additional qualifications required or desired by individuals.

(b) For the agency-provider model, the State must define in writing adequate qualifications for providers in the agency model of Community First Choice services and supports.

(c) For the self-directed model with service budget, an individual has the option to permit family members, or any other individuals, to provide Community First Choice services and supports identified in the person-centered service plan, provided they meet the qualifications to provide the services and supports established by the individual, including additional training.

(d) For other models, the applicability of requirements at paragraphs (b) or (c) of this section will be determined based on the description and approval of the model.

§ 441.570 State assurances.

A State must assure the following requirements are met:

(a) Necessary safeguards have been taken to protect the health and welfare of enrollees in Community First Choice, including adherence to section 1903(i) of the Act that Medicaid payment shall not be made for items or services furnished by individuals or entities excluded from participating in the Medicaid Program.

(b) For the first full 12 month period in which the State plan amendment is implemented, the State must maintain or exceed the level of State expenditures for home and community-based attendant services and supports provided under sections 1115, 1905(a), 1915, or otherwise under the Act, to individuals with disabilities or elderly

individuals attributable to the preceding 12 month period.

(c) All applicable provisions of the Fair Labor Standards Act of 1938.

(d) All applicable provisions of Federal and State laws regarding the following:

(1) Withholding and payment of Federal and State income and payroll taxes.

(2) The provision of unemployment and workers compensation insurance.

(3) Maintenance of general liability insurance.

(4) Occupational health and safety.

(5) Any other employment or tax related requirements.

§ 441.575 Development and Implementation Council.

(a) States must establish a Development and Implementation Council, the majority of which is comprised of individuals with disabilities, elderly individuals, and their representatives.

(b) States must consult and collaborate with the Council when developing and implementing a State plan amendment to provide Community First Choice services and supports.

§ 441.580 Data collection.

A State must provide the following information regarding the provision of home and community-based attendant services and supports under Community First Choice for each Federal fiscal year for which the services and supports are provided:

(a) The number of individuals who are estimated to receive Community First Choice services and supports under this State plan option during the Federal fiscal year.

(b) The number of individuals who received the services and supports during the preceding Federal fiscal year.

(c) The number of individuals served broken down by type of disability, age, gender, education level, and employment status.

(d) The specific number of individuals who have been previously served under sections 1115, 1915(c) and (i) of the Act, or the personal care State plan option.

(e) Data regarding how the State provides Community First Choice and other home and community-based services.

(f) The cost of providing Community First Choice and other home and community-based services and supports.

(g) Data regarding how the State provides individuals with disabilities who otherwise qualify for institutional care under the State plan or under a waiver the choice to receive home and community-based services in lieu of institutional care.

(h) Data regarding the impact of Community First Choice services and supports on the physical and emotional health of individuals.

(i) Other data as determined by the Secretary.

§ 441.585 Quality assurance system.

(a) States must establish and maintain a comprehensive, continuous quality assurance system, described in the State plan amendment, which includes the following:

(1) A quality improvement strategy.

(2) Methods to continuously monitor the health and welfare of each individual who receives home and community-based attendant services and supports, including a process for the mandatory reporting, investigation, and resolution of allegations of neglect, abuse, or exploitation in connection with the provision of such services and supports.

(3) Measures individual outcomes associated with the receipt of home and community-based attendant services and supports as set forth in the person centered service plan, particularly for the health and welfare of individuals receiving such services and supports. These measures must be reported to CMS upon request.

(4) Standards for all service delivery models for training, appeals for denials and reconsideration procedures for an individual's person-centered service plan.

(5) Other requirements as determined by the Secretary.

(b) The State must ensure the quality assurance system will employ methods that maximizes individual independence and control, and provides information about the provisions of quality improvement and assurance to each individual receiving such services and supports.

(c) The State must elicit and incorporate feedback from individuals and their representatives, disability organizations, providers, families of disabled or elderly individuals, members of the community and others to improve the quality of the community-based attendant services and supports benefit.

§ 441.590 Increased Federal financial participation.

Beginning October 1, 2011, the FMAP applicable to the State will be increased by 6 percentage points, for the provision of Community First Choice services and supports, under an approved State plan amendment.

Authority

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

Dated: April 24, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 24, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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