

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 441

[CMS-2229-F]

RIN 0938-AO52

Medicaid Program; Self-Directed Personal Assistance Services Program State Plan Option (Cash and Counseling)

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

ACTION: Final rule.

SUMMARY: This final rule provides guidance to States that want to administer self-directed personal assistance services through their State Plans, as authorized by the Deficit Reduction Act of 2005. The State plan option allows beneficiaries, through an approved self-directed services plan and budget, to purchase personal assistance services. The rule also provides guidance to ensure beneficiary health and welfare and financial accountability of the State Plan option.

DATES: *Effective date:* November 3, 2008.

FOR FURTHER INFORMATION CONTACT: Marguerite Schervish, (410) 786-7200.

SUPPLEMENTARY INFORMATION:

I. Background

A. Section 6087 of the Deficit Reduction Act of 2005

The Deficit Reduction Act (DRA) of 2005 was enacted into law on February 8, 2006 (Pub. L. 109-171). Section 6087 of the DRA provided for a new State Plan option that is built on the experiences and lessons learned from the disability rights movement and States that pioneered self-direction programs. Self-direction is an important component of independence, as it promotes quality, access, and choice.

Specifically, section 6087 of the DRA amended section 1915 of the Social Security Act (the Act) to add new paragraph (j). Section 1915(j)(1) of the Act would allow a State the option to provide, as "medical assistance," payment for part or all of the cost of self-directed personal assistance services (PAS) provided pursuant to a written plan of care to individuals for whom there has been a determination that, but for the provision of such services, the individuals would require and receive State Plan personal care services, or section 1915(c) home and

community-based waiver services. Section 1915(j)(1) of the Act also expressly excludes Medicaid payment for room and board. Finally, section 1915(j)(1) of the Act requires that self-directed PAS may not be provided to individuals who reside in a home or property that is owned, operated, or controlled by a provider of services, not related by blood or marriage.

Section 1915(j)(2) of the Act sets forth five assurances that States must provide in order for the Secretary to approve self-directed PAS under this State Plan option. First, States must assure that necessary safeguards are in place to protect the health and welfare of individuals provided services under this State Plan option, and to assure the financial accountability for funds expended with respect to such services. Second, States must assure the provision of an evaluation of the need for State Plan personal care services, or personal services under a section 1915(c) waiver. Third, States must assure that individuals who are likely to require State Plan personal care services, or section 1915(c) waiver services, are informed of the feasible alternatives to the self-directed PAS State Plan option (if available) such as personal care under the regular State Plan option or personal assistance services under a section 1915(c) waiver program. Fourth, States must assure that they provide a support system that ensures that participants in the self-directed PAS program are appropriately assessed and counseled prior to enrollment and are able to manage their budgets. Fifth, States must assure that they will provide to the Secretary an annual report on the number of individuals served under the State Plan option and the total expenditures on their behalf in the aggregate. States must also provide an evaluation of the overall impact of this new option on the health and welfare of participating individuals compared to non-participants every 3 years.

Section 1915(j)(3) of the Act indicates that States that offer self-directed PAS under this State Plan option are not subject to the statewideness and comparability requirements of the Act. Section 1915(j)(4)(A) of the Act defines self-directed PAS to mean personal care and related services under the State Plan, or home and community-based waiver services under a section 1915(c) waiver, provided to a participant eligible under this self-directed PAS State Plan option. Furthermore, the statute states that within an approved self-directed services plan and budget, individuals can purchase personal assistance and related services and hire,

fire, supervise, and manage the individuals providing such services.

Section 1915(j)(4)(B) of the Act gives States the option to permit participants to hire any individual capable of providing the assigned tasks, including legally liable relatives, as paid providers of the services. The statute also gives States the option to permit participants to purchase items that increase independence or substitute for human assistance to the extent that expenditures would otherwise be made for the human assistance.

Section 1915(j)(5) of the Act sets forth the requirements for an "approved self-directed services plan and budget." Section 1915(j)(5)(A) of the Act authorizes the individual or a defined representative to exercise choice and control over the budget, planning, and purchase of self-directed PAS, including the amount, duration, scope, provider, and location of service provision. Section 1915(j)(5)(B) of the Act requires an assessment of participants' needs, strengths, and preferences for PAS. Section 1915(j)(5)(C) of the Act requires States to develop a service plan based on the assessment of need using a person-centered planning process. Section 1915(j)(5)(D) of the Act requires States to develop and approve a budget for participants' services and supports based on the assessment of need and service plan and on a methodology that uses valid, reliable cost data, is open to public inspection, and includes a calculation of the expected cost of such services if those services were not self-directed. The budget may not restrict access to other medically necessary care and services furnished under the State Plan and approved by the State but not included in the budget.

Section 1915(j)(5)(E) of the Act requires that there are appropriate quality assurance and risk management techniques used in establishing and implementing the service plan and budget that recognize the roles and responsibilities in obtaining services in a self-directed manner and assure the appropriateness of such plan and budget based upon the participant's resources and capabilities.

Section 1915(j)(6) of the Act indicates that States may employ a financial management entity to make payments to providers, track costs, and make reports. Payment for the activities of the financial management entity shall be at the administrative rate established in section 1903(a) of the Act.

Note: CMS released a pre-print for use by States, at their discretion, to submit a State plan section 1915(j) amendment, which was approved under OMB #0938-1024.

B. History of Self-Direction

The Independent Living movement in the 1960s was premised on the concept that people with disabilities should have the same civil rights, options, and control over choices in their own lives as do people without disabilities, and that individuals with cognitive impairments should not be prohibited from exercising control over their lives. One mechanism that allows individuals to exercise more involvement, control, and choice over their lives is self-directed care. Self-directed care is a service delivery mechanism that empowers individuals with the opportunity to select, direct, and manage their needed services and supports identified in an individualized service plan and budget plan. Self-direction is not a service, but rather an alternative to the traditional service delivery model whereby a worker hired by the Medicaid recipient will furnish the Medicaid service to the Medicaid recipient and the Medicaid recipient retains the control and authority over who provides the services, how the services are provided, the hours they work, and their rate of pay.

Two national pilot projects demonstrated the success of self-directed care. During the mid-1990s, the Robert Wood Johnson Foundation awarded grants to develop self-determination in 19 States. These projects primarily evolved into Medicaid-funded programs under the section 1915(c) home and community-based services waiver authority. In the late 1990s, the Robert Wood Johnson Foundation again awarded grants to develop the "Cash & Counseling" national demonstration and evaluation project in three States. These projects evolved into demonstration programs under the section 1115 authority of the Act.

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 worker turnover, and maximized the efficient use of community services and supports.

On February 1, 2001, the President announced the *New Freedom Initiative*, which included the following three elements: promoting full access to community life through efforts to implement the Supreme Court's decision in *Olmstead v. L.C.*, 527 U.S. 581 (1999) ("*Olmstead*"), integrating

Americans with disabilities into the workforce with programs under the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA) (Pub. L. 106–170, enacted on December 19, 1999), and creating the National Commission on Mental Health. The President subsequently expanded this initiative through *Executive Order 13217* (June 18, 2001) by directing Federal agencies to work together to "tear down the barriers" to community living by developing a government-wide framework for providing elders and people with disabilities the supports necessary to learn and develop skills, engage in productive work, choose where to live, and fully participate in community life.

On May 9, 2002, as part of its response to the *New Freedom Initiative*, the Department of Health and Human Services unveiled the *Independence Plus* templates and the initiative to help States broaden their ability to offer individuals the opportunity to maximize choice and control over services in their own homes and communities. The Department developed two templates that allowed States to choose different self-directed design features to satisfy their unique programs. The section 1115 demonstration template was developed for States that wanted to permit individuals to receive a prospective cash allowance equivalent to the amount of their Medicaid personal care benefit. Under the section 1115 authority, individuals could directly manage their cash allowance and direct the purchases of their personal care and related services and goods. For those States not wanting to offer the cash allowance, a section 1915(c) home and community-based services waiver template was developed. The section 1915(c) waiver template allowed Medicaid recipients to self-direct a wide array of services, so long as these services are required to keep a person from being institutionalized in a hospital, nursing facility or intermediate care facility for the mentally retarded (ICF-MR).

However, a program was only given the *Independence Plus* designation when a State demonstrated a strong commitment to self-direction by developing a comprehensive program that offered a person-centered planning process, individualized budgeting, self-directed supports including financial management services, and a quality assurance and improvement plan. The intended purposes of the *Independence Plus* Initiative were to:

- Delay or avoid institutional or other high cost out-of-home placement by

strengthening supports to individuals or families.

- Recognize the essential role of the individual or family in the planning and purchasing of health care supports and services by providing individual or family control over an agreed upon resource amount.

- Encourage cost effective decision-making in the purchase of supports and services.

- Increase individual or family satisfaction through the promotion of self-direction, control, and choice—a major theme expressed during the New Freedom Initiative—National Listening Session.

- Promote solutions to the problem of worker availability.

- Provide supports including financial management services to support and sustain individuals or families as they direct their own services.

- Assist States with meeting their legal obligations under the Americans with Disabilities Act (ADA) and the U.S. Supreme Court's *Olmstead* decision.

- Provide flexibility for States seeking to increase the opportunities afforded individuals and families in deciding how best to enlist or sustain home and community services.

A new section 1915(c) waiver application was also developed effective spring 2005 that incorporates our requirements for an *Independence Plus* program.

In 2003 we awarded 12 systems change grants to States for the development of *Independence Plus* programs. On October 7, 2004, the Robert Wood Johnson Foundation awarded a second round of "Cash & Counseling" grants to 11 States to develop *Independence Plus* programs using either the section 1915(c) waiver or section 1115 demonstration application. As of March 20, 2006, 15 States had 17 approved *Independence Plus* programs. In addition, there were 2 other States that included self-direction options in their section 1115 demonstrations and a multitude of States that offered self-directed program options in their section 1915(c) home and community-based services waiver programs.

This final rule finalizes provisions set forth in the January 18, 2008 proposed rule.

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

We received a total of 55 timely comments from home care agencies and provider associations, State Medicaid directors, home care providers, unions, beneficiaries, and other individuals and

professional associations. The comments ranged from general support or opposition to the proposed provisions to very specific questions and detailed comments regarding the proposed changes. A summary of our proposals, the public comments, and our responses are set forth below.

General

Comment: Several commenters expressed support for the rule and the options, rights, support, and safeguards the provisions gave to participants. One commenter was appreciative of the possibility to be able to hire a caregiver of her own choosing. Another commenter stated that her “hard to serve” clients were satisfied with hiring persons of their choosing and that another client was able to get more hours of “flexible” care to fit her individualized needs and wishes.

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

Comment: Several commenters indicated opposition to the self-directed service delivery model. Some commenters stated that the model was not appropriate for most Medicaid beneficiaries. Other commenters were concerned that under the self-directed delivery model, caregivers were inadequately trained, that there was insufficient oversight of the care being provided beneficiaries, and that the potential for fraud, abuse, neglect, and exploitation increased.

Response: We disagree that the self-directed service delivery model is an inappropriate model. Our experience with programs that offer self-direction in section 1915(c), home and community-based services waiver programs and section 1115 demonstration programs, has confirmed the positive results found in the formal evaluation of the “Self-Determination” and “Cash & Counseling” projects. These programs successfully offered the self-directed service delivery model to children, older persons, and persons with cognitive impairments, developmental disabilities, and mental health needs. This final rule requires numerous participant safeguards, including the requirement for a support system that provides information about self-direction, as well as any counseling, training and assistance that may be needed or desired by participants to effectively manage their services and budgets. Key components of the support system are the support brokers and consultants who help participants perform tasks (for example, locating and accessing needed services, developing a service budget plan, and monitoring the

beneficiary’s management of the PAS and budget). Additionally, the support system includes financial management services entities that perform, or assist participant beneficiaries who have elected the cash option to perform, the employer-related and tax responsibilities. States may also add other activities that they deem necessary or appropriate in their support systems.

Other participant protections include requirements for an assessment of the individual’s needs, strengths, and preferences for self-directed PAS; the use of a representative when needed; a person-centered planning process that engages the individual and also involves the individual’s family, friends, and professionals in the planning or delivery of services or supports; a quality assurance and improvement plan; and individualized backup plans that address critical contingencies or incidents that would pose a risk of harm to the participant’s health and welfare. We also require that States have in place a risk management system that identifies potential risks to the participant and employs tools or instruments (for example, criminal and worker background checks) to mitigate risks. The statute and this final rule further require States to assure that necessary safeguards have been taken to protect the health and welfare of individuals furnished services under this program and to assure financial accountability for the funds expended for self-directed services.

Comment: Some commenters requested clarification about the impact of funds paid to legally liable relatives, including a parent-caregiver, on the individual’s or family’s resources for other public benefit programs. The commenters urged that CMS work with other Federal partners to ensure that the receipt of cash would not jeopardize other public benefit programs and that we work to enact needed changes through legislation.

Response: The scope of this regulation does not extend to the impact of funds paid to legally liable relatives on their receipt of public benefits. However, we will take under advisement the suggestion of working with other agencies to address the impact of the cash option on the receipt of other public benefits.

Comment: One commenter sought clarification on whether CMS will require a State that has already implemented elements of self-direction under its State plan and waivers to modify these existing programs or submit a State plan amendment in compliance with the new rule. This same commenter sought clarification on

whether the section 1915(j) option would be the exclusive authority for self-directed services or whether States may pursue or rely on other Medicaid authorities.

Response: We have not required and do not intend to require any State to submit a section 1915(j) State plan amendment, nor is the section 1915(j) opportunity the exclusive opportunity for a State to pursue the self-directed service delivery model. States are free to use some, all, or none of the appropriate Medicaid authorities that are available for use of the self-directed service delivery model.

Comment: One commenter requested clarification on the impact of the rule on a participant’s eligibility for self-directed PAS, generally focusing on the interaction with a section 1915(c) waiver program. The commenter requested clarification on the following:

(1) Whether a participant may receive a budget for self-directed PAS and concurrently receive waiver services, or whether States may limit or deny access to waiver services.

(2) Whether waiver recipients who elect the self-directed PAS service option are considered enrolled in the waiver, and whether waiver “slots” must be set aside for persons who may disenroll from the option.

(3) Whether CMS intends to allow States to cover services beyond personal care and items that increase independence or substitute for human assistance.

(4) Whether individuals who are eligible for section 1915(c) waiver services under the special income group may be eligible for the self-directed PAS State plan option.

(5) Whether the individual would have to maintain enrollment in a waiver and what threshold is required to maintain that enrollment (for example, meeting the level of care criteria, having a plan of care, or receiving a waiver service on a periodic basis).

Response: Our response follows the order of the commenter’s questions as noted above.

(1) It is permissible for an individual to participate in the self-directed PAS State plan option and concurrently receive services under a section 1915(c) waiver program as a State can select which of the section 1915(c) waiver services participants will have the opportunity to self-direct. It is not permissible to limit or deny a participant the other section 1915(c) waiver services for which the participant is eligible but not self-directing. Specifically, 42 CFR 441.472(d) requires that the “budget may not restrict access to other

medically-necessary care and services furnished under the plan and approved by the State but not included in the budget.”

(2) Participants who elect the self-directed PAS State plan option may remain “enrolled” in their section 1915(c) waiver program and their so-called “slots” must be kept available in the event the participant voluntarily disenrolls or is involuntarily disenrolled from the self-directed PAS State plan option.

(3) When a State offers the opportunity to self-direct State plan personal care services (PCS), we do not believe it would be permissible for participants to purchase services that are not included within the State’s definition of its PCS benefit. However, we recognize that both the statute and regulation at § 441.470(d) allow a State, at the State’s election, to offer participants the opportunity to reserve funds to purchase items that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for human assistance, including additional goods, supports, services, or supplies. We intend to issue further guidance on the criteria for permissible purchases to assist States in deciding the scope of the permissible purchases in their self-direction programs. We believe that, at a minimum, the permissible purchase must relate to a need or goal identified in the service plan.

(4) Individuals who are eligible for section 1915(c) home and community-based waiver services under the special income group may be eligible for the self-directed PAS State plan option.

(5) A participant would have to maintain all eligibility, level of care, and other requirements for the section 1915(c) waiver program. If, upon reassessment, a participant would no longer be eligible for the section 1915(c) waiver services through which the participant was able to self-direct their PAS, then the participant would no longer be able to self-direct their PAS under this State plan option.

Comment: Some commenters stated that they believe that the self-directed service delivery model would reduce the viability of agencies that deliver traditional agency-delivered services especially in rural or difficult to serve areas, would force individuals into a more expensive option, such as a skilled nursing facility (SNF) or hospital, and would delay hospital discharges and would force more agencies to only serve private pay clients.

Response: The evaluations conducted on the “Self-Determination” and the

“Cash & Counseling” national projects have provided evidence of consumer satisfaction and quality of care. In addition, our experience with the section 1115 demonstration and section 1915(c) waiver programs has not shown this impact on traditional agency-delivered services. Therefore, we do not believe that the consequences noted in the comments regarding the self-directed service delivery model are necessarily predicted outcomes.

Comment: One commenter disagreed that the self-directed service delivery model costs less than traditional agency-delivered services.

Response: We have not asserted that the self-directed PAS State plan option costs less than the traditional agency-delivered service model. Two national pilot projects demonstrated the success of the self-directed service delivery model. The “Self-Determination” and the “Cash & Counseling” national projects were evaluated in a scientifically designed study. The evaluation results of those projects were similar and concluded that 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 worker turnover; and maximized the efficient use of community services and supports. The results did not necessarily confirm that self-directed care costs less. For example, the results in the “Cash & Counseling” States indicated that Medicaid personal care costs were somewhat higher under “Cash & Counseling”, mainly because enrollees received more of the care they were authorized to receive, as compared to the services delivered under the traditional agency model. Another finding was that increased Medicaid personal care costs under “Cash & Counseling” were partially offset by savings in institutional and other long-term-care costs. Furthermore, the findings also suggested that “Cash & Counseling” need not cost more than traditional programs if states carefully design and monitor their programs. For example, States could design their “Cash & Counseling” programs so that the cost per month is budgeted to match the cost per month of its traditional system, assuming that home care agencies will fully meet their care obligations. If the traditional system delivers the services beneficiaries are authorized to receive, there should be no difference in planned costs.

Comment: Two commenters expressed concern that the proposed rule added too many additional

administrative requirements that would be burdensome or costly to States. One commenter thought that the rule would eliminate the efficiencies intended by the Congress.

Response: We acknowledge that States that have not yet developed the infrastructure necessary to support the self-directed service delivery model, in particular developing a support system, may experience higher initial administrative burdens and costs when designing their self-directed PAS programs. Regardless of whether a State uses its self-directed PAS State plan option, a section 1915(c) home and community-based services waiver option, or a section 1915(i) home and community-based services State plan option to offer the self-directed service delivery model, there will be administrative and support system requirements, and State Medicaid agencies must exercise administrative and oversight functions over their Medicaid programs.

Basis, Scope & Definitions (§ 441.450)

We proposed to implement section 1915(j) of the Social Security Act (the Act) concerning the self-directed PAS option through a State plan. We proposed that individuals who self-direct their PAS under this option have the decision-making authority to identify, access, manage, and purchase their PAS including a proposed list of minimum activities over which the individuals may exercise decision-making authority. We proposed several definitions specific to the self-directed PAS State plan option.

Comment: One commenter recommended that CMS add a reference to “or their representative(s)” whenever the rule refers to individuals or participants.

Response: We agree with the comment because the use of a representative to assist the individual or participant in exercising their decision-making authority is consistent with the self-directed service delivery model. Accordingly, we have revised the part 441, subpart J in relevant places by adding “or their representatives” when we refer to “individuals” or “participants.”

Comment: A few commenters suggested that CMS add “training” of the PAS providers to the list of items subject to the participant’s authority in § 441.450(b) and that participants have access to training provided by or through the State.

Response: We agree with the comment about adding “training” to the list of items subject to the participant’s authority because the ability of a

participant to train the provider of their PAS in the participant's needs and in a manner that comports with the participant's preferences is crucial to the self-directed service delivery model. Accordingly, we have revised the authority provision at § 441.450(b)(4) to expressly include the ability of the participant to train their workers. We also believe that there are circumstances in which participants may desire that their PAS providers secure additional training beyond what the participants can provide. Accordingly, we have further revised the authority provision at § 441.450(b)(4) to permit participants to have access to other training provided by or through the State so that their PAS providers can meet any additional qualifications that participants think their providers may need.

Comment: Some commenters thought that § 441.450(b) should be revised to include the ability of the participant to select his or her own financial management services (FMS) entity and his or her own supports brokers or consultant.

Response: We believe that the services of the FMS entities are administrative functions and that States have the authority to determine whether or not to limit the FMS entities that will provide the FMS functions. We believe that the functions of a supports broker or consultant comprise a service that is unique to this State plan option and, as such, recognize that States would want to be able to claim Federal medical assistance percentages (FMAP) for this service. The supports broker or consultant performs a variety of key functions that include the provision of information, counseling, training and assistance, or helping participants access needed information, counseling, training and assistance to help participants effectively manage their PAS. Typically, they may assist participants in locating and accessing needed services, developing service budget plans and helping participants to fulfill their roles and responsibilities as an employer. Based on our experience with self-direction programs under section 1115 demonstrations or section 1915(c) waiver programs, we have learned that participants desired the opportunity to select a different supports broker or consultant if the relationship between an assigned supports broker or consultant and the participant was not satisfactory. We have revised the rule at § 441.450(c) to add a definition for "supports broker" or "consultant." Further detail on the definition is provided in response to another comment.

Comment: Some commenters expressed disagreement with the requirement that participants are allowed to determine the amount paid for a service, support, or item stating that a State law or collective bargaining agreement could conflict with this authority. One commenter thought that this requirement was inconsistent with the statutory language and congressional intent and would deprive States of their "traditional wage standard-setting role." Another commenter asked for clarification on how the requirement comports with State plan rate-setting requirements, including the requirement that there must be public notice of any significant proposed change in methods and standards for setting payment rates.

Response: We believe that the statutory authority contemplates including participants in the decision-making authority over the amount paid for a service, support or item. We believe that only a few States have actually set the precise wages for participants of self-direction programs. Indeed, we believe that most States reimburse varying amounts even for services provided by traditional service models. We further note that the requirement for public notice applies to rates paid by the Medicaid agency for services. In the case of self-directed services, it would be the budget amount upon which Medicaid reimbursement would be based. The rate that the participant pays their provider of PAS from the available budgeted amount is outside the scope of the requirement for public notice of Medicaid rate setting.

Comment: One commenter was confused about the apparent multiple meanings for the word "support" or "supports." The commenter suggested that we amend the rule to clarify that the State has the discretion to limit supports that are beyond the State's obligation, such as repeated counseling, training, and assistance sessions.

Response: To clarify, in the context of self-directed PAS, "supports" generally means a service or item that a participant can purchase and "support" generally means the information, counseling, training, or assistance provided under the support system, including that provided by a support broker or consultant. We disagree that the regulation needs further amending to allow the State to provide limits to the PAS supports. If participants demonstrate that they cannot effectively manage their PAS or budgets, the rule provides States with options such as offering additional assistance, including FMS; mandating the use of a representative; or involuntarily

disenrolling a participant from the self-directed PAS option.

Comment: One commenter requested clarification about how the requirement that States have a mechanism that satisfies the Medicaid requirements on provider agreements would apply when vendors furnish items and supplies. It is unclear who the "enrolled provider" is when services, items, or supplies are purchased with cash.

Response: As self-directed PAS is not "cash assistance" but rather is a service delivery model, the requirements on provider agreements at section 1902(a)(27) of the Act would not be a barrier if a State elected the cash option.

Comment: One commenter thought the definition of "assessment of need" was too vague. The commenter recommended use of a standardized assessment instrument.

Response: We believe the definition of "assessment of need" is adequate. We acknowledge that a standardized assessment instrument could lead to more uniformity in determining an individual's PAS needs and encourage their use where possible. However, it may not be useful in determining the strengths, personal goals, and preferences of the individual for PAS which is essential in a self-directed service delivery model. Accordingly, we are not amending the definition of "assessment of need" to require States to use a standardized assessment instrument, but recognize a State may nonetheless choose to do so.

Comment: Some commenters suggested language to be included in the definition of "individualized backup plans." The recommended language included additional language for the following areas: respecting the individual's choices and preferences, planning for emergency preparedness, and a State assessment of worker shortage that could possibly impact the ability of an agency to provide back-up care, and if a shortage exists, require that the individual cannot enroll unless a backup plan can be developed that relies on family, personal, and available community services.

Response: We agree with the comment that an individualized backup plan has to respect the individual's choices and preferences and not substitute the individual's choices with those of others who may be participating in the development of the backup plan. We believe that this is consistent with the "dignity of risk" concept that recognizes as individuals experience greater choice and control, they may also desire to assume more of the responsibilities and risks associated with the provision of their PAS. The

individualized backup plan is related to the provisions of the rule at § 441.476 on risk management and should occur as part of the discussion about the risks an individual is willing and able to assume. As it is of utmost importance that the backup plan is individually tailored to the individual's needs and preferences, we believe that a State or regional approach that treats all participants' contingencies the same by imposing a requirement that participants should simply contact 911 emergency services in the event of a critical contingency or incident, is not a sufficiently individualized backup plan. We have revised the definition of "individualized backup plan" in § 441.450(c) to clarify that the individualized backup plan must demonstrate an interface with the risk management provision at § 441.476 which requires States to assess and identify the potential risks to the participant (such as any critical health needs), and ensure that the risks and how they will be managed are the result of discussion and negotiation among persons involved in the service plan development. We have also revised the definition to include that the backup plan must be individualized as well as not include a 911 emergency system or other emergency system as the sole backup feature of the plan.

We also agree that emergency preparedness may be a part of the individualized backup planning; however, we must stress that these two things are not the same. We view "emergency preparedness" as addressing the contingency of a natural disaster or other similar catastrophic disaster and planning for how the participant will be secured or evacuated to safety. We view the "individualized backup plan" as a much broader participant protection than emergency preparedness. We view the individualized backup plan as a cornerstone to self-directed PAS because it sets forth the participant's wishes in a critical contingency or incident that would pose a risk of harm to the participant's health or welfare. While "emergency preparedness" can be part of an individualized backup plan, we do not believe additional language is necessary for it to be included.

We disagree with the comment that individuals should not be permitted to enroll in the self-directed PAS State plan option if an individualized backup plan cannot be developed which relies on family, personal, and available community services. While we are aware that some individuals who select the self-directed State plan option will

not have access to family and personal resources or to community resources, in these instances, the supports broker or consultant would help the individual locate and access the providers of PAS needed by the individual. If, after reasonable effort by the supports broker or consultant, it is not possible to locate providers of PAS suitable to the individual, then it would be permissible to delay the individual's enrollment in the self-directed PAS option until such time as suitable providers of their PAS can be found. We do not believe that the definition of "individualized backup plan" needs to be revised to reflect this procedure because the definition of "supports broker or consultant" indicates that one of the roles of the supports broker or consultant is to help an individual locate and access needed PAS, if necessary.

Comment: We invited comments on other possible relationships that could be included within the definition of "legally liable relatives" (LLRs). One commenter thought that "significant others" should be included in the definition. Some commenters suggested that we amend the rule to include provider training requirements and other safeguards. Another commenter suggested that we amend the regulation to require States to have a mechanism to deal with situations in which participants may be pressured to hire a family member or friend or are having difficulty discharging a family member or friend.

Response: We disagree that the definition should be revised to include "significant others." We believe it is up to the States to determine what relationships they include in their definition of "legally liable relatives". We also disagree that the regulation should be revised to specify certain safeguards, such as minimum training requirements, competency evaluations, criminal background checks, or other modifications to ensure that PAS workers, including LLRs, are properly trained and qualified to perform the functions of their jobs. One of the most valued aspects of a self-directed program is that participants have the authority to train their providers of PAS in what they need and how to deliver the PAS in accordance with their personal, cultural, and religious preferences. As noted previously, we have revised the regulation at § 441.450 to permit participants to have access to other training provided by or through the State so that their PAS providers can meet any additional qualifications that participants think are needed or desired. Accordingly, we do not believe that the rule needs to be revised to specify

provider training requirements as this will vary from participant to participant. We further do not believe that the regulations need to be revised to require that States have a mechanism to deal with situations in which participants may be pressured to hire a family member or friend or where they are having difficulty discharging a family member or friend. The role of the supports broker or consultant is to assist the participant in managing their PAS and budget plans, including how to hire the person most suitable to the participant, and how to discharge the worker if necessary. Finally, as noted above, we do not believe the regulation needs to be revised to add more safeguards to detect whether needed services are actually being provided. We believe that the regulation provides sufficient participant protections to detect whether needed services are actually being provided. It is CMS' expectation that participants' services and budget plans will be monitored by supports brokers or consultants; that the FMS entities, as required in the rule, will report any irregularities detected to participants and States; and that the State Medicaid agency will exercise ongoing oversight and monitoring of the provision of PAS through its Quality Assurance and Improvement Plan and remediate any problematic issues for participants.

Comment: One commenter noted that the definition of "self-direction" did not acknowledge that participants who self-direct their PAS must have the ability to perform the required roles and responsibilities. Another commenter sought further clarification of the definition of "self-direction." The commenter stated that a clarification may be needed to ensure that the maximum amount and scope of a person's budget will not exceed the level of services determined by the assessment or the budget established by the valid budget methodology.

Response: The self-directed service delivery model does not presume who can and cannot self-direct their PAS. Instead, the model requires that the participant is assessed for their need for PAS, and furnished the necessary information, counseling, training, and assistance so that the participant can manage his services and budget. In addition to the support system, the regulations provide several other mechanisms that enable participants to manage their services and budgets such as the use of a representative to assist the participant to exercise his decision-making authority over the services and budget. If a participant is no longer able or willing to self-direct their PAS, the

State is allowed to require additional assistance for the participant, mandate the use of a representative, or, if need be, involuntarily disenroll the participant. Therefore, we have not revised the regulation as we do not believe any clarification is necessary. Moreover, the regulation at § 441.470 clearly sets out the steps for determining a participant's budget amount such that we do not believe that the budget will exceed the level of needed PAS.

Comment: A few commenters had concerns about the definition of the "service plan." One commenter suggested that the definition not require unpaid caregivers to attend the planning meeting, but instead, provide the service hours that are included in the service plan. One commenter cautioned against a reduction in the budget based on an erroneous assumption that informal support is available and another sought minimum qualifications for those responsible for development of the service plan.

Response: The definition of "service plan" permits the participant to direct the planning process, including inviting the participant's family or others of the participant's choosing to the planning meeting. This is not a requirement, however. In addition, we believe it would be inappropriate to revise the definition to require any minimum qualifications of individuals responsible for development of the service plan as States should have the flexibility to craft their own requirements. However, we acknowledge that there may be a "lead" person who will assume responsibility for assuring that the planning meetings occur and that the resultant plan meets the regulatory requirements. We would expect that this individual or individuals would minimally be familiar with person-centered and directed planning and person-centered services, and preferably possess demonstrated skill to facilitate person-centered and directed planning. We wish to clarify that our reference to persons who are "required" to attend the planning meeting was to include those persons who may be required by the State to attend the person-centered planning meeting. We did not intend to suggest that the participant should require the attendance of family, friends, or others who do not wish to participate in the meeting. Finally, we agree that the service budget should not be reduced based on an erroneous assumption about the level of service that an informal caregiver would be providing.

Comment: Two commenters indicated that the requirements for a comprehensive assessment, care

planning, health and welfare assurances, and monitoring appear to meet the definition of case management as defined in section 6052 of the DRA, Optional State Plan Case Management Services. They also requested clarification on whether a participant who elects this option will be unable to receive any other type of case management covered by Medicaid. One commenter asked how States would reconcile the requirements of the self-directed PAS State plan option final rule with section 6052 of the DRA. For example, as outlined in the January 18, 2008 self-directed PAS State plan option proposed rule, CMS "requires case management services under self-directed PAS," but the case management provision of the DRA prohibits States from requiring beneficiaries to receive case management. Furthermore, the commenter suggested that the self-directed PAS State plan option proposed rule requires "gate-keeping" and advocacy functions but the case management DRA provision requires these functions to be separated by payment source and beneficiaries to be allowed to select from all qualified providers. One commenter asked how CMS could require a case manager to monitor the participant's service plan under the self-directed PAS State plan option, if, as stated in the case management DRA provision, the State cannot bill for services defined as "case management" as administrative or other services.

Response: We believe that the functions that are required of the supports broker or consultant are not "case management" within the definition of case management provided pursuant to section 1915(g)(2) of the Act, as revised by section 6052 of the DRA. Section 1915(g)(2) of the Act defines case management services for purposes of section 1915(g) of the Act as services that will "assist individuals eligible under the State plan in gaining access to needed medical, social, educational, and other services." Case management includes the following: Assessment of an eligible individual to determine service needs, including activities that focus on needs identification; development of a specific care plan based on the information collected through the assessment; referral and related activities to help an individual obtain needed services, including activities that help link the eligible individual with medical, social, educational providers, or to other programs and services that are capable of providing needed services; and

monitoring and follow-up activities, including activities and contacts that are necessary to ensure that the care plan is effectively implemented and adequately addresses the needs of the eligible individual.

We believe that the relationship between a supports broker or consultant and a participant and the assistance provided by the supports broker or consultant in the self-directed PAS State plan option is fundamentally different than the relationship required between a case manager and beneficiary and the assistance provided by a case manager. Supports brokers or consultants are agents of the participants in that they are primarily responsible for facilitating participants' needs in a manner that comports with the participants' preferences. As the relationship that develops must be supportive and ongoing, participants may request a different supports broker or consultant if the relationship is not working out. Furthermore, the functions performed by supports brokers or consultants are unique to the self-directed service delivery model because supports brokers or consultants are primarily responsible for providing information, training, and counseling and assistance, as desired by participants, that help participants effectively manage their PAS and budgets. These functions include helping participants develop their service budget plans and fulfill their employer-related responsibilities. This assistance can also include helping participants locate and access PAS, but supports brokers or consultants do not perform assessments of need or develop care plans. Although supports brokers or consultants do perform a monitoring function for the purpose of checking whether participants' health status has changed, they are also verifying whether expenditures of funds are being made in accordance with the service budget plans.

Because of the unique position of a supports broker or consultant under the self-directed PAS State plan model, we believe that a traditional case manager can perform the functions of supports brokers or consultants only if they receive training in the self-directed service delivery model that includes a demonstrated capacity to understand that they are to assist the participants with fulfilling their preferences, and not supplant the participants' preferences with their views or preferences. As evidenced by the comment, it is important to avoid confusion between the functions of a supports broker or consultant and the services furnished by a case manager, and we believe a definition of supports broker or

consultant would clarify the functions. Accordingly, we have revised § 441.450(c) to add a definition of supports broker and consultants that reflects the unique role and functions of the supports broker or consultant; that requires States to develop a protocol to ensure that supports brokers or consultants are accessible to participants, have regularly scheduled phone and in-person contacts with participants, monitor whether participants' health status has changed and whether expenditure of funds are being made in accordance with service budget plans; and to require that supports brokers or consultants meet the training and monitoring requirements and qualifications required by their respective State. We have also added to § 441.450(c) the requirement that support brokers or consultants be available to each participant as part of the support system.

Comment: One commenter suggested that we include a definition of "person-centered services" or "person-directed planning" because it is critical that States have a uniform understanding and application of these concepts.

Response: We include in the regulations at § 441.468(b)(1) a requirement that the service planning process be "person-centered and directed" to ensure the identification of each participant's preferences, choices, and abilities, and strategies to address those preferences, choices, and abilities. We further require at § 441.468(c)(1) that the State's procedures governing service plan development allow the participant to engage in and direct the process to the extent desired, and allow the participant the opportunity to involve family, friends, and professionals. We do not believe that the regulation should be revised to add definitions of "person-centered services" or "person-directed planning," because the intent of such processes is clear and we wish to provide flexibility in implementing the concepts. We wish to note there are numerous resources available that define "person-centered planning" and "person-centered services" to assist the States. There are also different models (for example, MAPS, PATH, ELP, Personal Futures Planning) of person-centered planning. According to one resource, (Schwartz, A.A., Jacobson, J.W., & Holburn, S. (2000)). Defining "person-centeredness": Results of two consensus methods. *Education & Training in Mental Retardation & Developmental Disabilities*, each model has a different emphasis and should be applied based on the needs of the individual. Furthermore, the authors indicate that all models share a common

underlying set of eight basic characteristics. These characteristics include the following:

- The person's activities, services and supports are based on his or her dreams, interests, preferences, strengths, and capacities
- The person and people important to him or her are included in planning, and have the opportunity to exercise control and make informed decisions
- The person has meaningful choices, with decisions based on his or her experiences
- The person uses, when possible, natural and community supports
- Activities, supports and services foster skills to achieve personal relationships, community inclusion, dignity, and respect
- The person's opportunities and experiences are maximized, and flexibility is enhanced within existing regulatory and funding constraints
- Planning is collaborative, recurring, and involves an ongoing commitment to the person
- The person is satisfied with his or her activities, supports and services.

Generally, any model for person-centered planning a State uses should be based on the wishes and needs of the individual. With respect to the concept of "person-directed" planning, we expect that participants will actually direct the service planning and budget development. We think this is an important aspect of person-centered planning in order to ensure that the resultant service and budget plan actively engages a participant, accurately reflects a participant's abilities, preferences, and choices, and better meets the underlying purpose of the self-directed PAS option. We are available to provide information and technical assistance to any State that desires it.

After consideration of public comments received, we are finalizing § 441.450 with revision to the definition of individualized backup plan and addition of a definition of supports broker or consultant. We have also generally added "representative" throughout the regulations, as applicable.

Self-Direction: General (§ 441.452)

We proposed that States must have in place, before electing the self-directed PAS option, personal care services through the State plan, or home and community-based services under a section 1915(c) waiver. We proposed that the State must have both traditional service delivery and the self-directed PAS service delivery option available in the event that an individual voluntarily

disenrolls or is involuntarily disenrolled, from the self-directed PAS service delivery option. We also proposed that the State's assessment of an individual's needs must form the basis of the level of services for which the individual is eligible and that nothing in the self-directed PAS State plan option would be construed as affecting an individual's Medicaid eligibility, including that of an individual whose Medicaid eligibility is attained through receipt of section 1915(c) waiver services.

Comment: One commenter requested that CMS recognize other delivery models as "traditional" besides "agency-delivered" services. This same commenter asked whether a State that offers home health services under its State plan could meet the requirement for a "traditional" service-delivery model under this rule. Finally, this commenter sought clarification on whether the requirement that States offer a "non-self-directed" model refers only to the "agency-delivered" service model. Another commenter indicated that it is imperative that all participants retain the option to use the "traditional" service-delivery system.

Response: In the preamble to the proposed rule, we construed the "traditional" service-delivery model to mean "traditional agency-delivered services", *i.e.*, the personal care and related services and section 1915(c) waiver services that are delivered by personnel hired, supervised, and managed by a home care or similar agency. We agree with the commenters that we should not limit the "traditional" delivery system to "agency-delivered services" and now construe "traditional" delivery system to mean the delivery system that the State has in place to provide their State plan optional personal care services benefit or their section 1915(c) waiver services for individuals who are not self-directing their PAS under a section 1915(j) State plan option.

"Personal care and related services" as used in section 1915(j)(4)(A) of the Act are those services that are included in the State's definition of its optional personal care services benefit and not other State plan services such as home health. We further note section 1915(j)(2)(C) of the Act already requires that participation in the self-directed PAS State plan option is voluntary. Also, the regulation at § 441.456 permits participants to voluntarily disenroll from the self-directed PAS option. Finally, the regulation at § 441.458 allows States to involuntarily disenroll participants. In the event of a voluntary or involuntary disenrollment,

participants must resume receiving traditional services to which they are eligible under the State plan personal care service benefit or a section 1915(c) waiver program.

After consideration of the public comments received, we are finalizing § 441.452 without revision.

Use of Cash (§ 441.454)

We proposed that States have the option to disburse cash prospectively to participants self-directing their PAS, and further, that States must ensure compliance with all applicable Internal Revenue Service requirements; that participants, at their option, could use the financial management entity for some or all of the functions described in § 441.484(c); and that States must make a financial management entity available to participants if they demonstrated, after additional counseling, information, training, or assistance, that they could not effectively manage the cash option.

Comment: One commenter thought that allowing individuals who choose the cash option to perform tax-related reporting functions puts the individual at risk with the Internal Revenue Service (IRS). One commenter asserted that older persons and persons with disabilities are unlikely to be able to properly manage the quarterly IRS tax payments. One commenter suggested that the rule be revised to permit the State to require a participant to use the financial management services (FMS) entity for all or part of the functions described in § 441.484(c). One commenter thought that making use of the FMS entity optional would add an additional administrative and cost burden to the States. Also, the commenter stated that it is unwise for CMS to allow the practice of the hours of needed PAS to be determined by the wage/pay needs of the provider of care rather than the hours of PAS actually needed by the individual.

Response: On September 13, 2007, we released a State Medicaid Director Letter (SMDL#07-013), with preprint, for the self-directed PAS State plan option. In the preprint, we indicate that States must assure that all IRS requirements regarding payroll/tax filing functions will be followed, including when participants perform these functions themselves. In the regulation at § 441.454, we require that States can elect to disburse cash prospectively to participants who are self-directing their PAS and must ensure compliance with the IRS requirements if they adopt this option. We have revised the regulation at § 441.454(b) to add a minimum list of the tax-related responsibilities that are required by the IRS because we believe

these examples will help to illustrate some of the tax-related responsibilities that must be performed. We recognize that not all participants who select the cash option will have the interest or skill to bear these responsibilities, so the regulation at § 441.454(c) notes that participants may use a FMS entity to perform some or all of the employer and tax-related functions. We disagree that the regulation should permit the State to require a participant to use an FMS entity if that individual has selected the cash option and have not changed the rule. The purpose of the self-directed service delivery model is to vest participants with the choice and authority over decisions about their PAS and budget purchases. Therefore, when participants who have selected the cash option also choose to perform some or all of their employer and tax-related functions, we intend for that decision to be respected. Thereafter, if participants experience difficulty in performing some or all of these functions, or no longer choose to perform them, the regulation at § 441.454(c) permits participants to use the services of the FMS entity. We acknowledge that States who have not yet built an infrastructure to support this self-directed State plan option will likely experience an initial higher administrative and cost burden, but again, the State is best suited to make a determination on how best to expend its resources. Lastly, the commenter misconstrues the link of needed hours of PAS to the wage/pay needs of the provider. The regulation does not permit the wage/pay needs of the provider of PAS to determine the wage/pay they will be paid; rather, the participant determines the amount to be paid for a service, support, or item.

Comment: One commenter requested guidance on whether the FMS functions can be divided between a State and an FMS entity. Another commenter asked that we delineate the fiscal responsibilities that a participant who chooses the cash option may manage without the involvement of an FMS entity, and those that the State or FMS must retain, for example, disbursing the cash and monitoring spending.

Response: We believe these issues are best handled on a case-by-case basis as we believe it is important that States have the flexibility in the oversight of the functions it has delegated to an FMS entity versus those it has retained.

Comment: One commenter requested more detail in the requirements pertaining to the cash option.

Response: We believe the requirements for the cash option have been adequately addressed in § 441.454(c) of the regulation. We can

work to provide further technical guidance and assistance to States on a case-by-case basis, as needed.

Comment: One commenter had concerns about how the IRS would treat the cash received by a participant and asked if there is an IRS ruling on the income tax consequences for participants who choose the cash option.

Response: We are unaware of any IRS ruling regarding the cash option under the self-directed PAS State plan option.

After consideration of the public comments received, we are finalizing § 441.454 with revision to provide examples of tax-related responsibilities required by the IRS.

Voluntary Disenrollment/Involuntary Disenrollment (§ 441.456 and § 441.458)

In these provisions, we proposed that States must permit a participant to voluntarily disenroll from the self-directed PAS option at any time, and that States must specify the conditions under which a participant may be involuntarily disenrolled from the self-directed PAS option. We proposed that CMS must approve the State's conditions under which a participant may be involuntarily disenrolled. In both situations, we proposed that the State must specify in the State plan the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS to the traditional service delivery system.

Comment: Some commenters stated that States would not have the ability to guarantee "continuity of services during the transition from self-directed PAS" such that the rule needs to clarify that the safeguards to ensure continuity of services belong in the section 1915(j) State plan amendment, and not in other parts of a State's plan; and that States be required to have a "transition period" in the State plan amendment.

Response: We continue to believe that States must have the discretion and flexibility to design their own procedures to guarantee the continuity of services when a participant voluntarily or involuntarily disenrolls from the self-directed PAS State plan option. We further believe States have the ability to guarantee "continuity of services during the transition from self-directed PAS." Accordingly, we have not revised the regulations to provide a transition period as the commenters suggested. However, we agree with the commenters that the safeguards are better suited in the section 1915(j) State plan amendment. Accordingly, we have revised the regulation at § 441.456(b) and § 441.458(c) to make the technical change that the safeguards be listed in

the section 1915(j) State plan amendment and not other parts of a State plan.

Comment: Some commenters suggested that participants receive information about disenrollment at the time of enrollment and that information about feasible alternatives and disenrollment should be communicated in a manner that is clearly understandable by the individual.

Response: We agree that individuals should receive information about disenrollment at the time of enrollment and we believe that this information would be best communicated as part of the initial counseling that is provided to the individual. Accordingly, we have revised the regulation at § 441.464(d)(1) to require that a State inform individuals about disenrollment at the time of counseling prior to enrollment. We also agree with the comments that all information be communicated to the individual in a manner and language understandable by the individual. We have revised the regulations at § 441.464(c) and § 441.464(d) to reflect this requirement. We believe that these issues are better suited to the regulations at § 441.464 as we believe that areas such as information and effective communication are more properly within the scope of the support system provisions at § 441.464, and thus have revised those regulations accordingly.

Comment: One commenter recommended that the rule be revised to require that if a participant is dissatisfied with their FMS entity or their "agency with choice" entity, that the State offer the participant another entity to furnish these supports before disenrolling a participant who seeks to voluntarily disenroll from the self-directed PAS option.

Response: We believe decisions about whether to offer another entity to a participant and the circumstances under which participants may be disenrolled are best determined by each State when they design their self-directed PAS State plan option. Accordingly, we have not changed the regulation to require that a State offer a participant another FMS or agency with choice entity if the participant becomes dissatisfied with their current one. We do, however, encourage States to design their self-directed PAS State plan option to optimize the choice and authority participants will be able to exercise over their needed supports.

Comment: One commenter suggested that we include protections for workers in the rule at § 441.458. Specifically, the commenter recommended that the rule be revised to permit the State to

involuntarily disenroll a participant who is violating anti-discrimination laws and other applicable federal or state labor laws and regulations.

Response: We believe that issues about potential worker discrimination or violations of labor laws and regulations are best handled as part of the initial and ongoing information, counseling, training, and assistance that are provided by the supports brokers or consultants to the participants. We further believe that States could make the determination whether potential worker discrimination or violations of labor laws and regulations could be a condition of disenrollment from the self-directed PAS State plan option. As we believe that States are best suited to make this determination, we do not believe it requires a revision to the regulations.

Comment: One commenter stated that States should not involuntarily disenroll participants because of discomfort with the participant's personal preferences. Also, the commenter suggested that the participant be given an opportunity to rebut a decision of involuntary disenrollment. Another commenter recommended that CMS revise the regulations to clarify that States should not be allowed to involuntarily disenroll a participant when that participant is fully accessing services pursuant to the service plan and, as applicable, complying with his risk management agreement.

Response: We agree that States should not disenroll a participant based on discomfort with a participant's personal preferences, or when a participant is fully accessing services pursuant to the service plan and complying with any applicable risk management agreement. We will be carefully reviewing the State's submission of the conditions for involuntary disenrollment. We strongly encourage States to respect participants' personal preferences and to afford participants their dignity of risk. As stated previously, the concept of "dignity of risk" recognizes that as individuals experience greater choice and control, they may also desire to assume more of the responsibilities and risks associated with the provision of their PAS. If a State has concerns about participants' personal preferences or other risks participants may wish to assume, we encourage States to use risk mitigation strategies, such as the use of a risk agreement. A "risk agreement" is an agreement entered into between the participant and relevant and necessary parties. It identifies the risks that the participant is willing to assume, the responsibilities that the participant and others are willing to undertake to

mitigate the identified risks, and the circumstances that might cause the agreement to be terminated. The risks that participants may assume and how to mitigate them are subjects of discussion and negotiation as required in the regulations at § 441.476. We do not believe that the rule requires further revision as suggested by the commenter since the regulations at § 441.476 adequately address risk management requirements.

After consideration of the public comments received, we are finalizing § 441.456 and § 441.458 with revision for a technical change to specify that the safeguards for ensuring continuity of services during the transition from self-directed PAS be listed in the 1915(j) State Plan Amendment.

Participant Living Arrangements (§ 441.460)

In order to reflect the requirement at section 1915(j)(1) of the Act, we proposed that self-directed PAS are not available to an individual who resides in a home or property that is owned, operated, or controlled by a provider of services who is not related to the individual by blood or marriage. We proposed that States may specify additional restrictions on a participant's living arrangements if they have been approved by CMS.

Comment: A few commenters opposed the inclusion of assisted living facilities (ALFs) within the requirement that self-directed PAS cannot be provided in a home or property owned, operated, or controlled by a provider of services who is unrelated by blood or marriage to the individual. The commenters offered a variety of reasons that would support how ALFs could successfully provide PAS. A few other commenters noted that the limitation on living arrangements should not apply to individuals who choose to live in the home of a non-related provider of services, for example, a domestic partner or a friend, who is the paid provider of their PAS. Some commenters stated that the rule should be revised to clarify that an individual should not be precluded from the self-directed PAS option unless they are living in arrangements where the housing and the PAS are provided by the same individual or entity and the PAS are part of the paid services. A commenter suggested that we clarify that the prohibition would not apply to a landlord-tenant relationship that meets local and State tenant laws; a housing provider who co-signs a lease to allow an individual to secure affordable housing; or a service provider's housing corporation that helps the individual

secure housing, when the housing corporation has separate governance from the service provider. A commenter thought that the requirement was too restrictive and would preclude persons with severe disabilities who need extensive support from the option to self-direct their PAS.

Response: The statute is very clear as to the type of living arrangements that could be entered into under this self-directed PAS State plan option. The living arrangements should optimize participant independence, choice, and community integration and are intended to mitigate the control that some providers of PAS could exert over participants if participants lived in a setting owned, operated, or controlled by the unrelated providers of PAS. The exception is if the provider of PAS is related by blood or marriage to the participant because it is presumed that providers of PAS related by blood or marriage to the participant will not exert undue influence over the participant and will facilitate, and not impede, the participant's self-direction of the participant's PAS and budget.

In the proposed rule published on January 18, 2008, we noted that, "programs that have successfully provided the self-directed care option have typically provided it to individuals who live in homes of their own or in the homes of their families." We also noted that we believe that "successfully directing one's own care may become less feasible when individuals receive services and reside in large, provider-owned, operated, or controlled residential living arrangements." We provided an example of a residential facility that also provides and receives payment for the provision of personal care and related services that may prohibit the self-directed service delivery option for fear of duplication of services. We further noted that we believed this limitation should be applied to individuals residing in ALFs, as we anticipated that the provider would both control the housing and be expected to provide the PAS. However, we noted that we did not believe this limitation would apply to situations in which the individual resided in the home of another whom the individual wished to employ under the self-directed PAS option. We are now clarifying that any living arrangement, irrespective of the home-like nature of the setting, that is owned, operated, or controlled by a provider of the participant's PAS, not related by blood or marriage to the participant, is not permitted by statute in the self-directed State plan option. We agree with the commenters that stated that the

regulations should be revised to clarify that an individual should not be precluded from the self-directed PAS option unless they are living in arrangements where the housing and the PAS are both provided by the same individual or entity and the PAS are part of the paid services. We have revised the regulation at § 441.460(a) to insert "PAS" before "provider", thereby indicating that the limitation only applies where the living arrangement and the PAS are provided by one and the same individual or entity. We further wish to clarify that when we referenced the "home of another" in the proposed rule, we intended that the home was controlled, operated, or owned by someone related by blood or marriage to the participant and so we allowed this under the exception to the statutory limitation.

Based on the comments we received pertaining to ALFs, we understand that there are some ALFs that are not in the business of providing PAS. Accordingly, we believe that where the living arrangements, including ALFs, do not furnish PAS (as that term is defined under the self-directed PAS State plan option), then the living arrangements may be conducive to the participant's successful and effective self-direction of their PAS and budgets. If a supports broker or consultant, the State, or other person known to the participant, becomes aware that the participant's exercise of choice over their PAS and budgets is hindered because the nature of the living arrangement has changed, the living arrangement begins to offer PAS, or other conditions arise making self-direction of the participant's PAS overly difficult or impossible, then the State must promptly rectify the situation by assisting the participant to find other acceptable and safe housing.

Comment: A commenter recommended that we delete § 441.460(b), which permits States to specify additional restrictions on participant's living arrangements if approved by CMS. The commenter stated that this provision could possibly be used by States to overly restrict self-directed PAS.

Response: We will be reviewing any State proposal further restricting participant living arrangements to ensure all proposals further enable the participant to engage in meaningful self-direction of PAS and are not a restriction to self-directed PAS.

Based upon consideration of public comments received, we are finalizing § 441.460, with revision, to clarify the living arrangement prohibition is for a living arrangement where the living

arrangement and a PAS provider are one and the same individual or entity.

Statewide, Comparability, and Limitations on Number Served (§ 441.462)

To reflect the requirements at section 1915(j)(3) of the Act, we proposed that States may provide self-directed PAS without regard to the requirements of statewide, comparability of services, or the number of individuals served.

Comment: Some commenters disagreed with CMS that the Medicaid requirements for statewide and comparability should be disregarded. One commenter stated that States would not offer the self-direction option to certain population groups that the State perceived as unable to self-direct their PAS. Another commenter thought that to disregard comparability and statewide would unfairly disadvantage agencies that have to meet stricter or more burdensome requirements. In contrast, one commenter urged that we "encourage" or "require" States that have never implemented or had oversight for a self-directed PAS program to first implement a program in a particular region and to a particular population or both. Alternatively, the commenter recommended that the number of people served should be limited.

Response: The regulation at § 441.462 reflects the requirement in section 1915(j)(3) of the Act that permits a State to provide self-directed PAS without regard to statewide, comparability of services, or the number of individuals served. We believe that by providing States this flexibility, States could allow for incremental growth in offering self-directed PAS under the State plan option. As States gain more experience, they can amend their State plans to allow self-directed PAS statewide, to different populations and to more individuals. We note § 441.462 reflects the provisions of section 1915(j)(3) of the Act, and is not intended to disadvantage agencies that provide traditionally delivered services or to adversely affect certain population groups. We believe that all population groups can successfully self-direct their PAS if they have the appropriate information, counseling, training, and assistance they need.

Comment: A commenter sought clarification about the "populations" that could be targeted. Moreover, this commenter suggested we clarify that the State may subject each population to its own enrollment cap and specific eligibility criteria if the State so chooses.

Response: Section 1915(j)(1) of the Act sets forth the initial eligibility criteria for participation in a self-directed PAS State plan option. Specifically, section 1915(j)(1) requires that the self-directed PAS State plan opportunity be available to individuals for whom there has been a determination that, but for the provision of such services, would require and receive State plan personal care services or section 1915(c) waiver services. We believe that section 1915(j)(3), regarding comparability, permits States to target persons who are eligible for and receiving State plan personal care services or section 1915(c) waiver services. Section 1915(j) of the Act does not broaden or narrow a State's definitions of the State's personal care services benefit or section 1915(c) waiver services.

Comment: A commenter asked whether the services described in the rule are mandatory under the early and periodic screening, diagnostic and treatment (EPSDT) system.

Response: This rule implements section 1915(j) of the Act allowing States the option to amend their State plans to offer individuals the opportunity to self-direct their PAS. Therefore, Section 1915(j) of the Act offers the self-directed service delivery model as an alternative to traditionally delivered services. There are no new services that can be self-directed; rather, participants are afforded the opportunity to self-direct State plan personal care services and section 1915(c) waiver services that they are already receiving. Accordingly, there is no "service" under section 1905(a) of the Act that must be provided under the EPSDT benefit.

After consideration of the public comments received, we are finalizing § 441.462 without revision.

State Assurances (§ 441.464)

We proposed to reflect the requirements at section 1915(j)(2) of the Act that States must provide several assurances: (1) That necessary safeguards have been taken to protect the health and welfare of individuals furnished services under the program and the financial accountability for funds expended for self-directed services; (2) that States perform an evaluation of the need for personal care under the State Plan or services under a section 1915(c) waiver program; (3) that individuals who are likely to require personal care under the State plan, or home and community-based services under a section 1915(c) waiver program are informed of the feasible alternatives, when available; (4) that

States must provide a support system that meets several delineated conditions; (5) that the State must provide to CMS an annual report on the number of individuals served and the total expenditures on their behalf in the aggregate; and (6) that the State must provide to CMS an evaluation of the overall impact of the self-directed PAS option on the health and welfare of participating individuals compared to non-participants every 3 years.

Necessary Safeguards (§ 441.464(a))

Comment: A few commenters stated that the Federal and state level of assurances should be the same between the self-directed and agency-delivered models of service delivery. The commenters offered several suggestions of safeguards that govern traditional agency-delivered services that CMS should require in the rule governing the self-directed PAS State plan option.

Response: We disagree that the regulations should be revised to add the safeguards in the traditional agency-delivered service model suggested by the commenters because we believe that the requirements concerning needed safeguards are sufficient and adequately address the concerns and needs in a self-directed service delivery model. Furthermore, the self-directed service delivery model has been formally evaluated in the "Self-Determination" and "Cash & Counseling" national projects and the regulatory requirements reflect the safeguard analyses and conclusions made from those national projects. We believe it is also important to note that States retain oversight and monitoring functions and must fulfill the obligations in their QA/QI plans to discover critical incidents and complaints and to subsequently remediate them.

Comment: A commenter suggested that CMS add safeguards to protect workers' rights, health, and safety.

Response: These issues are outside the scope of these regulations as they do not extend to workers' rights, health, and safety. Therefore, we are not revising the regulations as the commenter suggested. However, as this self-directed PAS opportunity is a service delivery model it is not intended to conflict with existing laws governing workers' rights, health, or safety issues. We understand the States and participants would comply with these laws and we encourage States and participants to consider affording workers these kinds of worker protections.

Comment: A commenter recommended that CMS establish a federally-mandated resolution process

that States would implement when problems would arise between consumers and providers.

Response: We do not believe a mandated resolution process is either necessary or appropriate because we believe existing safeguards are sufficient to assist participants when problems arise between them and their PAS providers. We encourage participants to seek out any needed or desired training on how to be a better employer, or to consult with their supports broker or consultant or a person of their choosing, when there are employer-employee problems. There are also resources available to assist in resolving these issues, such as voluntary dispute resolution programs. If these types of programs exist in the participant's community, and they may be of help, then we encourage participants and workers to avail themselves of that opportunity if they choose to do so. States may wish to consider providing such information during the counseling session with participants prior to their enrollment in the self-directed PAS State plan option.

Comment: A commenter stated that at § 441.464(a), CMS should add "quality of life" in addition to health and welfare for which States must have necessary safeguards. The commenter further recommended that we add a specific listing of safeguards related to the health and welfare and the quality of life of participants to the current list of financial safeguards.

Response: We believe that States may measure "quality of life" issues in the quality assurance and improvement plan as well as in the three-year evaluation that the regulations require, if they choose to do so. Therefore, while we do not believe that the regulations should require "quality of life" safeguards, we do not prohibit States from incorporating them into the design of their QA/QI plan or their three-year evaluation. It should be noted that we will be issuing related guidance on the requirement for the three-year evaluation of the impact of the self-directed PAS option on the health and welfare of participating individuals compared to non-participants. We believe that States could measure and analyze "quality of life" issues such as whether participants experienced greater independence, increased community access, or were able to work. Therefore, we are not adopting the commenter's suggestion to change the regulations as we think States have the flexibility to design their QA/QI plans and their three-year evaluations to consider "quality of life" issues.

Financial Accountability (§ 441.464(a))

Comment: One commenter stated that the language describing necessary safeguards was too vague and would not assure financial accountability. The commenter recommended program controls and controls in the timekeeping system.

Response: We agree that there should be program controls and controls in the timekeeping system, but we believe that States should have flexibility to set up their own program controls and timekeeping controls in order to meet the financial accountability requirements. We believe that the oversight functions of the service budgets and expenditures, required to be performed by the FMS entity, the supports brokers and consultants, and States, should adequately address the commenter's concerns by providing adequate financial accountability.

Comment: One commenter recommended that the amount of the budget not be allocated on a monthly or quarterly basis as indicated in § 441.464(a)(2)(iii) because it would be too rigid. The commenter proposed that the regulation be revised to permit participants to plan for periods of greater or lesser needed coverage "during the State's budget period."

Response: We believe that prior planning for periods of greater or lesser utilization and the ability of States to allocate funds consistent with a participant's plan, during the State's budget period, is already provided for in the regulation. The prefatory language at section 441.464(a)(2) indicates that the listed safeguards, including allocating the budget on a monthly or quarterly basis, are permissive, not mandatory. Furthermore, we believe that the regulation at § 441.470, concerning the service budget elements, further affords the flexibility that the commenter desires. In § 441.470, the service budget must include procedures as to how the participants may adjust the budget plan, including how the participant may freely make changes to their budget plan and the circumstances, if any, that may require prior approval before a budget plan adjustment is made.

Comment: Two commenters stated that abuse of funds could occur when participants selected the cash option. The commenters recommended that participants using the cash option be required to use a qualified financial management entity; that participants and their PAS providers are closely monitored to ensure that authorized services were actually delivered and properly accounted for in timesheets; and, that CMS develop criteria to ensure

the financial accountability required, including one set of national guidelines.

Response: At the core of the self-directed service delivery model is participant "choice and control" over their services and budgets. The ability of participants to choose to perform some or all of their employer and tax-related responsibilities is in keeping with this tenet. If a participant discovers that he is not interested in or able to assume these responsibilities, then the participant may use the service of the FMS entity. While we understand the commenters' concerns, we believe that the requirements for the State assurances at § 441.464(a), and for the supports system at § 441.454 and § 441.464(d) adequately address the commenters' concerns and provide the requested financial accountability and oversight.

Comment: One commenter stated that although financial accountability is important, States should not become overly prescriptive about the ways in which individuals spend their budgets.

Response: We agree with the comment that flexibility in the budget planning and spending should be encouraged by the State.

Evaluation of Need (§ 441.464(b))

We proposed that the State must perform an evaluation of the need for personal care under the State plan or services under a section 1915(c) waiver program for certain individuals. We received no comments on this proposal.

Notification of Feasible Alternatives (§ 441.464(c))

Comment: One commenter recommended that at the time feasible alternatives are discussed, participants be given information about agency-delivered or traditionally-delivered care and self-directed care, including licensure and certification of agency or other entity staff, required training and competency evaluation, criminal background checks, and the ability to contact the agency or entity to request a substitute caregiver if the initial caregiver does not show up.

Response: Section 1915(j)(2)(C) of the Act requires States to provide an assurance that individuals who are likely to require personal care under the State plan, or home and community-based services under a section 1915(c) waiver program, are informed of the feasible alternatives, where available, to self-directed PAS. The information on feasible alternatives would include information about agency-delivered or traditionally-delivered services. Furthermore, most participants will already be familiar with the agency-

delivered or traditionally-delivered services because most will have been receiving them under their State plan personal care benefit or a section 1915(c) waiver program. Section 441.464(d), which implements this statutory provision, provides a listing of information that must be provided to participants. We believe the kind of information noted by the commenter is included in the regulation as it states that individuals must be given necessary information about self-direction, their responsibilities and potential liabilities, the choice to receive section 1915(c) waiver services regardless of delivery system, and the option to receive and manage the cash amount of their budget allocation.

Support System (§ 441.464(d))

Comment: One commenter suggested that the support system for management of funds should include check-writing and accounting as part of the training to those who wish to receive the cash option and manage their own allocation.

Response: The extent and type of training needed or desired by a participant will vary depending upon the individual. We anticipate that participants will request any needed or desired training for management of funds, or that their representatives, supports brokers, or consultants will request this training including training along the lines as that noted by the commenter. We also anticipate that the State will offer the additional training that is desired or needed.

Comment: One commenter noted that the proposed regulations lacked a practical plan to operationalize the "freedom of choice of providers" requirement and asked that this requirement be clarified.

Response: We believe the requirement to allow participants the freedom to choose their PAS providers will be operationalized when participants hire the person of their choosing to provide their PAS. However, as indicated by the commenter, the intent of the requirement is to allow participants freedom to choose their PAS providers and to clarify this requirement, we are revising the regulations text at § 441.464(d)(2)(vii) to now read, "freely choose from available PAS providers."

Comment: One commenter recommended that the regulation be revised at § 441.464(d) to acknowledge that those participants with progressive dementias will need increasing support, as will their representatives or caregivers.

Response: We believe it is not necessary to revise the regulation to indicate that persons with dementia will

require increasing support as their condition worsens. Section 441.464(d)(3) already requires ongoing support throughout the period that a participant is self-directing their PAS under this option. Consequently, support for any worsening condition, like dementia, is contemplated under the regulations at § 441.464(d)(3).

Comment: One commenter urged that CMS “encourage” States to contract with or otherwise delegate certain responsibilities to organizations that are privately accredited to perform the supports broker or consultant function and financial management services functions.

Response: We believe that States are free to contract with entities to perform the required supports broker or consultant and FMS functions, provided these entities have demonstrated knowledge and skill in implementing the requirements of the self-directed PAS State plan option and that the entities meet State requirements for furnishing these support functions.

Comment: One commenter recommended that CMS clarify that States or local governments do not have to actually provide the training needed by participants, but may instead delegate the needed supports, services, and training (through contractual means) to other entities, including providers.

Response: We agree as it provides States with greater flexibility to manage this option and conforms to current practice with other services. Accordingly, we revised § 441.464(d) to indicate that, “States must provide, or arrange for the provision of, a support system that meets the following conditions.”

Comment: Another commenter stated that participants would possibly hesitate to complain about their workers for fear of retaliation. Accordingly, the commenter recommended that participants have direct access to an advocate.

Response: We agree that participants should have access to an advocate or advocacy organization and we have revised the rule at § 441.464(d)(2) (Support system) to add a new subsection (xv) that requires that participants be given information about the advocate or advocacy system in the State and how to contact the advocate or advocacy system. In the “Cash & Counseling” and *Independence Plus* programs, we required that an independent advocate or advocacy system be available to participants as part of the State’s support system. The independent advocate or advocacy system would not have to be newly

created by the State, but could possibly include the State’s Protection and Advocacy System, the State and Local Long-Term Care Ombudsman Program, or any other existing advocate or advocacy system within the State’s aging and disability networks. This requirement to inform participants of this right would not absolve States of their obligation to discover and investigate critical incidents and complaints that participants and others report, nor would it supplant the State’s requirements to investigate complaints of abuse, neglect, or exploitation made to their protective services agencies. Moreover, the purpose of the support system is to assist participants in effectively managing their service plans and budgets. Accordingly, the supports broker should be assisting the participant in learning how to be an effective employer, including how to discharge a worker, if necessary.

Annual Report and Evaluation of Impact (§§ 441.464(e) and 441.464(f))

Comment: We invited comments on the requirements and structure of the annual report required in the rule at section 441.464(e). Commenters suggested that a varying spectrum of information be included in the annual report. Commenters suggested that the following information be included:

- The number of individuals self-directing.
- The units of service they received.
- The expenditures for persons receiving self-directed services, agency-delivered/traditionally-delivered services and those receiving a mix of modes.
- The number of participants with representatives helping them.
- The number of participants who are directing the State plan personal care services benefit.
- The number of participants who are directing section 1915(c) home and community-based services, and type of waiver.
- The average per-participant spending (by eligibility) category for those who direct their services and those who receive agency-delivered or traditionally-delivered services.
- The services and items used by those self-directing and those who receive agency-delivered or traditionally-delivered services.
- Whether LLRs are permitted to be paid providers.
- Whether the State allows the purchase of items that increase independence.
- Whether the State allows the delivery of services in alternative living arrangements.

- The number of individuals who expressed interest in the option, but were denied, and the reason for the denial.

- The number who voluntarily disenrolled and the reasons for the disenrollment.

- The number who were involuntarily disenrolled and the reasons for the disenrollment.

- The number of fiscal intermediaries.

- The number of providers.

- A summary of critical events reported by participants.

As to the structure of the report itself, other commenters made the following suggestions:

- The Secretary should make the annual reports available to the public.

- CMS should closely monitor the costs associated with the self-directed service delivery model.

Response: We appreciate the ideas that commenters submitted for the annual report requirements. We will carefully consider these comments as we develop guidance on the structure and criteria of the annual report.

Comment: One commenter stated that the reporting requirements for the annual report were burdensome and overly broad.

Response: As we noted that specific guidance about the annual report requirements will be forthcoming, it is unclear what requirements the commenter was referring to. However, we will take the commenter’s perspective into consideration as we develop our guidance and will try to impose as little burden on the States as possible.

Comment: We invited comments on the requirements of what should be included in the three-year evaluation required in § 441.464(f). Two commenters had the following suggestions:

- The evaluation should separately address the experiences of those with and without cognitive impairments.

- The evaluation should address issues of quality of life of participants, family caregiver burdens and comparisons of the individuals with and without cognitive impairments.

- The evaluation should assess the effectiveness of the self-directed PAS option, especially for populations with cognitive impairments.

Another commenter suggested CMS streamline any evaluation requirements in our future guidance, given that the efficacy of consumer-directed services has been evaluated through the cash and counseling demonstration projects.

Response: We thank the commenters for their input and we will take these

recommendations under consideration as we develop guidance on the structure and implementation of the evaluation.

Comment: One commenter asked that CMS clarify what was meant by “overall impact” of the self-directed PAS on the health and welfare of participating individuals compared to non-participants.

Response: We do not expect that States will need to conduct a “scientific” research study and evaluation as was done in the national projects. We anticipate that our guidance will include minimum criteria that will form the basis of what we expect States to evaluate. We also anticipate that the guidance will include insight into the numbers of participants versus non-participants to be evaluated.

After consideration of the public comments received, we are finalizing § 441.464, with revision, to clarify that participants may freely choose from available PAS providers, that the State may provide under arrangement, the provision of support services, and that the State must provide information about advocates and the advocacy system in the State and how to access them. As explained in response to a prior comment, we also note changes were made to indicate that information provided to individuals and participants be communicated in a manner and language understood by the individual and participant and that the support system includes counseling about disenrollment, prior to when an individual enrolls.

Assessment of Need (§ 441.466)

We proposed that States must conduct an assessment of the participant’s needs, strengths, and preferences and indicated that the assessment information is crucial as it supports the determination that an individual requires PAS and also supports the development of the service plan and budget.

Comment: Some commenters offered various suggestions on specifics for the assessment of need, including that it be standardized; performed by registered nurses or trained medical personnel; based on a prescribed scale; use a national standard to assess the amount of assistance needed; and that States be given latitude to develop their own assessment criteria and to use their existing assessment tools. Another commenter stated that the assessment was more burdensome than it needed to be. One commenter stated that CMS should amend the definition of “assessment of need” regulations at § 441.450(c) and the assessment requirements at § 441.466 to specifically add that an individual’s cognitive

function and mental health conditions must be assessed, where indicated, including the individual’s need for “cueing” or supervision.

Response: Section 441.466 requires the assessment of need but does not specify the type of personnel that should perform the assessment. We agree that appropriately trained medical personnel should be trained and available, if an individual’s condition warrants a need for assessment. We also believe that assessing personnel should be trained in the person-centered planning and directed process and person-centered services, or be accompanied by someone who is trained in these areas. While we have not specified the instruments or techniques that should be used to secure the required information in § 441.466(a), information about the individual’s health condition and functional limitations must be included in the assessment. This should include information about cognitive function and other health information. Moreover, States have been given latitude to develop their own assessment criteria and tool, and we expect that States will use that latitude to perform the assessment of all of the individual’s physical, cognitive mental health, and functional needs, as required, in order to fulfill the overall purpose of the assessment which is to obtain information “relevant to the need for and authorization and provision of services.” Given the importance of the assessment in light of the role it plays in self-directed PAS under this option, we do not believe that the listed information is burdensome to either assess or secure.

Comment: Two commenters recommended that CMS require that the assessment determine whether an individual is capable of directing his own care and that an individual’s ability to manage his own care must be established. The commenters suggested that the rule include minimum processes to screen out individuals incapable of directing their own care or who would require specialized medical treatments.

Response: As we interpret the commenter’s statements, it appears they are suggesting individuals should not be given the opportunity to self-direct their PAS under this option simply because they may need or desire supports to effectively manage their PAS and budgets. We disagree with the commenters that exclusionary criteria should be used to “screen out” participants. Individuals of different ages and various impairments and skill levels have successfully directed their

PAS when given the supports they need or desire. However, the assessment of needs, strengths, and preferences can be considered in determining the extent to which supports may be needed or desired.

Comment: Two commenters stated that CMS should revise §§ 441.466 and 441.468 to include in the assessment and the service plan, respectively, a requirement to identify potential caregivers and to assess their willingness and capacity to provide care to individuals. Additionally, the commenters stated that the service plan should not include hours of unpaid care.

Response: We believe that the assessment of need should take into consideration an assessment of the individual’s environment, including the presence or absence of unpaid care and is one of the factors relevant to the need for authorization and provision of services. However, we do not believe that the regulations should be revised to require this, and leave this determination to the States. We do not believe that the specifics of any unpaid care need to be included in the resultant service plan.

Comment: One commenter sought clarification on how States can bill for an assessment before a participant’s entry into the program.

Response: Individuals who will be permitted the opportunity to self-direct their PAS under this new State plan option will already be Medicaid-eligible beneficiaries. Therefore, the assessment for self-directed PAS under this new State plan option can be properly claimed by the State.

Comment: One commenter sought clarification on how the “assessment of need” differs from or relates to the “evaluation of need.”

Response: Section 1915(j)(2)(B) of the Act requires “an evaluation of the need” for personal care under the State plan or personal services under a section 1915(c) home and community-based services waiver program. Section 1915(j)(5) of the Act requires that States conduct an “assessment” of participants’ needs, strengths, and preferences for self-directed PAS. Section 1915(j)(2)(B) is intended to evaluate an individual’s need, generally, for personal care services or section 1915(c) waiver services. The “assessment of need” determines the specific needs, strengths and preferences of individuals in order to self-direct their PAS under this State plan option.

After consideration of the public comments received, we are finalizing § 441.466 without revision.

Service Plan Elements (§ 441.468)

We proposed minimum requirements that would be included in a service plan. We further proposed that the service plan must be developed using a person-centered and directed planning process. We also proposed that the State's applicable policies and procedures associated with service plan development be carried out and listed a minimum set of criteria that must be included in the State's policies and procedures. Furthermore, we proposed that if an entity that provides other State plan services is responsible for service plan development, the State must describe the safeguards that are in place to ensure that the service provider's role in the planning process is fully disclosed to the participant, and that controls are in place to avoid any possible conflict of interest. Finally, we proposed that the approved service plan conveys authority to participants to perform certain minimum tasks including recruiting and hiring their workers and determining the amount paid for a service, support, or item.

Comment: Two commenters suggested that CMS explicitly require that the participant be allowed to determine the wages paid to their providers of PAS. However, other commenters disagreed that a participant should determine the amount paid for a service, support, or item. One commenter noted that such a requirement conflicts with the commenter's State law that "regulates county wages for PAS." Another commenter noted that such a requirement would limit a State's ability to establish a minimum wage standard for personal care workers or to mandate a wage increase for personal care workers. A third commenter noted that the requirement appears to be in conflict with the collective bargaining agreement in the commenter's State between the State and unions representing workers. The commenter noted that "individual providers are unionized and the rates of pay and benefits for PAS are established through a collective bargaining process." The commenter asked CMS to clarify that a participant could determine the portion of the budget that goes to PAS, but that the collective bargaining agreement would govern the wage and benefit package for individual or agency PAS providers. Another commenter stated that applicable State or Federal minimum wage requirements should continue to apply.

Response: We believe that the statute requires participants to exercise control over the service plan and budget and that includes determining the amount paid for services, supports, or items.

Section 1915(j)(5) of the Act vests participants with decision-making authority over their service plans and budgets. The regulations at § 441.450(b) and § 441.468(e) implementing section 1915(j)(5) of the Act specifically grant participants the authority to hire, fire, supervise, and manage their workers, and to determine the amount paid for a service, support, or item. We do not believe that State laws or collective bargaining agreements should hinder the ability of participants to determine the amount they pay their workers. As this self-directed PAS opportunity is a service delivery model it is not intended to conflict with existing laws governing these issues. We understand the States and participants would comply with these laws and collective bargaining agreements and that support and education, as needed, would be furnished to participants to inform them of any necessary requirements.

Comment: One commenter stated that the rule should be revised to specifically allow a participant to request revisions to the service plan, based on a change in needs.

Response: We agree with the commenter and have revised the rule at § 441.468(c) to add a new subsection (8) to "[e]nsure that a participant may request revisions to a service plan, based on a change in needs or health status."

Comment: One commenter requested clarification of the language at § 441.468(c)(6) that those responsible for service plan development "reflect the nature of the program's target population."

Response: We were concerned that individuals developing the service plan have the necessary background to adequately develop a service plan for the person self-directing their PAS. In particular, individuals with the "lead" responsibility for service plan development should have knowledge about the population that will be self-directing their PAS under this State plan option. In keeping with the overall focus of a service plan, we also believe that those responsible for service plan development have demonstrated skill to facilitate person-centered and directed planning and to include person-centered services in the service plan.

Comment: One commenter suggested that CMS add "cognitive status" after "health status" in the regulation at § 441.468(c)(7).

Response: We believe that the term "health status" encompasses any physical, cognitive, mental health, behavioral, or functional change observed or discovered that would necessitate a reassessment more often

than annually, and therefore have not revised the regulation.

Comment: One commenter requested that we revise the rule at § 441.468(c) to clarify that States may delegate the reassessment of the need for PAS to a sub-unit of government as long as the State sets guidelines, exercises oversight, and performs quality assurance and improvement activities over these sub-units.

Response: We agree with the comment but do not believe it requires a revision in the regulations. States may delegate the reassessment of the need for PAS to an agency or sub-unit of government, provided the State retains all necessary administrative and monitoring oversight of the entity that performs reassessments for the State. We believe this will provide the State with the administrative option currently found in the provision of other Medicaid services.

Comment: One commenter noted that a verb is missing from section 441.468(c)(2) and should be inserted.

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

Comment: One commenter suggested that the rule "include that the older adult and person with disabilities have a choice of all the provider types available."

Response: This new State plan option permits States the option to amend their State plans to offer individuals the opportunity to self-direct their PAS. As eligible individuals may include older adults and persons with disabilities, we do not believe a regulation change is necessary. Moreover, these individuals are free to choose to self-direct their PAS under the section 1915(j) State plan option or to remain with a traditional service delivery model. Individuals who do not wish to self-direct their PAS under this State plan option may consider other models of care available to them and for which they are eligible, such as the Program of All Inclusive Care for the Elderly (PACE). As required by both statute and regulations, a State's feasible alternatives, if applicable, should be discussed with individuals before they enroll in this new State plan option.

After consideration of public comments received, we are finalizing § 441.468, with revision, to correct a technical error and to provide that participants may request a change to the service plan, as needed.

Service Budget Elements (§ 441.470)

We proposed that a service budget must be developed and approved by the State based on the assessment of need and service plan. We also proposed

certain budget elements that govern the service budgets, including that the participants have knowledge about the specific dollar amount available for their PAS; how they may adjust the budget plan; the procedures that govern how a person, at the election of the State, may reserve funds to purchase items that increase independence or substitute for human assistance; how a person may use a discretionary amount, if applicable, to purchase items not otherwise delineated in the budget; and how participants are afforded the opportunity to request a fair hearing if a participant's request for a budget adjustment is denied or the amount of the budget is reduced.

Comment: One commenter thought that we needed to provide more detail on the steps used in developing the service budget. The commenter was also concerned that some States may "discount" a participant's service budget as a cost-cutting tool. The commenter stated that it could result in inadequate provision of services.

Response: We believe that the regulations at §§ 441.450 and 441.470 provide ample detail and give sufficient guidance in the development of service budgets and no further detail is necessary. There are numerous resources that can provide further guidance to States in the development of service budgets and we are available to provide technical assistance if necessary. We agree with the comment that a person's budget should not be "discounted" in order for a State to cut costs and do not believe that it would be proper for States to do so.

Comment: One commenter recommended that each State be required to develop a methodology for the timely recoupment of unused funds and that these funds be used for the self-directed PAS option.

Response: We believe that it is important for States to have a procedure to timely recoup unused funds. We believe that § 441.464(a), that requires States to assure the financial accountability of funds expended under this State plan option, would encompass the recoupment of unused funds. Accordingly, we are not adopting the commenter's suggestion.

Comment: Two commenters suggested that CMS add the language, "earmarked for savings," to the regulations text at § 441.470(e) to permit individuals to use a discretionary amount of their budget to purchase items not otherwise delineated in the budget plan or "earmarked for savings," since that is the language we used in the preamble.

Response: We agree and have revised the regulation at § 441.470(e) to indicate

that the discretionary amount could be used to purchase items not otherwise delineated in the budget plan or "reserved for permissible purchases." We believe the phrase "reserved for permissible purchases" better reflects this concept rather than "earmarked for savings" because permissible purchases, under this self-directed PAS State plan option, are those supports, goods, equipment, or supplies that increase independence or substitute for human assistance, and are purchased with the amount of funds that a participant is able to save or "reserve".

Comment: One commenter suggested that we eliminate the requirements in the regulation at § 441.470(a) and (b) with regard to informing the participant of the amount of the budget and conveying that information before the service plan is finalized.

Response: We disagree with the commenter. The requirement in § 441.470(a) that participants be informed of the "specific dollar amount a participant may utilize for services and supports" is crucial so that the participant, with assistance as needed or desired, can develop a service plan and budget plan that properly reflects the participant's needs, and the way in which any reserve or discretionary funds, if permitted by the State, will be budgeted. Section 441.470(b) is a requirement that describes only that the participant will be told, at the time the service plan is developed, how the participant will learn of the service budget amount, once it is determined. The requirement was not meant to prescribe a particular process.

Comment: One commenter requested clarification on whether an individual could purchase services that are not currently covered within the State plan's definition of personal care services such as supervision and cueing.

Response: When a State offers the opportunity to self-direct State plan PAS, we do not believe it would be permissible for participants to purchase services that are not included within the State's definition of their PCS benefit. However, the statute and regulations at § 441.470(d) allow a State, at the State's election, to offer participants the opportunity to reserve funds to purchase items that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance, including additional goods, supports, services, or supplies. If this option is offered by the State, we believe that a participant can purchase goods, supports, services, or supplies that are not included within the definition of the State's PCS benefit.

Comment: A commenter requested clarification on how States are supposed to review and approve the service budgets of PAS participants when the participants are free to determine the amount they will be spending for goods and services.

Response: Under the self-directed service delivery model, individuals determine the rate or amount paid for their services, supports, and items. Moreover, while individuals direct the decisions about the purchases to be made with their service budget, they are still responsible for remaining within the budgeted amount noted in their budget plan. To clarify, we intended that States review and approve the budget plan to ensure that the budget plan is not exceeding the budget amount, that the participant's budget plan is in keeping with the assessment of need and the identified needs in the service plan, and because we believe it is an important step to ensure the financial integrity of the self-directed State plan option.

Upon consideration of the public comments received, we are finalizing § 441.470, with revision for a technical change and to note that the service budget may include a discretionary amount, if applicable, to purchase items not otherwise delineated in the budget or reserved for permissible purchases.

Budget Methodology (§ 441.472)

We proposed that the State's budget methodology to determine a participant's service budget meet certain criteria and generally tracked the statute at section 1915(j)(5)(D). We also proposed that the State have procedures in place to safeguard participants when the budgeted amount is insufficient to meet a participant's needs. We also proposed that the State have a method of notifying participants of the amount of any limit that applies to a participant's self-directed PAS and supports. We also proposed that the budget may not restrict access to other medically necessary care and services furnished under the plan and approved by the State but not included in the budget.

Comment: One commenter requested that CMS clarify what is intended by the requirement, "The State's method includes a calculation of the expected cost of the self-directed PAS and supports, if those services and supports were not self-directed."

Response: As persons eligible for self-directed PAS must already be eligible for and receiving the optional State plan personal care services benefit or services in a section 1915(c) waiver, the amount of the funds available to a participant

for their self-directed PAS "budget" is not to exceed the amount that the State would pay for the services and supports if those services and supports were provided under the traditional service delivery model.

Comment: Several commenters requested that CMS clarify what is meant when States are required to have a procedure to safeguard participants when budgeted service amounts are insufficient to meet participants' needs. One commenter asked whether the procedures to safeguard participants included the following: Appeal rights to challenge benefit levels that participants perceived to be inadequate; institutionalization; additional financial resources when a participant states that the funds or services are insufficient; or whether CMS expects participants to forego needed services. One commenter suggested that we revise the regulation at § 441.472 to indicate that service budget increases may be appropriate when it can be shown that some change in a participant's medical condition, functional status, or living arrangement requires it.

Response: It is important to note that at any time a reassessment is performed, ultimate decision-making authority for the amount of services authorized rests with the State, according to the State's medical necessity criteria applied against an individual's assessed needs. Therefore, we have revised § 441.472(a) to indicate that the budget methodology is established by the State in such a way as to ensure the State's role in service authorization. Section 441.470(f) permits participants to request a fair hearing if a participant's request for a budget adjustment is denied or the amount of the budget is reduced. We believe that this section will encompass a situation where a participant perceives that the amount of the service budget is inadequate to meet the participant's needs. However, the preferred process in such a situation would be for a discussion to initially occur between the participant, the participant's representative, if any, the supports broker or consultant or other members of the service planning team to explore an informal resolution to the participant's concern. We believe that a reassessment of the participant's need for PAS may be a proper solution to the participant's concern. We do not necessarily agree with the other alternatives mentioned by the commenters. Institutionalization is not an acceptable option in this case, as the intent of the section 1915(j) provision is to avoid institutionalization by strengthening supports to individuals. We also do not support any process

where participants forego needed services; rather, we would expect that the PAS provider, the representative, if any, the FMS entity or the supports broker or consultant would discover whether a reassessment is indicated and report this information to the State. As noted by the commenter, because reassessment is an appropriate step when the participant or representative, if any, feels the budgeted service amount is insufficient to meet a participant's needs, we have revised § 441.472 to add a new subsection (e) to indicate that a State must have a procedure to adjust a budget when a reassessment indicates a change in the participant's medical condition, functional status, or living situation.

Comment: One commenter recommended that we delete the word "medically" from the language in the rule at § 441.472(d). The commenter was concerned that the word "medically" would restrict a participant to the receipt of care or services related solely to a participant's medical condition or disease.

Response: Section 441.472(d) reflects the statutory language which states that, "The budget may not restrict access to other medically necessary care and services furnished under the plan and approved by the State but not included in the budget." Moreover, we believe that the term "medically necessary" is a commonly recognized term of art that encompasses all the services, supplies, or equipment that a State includes under its State plan, waiver, or other Medicaid programs, and for which an eligible individual has been determined to need.

Comment: One commenter recommended that the rule include an incentive system for payment to the counseling and fiscal agencies. Specifically, the commenter recommended that a higher, one-time payment be made to the counseling or FMS entity when an individual has selected the option, followed by a one-time payment when the spending plan is developed, and finally, by a monthly fee after the individual receives the budget allowance.

Response: We believe that States should design the approach for payment to FMS entities in a manner that comports best with the State's fiscal processes and procedures.

Comment: One commenter indicated that there are insufficient standards in the rule to ensure that budgets will not be arbitrarily reduced for participants who self-direct their PAS. The commenter further suggests that States should not assume that all participants will be able to secure services at a lower

cost than through the traditional service delivery model.

Response: We believe that there are sufficient standards in the regulations to ensure that budgets will not be arbitrarily reduced. The regulations require that the budget methodology be consistently applied to participants and that the budgeted amount be based on the assessment of the participant's needs, strengths, and preferences and the service plan. We believe that all these are safeguards against participants' budgets being arbitrarily reduced.

Comment: One commenter questioned the need for a budget methodology if participants are free to purchase what they need outside of any State-imposed pricing methodology. The commenter further noted that it seemed inappropriate to claim that participants would be free to determine the pay rate for their providers of PAS when they have no control over the total budget amount.

Response: We believe the commenter has confused the budget methodology with the ability of the participant to determine the amount paid for a service, support, or item. To clarify, among other things, the budget methodology is for the purpose of ensuring that the budget allocation for all participants is objective; evidenced based; utilizes valid, reliable cost data; is applied consistently to participants; is open to public inspection; and, includes a calculation of the expected cost of the self-directed PAS and supports, if those services and supports were not self-directed. Under the traditional service delivery model, the amount that the State has budgeted for an individual is based on these same factors. The only difference is that the participant in this self-directed model is directing how that amount will be used to purchase the services, supports, or items to meet his or her needs.

Upon consideration of the public comments received, we are finalizing § 441.472, with revision, to indicate that the budget methodology is established by the State in such a way as to ensure the State's role in service authorization, and to require the State to have a procedure to adjust a budget when a reassessment occurs and necessitates a change.

Quality Assurance and Improvement Plan (§ 441.474)

We proposed that the State must provide a quality assurance and improvement plan that describes the State's system of how it will perform activities of discovery, remediation, and quality improvement for self-directed

PAS. We proposed that the quality assurance and improvement plan describe the system performance measures, outcome measures, and satisfaction measures that the State must use to monitor and evaluate the self-directed State plan option.

Comment: One commenter suggested that we require the State to create a log of all critical events reported by participants.

Response: We do not accept the commenter's suggestion because we believe that the State would already be required to track the critical incidents reported by participants as part of the State's quality assurance and improvement (QA/QI) plan under § 441.474. Section 441.474 requires a State to have a QA/QI plan that includes a system to discover critical incidents or events that may pose harm to participants. Under such a system, critical incidents or events reported by participants must be tracked, and the results analyzed and evaluated, so that quality improvements that are needed to ensure participant health and welfare are continuously made under the self-directed PAS option.

Comment: One commenter indicated that State plans must address how the State will monitor quality for those with progressive, degenerative diseases (for example, Alzheimer's disease), developmental disabilities, or mental health conditions. The commenter stated that special attention to the experiences of those with cognitive impairments is critically important in a program that relies on participants to manage their own services.

Response: We agree that a State's QA/QI plan should take into consideration the changing needs of particular populations that are self-directing their PAS under this option. For example, a QA/QI plan could include adjustments for more frequent phone or face-to-face monitoring if the participants' conditions change. However, we do not believe a change to the regulation is necessary as we will evaluate a State's QA/QI plan during the review of the section 1915(j) State plan application.

Comment: Some commenters suggested specific performance, outcome and satisfaction measures be added as requirements for the QA/QI plan.

Response: We appreciate the commenters' input. Section 441.474 already requires that the QA/QI plan describe the system performance measures, outcome measures, and satisfaction measures that the State must use to monitor and evaluate the self-directed State plan option. We believe requiring certain measures and

indicators at this time may be premature as we currently have an initiative underway to evaluate whether certain quality measures and indicators should apply to all Medicaid programs. To assist us in determining which quality measures and indicators are generally being used in Medicaid, we are revising § 441.474(b) to indicate that quality of care measures must be made available to CMS upon request. Moreover, if we do identify such quality measures, we may wish to apply them to the self-directed PAS State plan option. In light of this possibility, we have revised § 441.474(b) to clarify that quality of care measures must be made available to CMS upon request and note that the QA/QI plan must include indicators approved or prescribed by the Secretary.

Comment: One commenter recommended that CMS revise the regulations to reflect the statutory language which requires only "appropriate quality assurance and risk management techniques" instead of the current requirements for a quality assurance and improvement plan and the system performance measures, outcome measures, and satisfaction measures.

Response: We do not agree with the commenter. Section 1915(j)(5)(E) of the Act requires States to provide appropriate quality assurance techniques to establish and implement the PAS service plan and budget. As we stated in the proposed regulation, such techniques must recognize the roles and responsibilities in obtaining services in a self-directed manner and assure the appropriateness of such plan and budget based upon the participant's resources and capabilities. For approximately 30 years, we have witnessed an increasing number of Medicaid recipients who want to move into or remain in the community in order to receive community-based care and services. Simultaneously, we have seen the growth in the number of individuals who want to self-direct their community-based care and services. States face the challenge of how to ensure each participant's health and welfare while also respecting individual autonomy and choice. We believe that this challenge can be met with an effective QA/QI plan that incorporates performance of discovery, remediation, and quality improvement activities and includes system performance measures, outcome measures, and satisfaction measures. Accordingly, we believe that the appropriate techniques must reflect, at a minimum, the need for discovery, remediation, and quality improvement activities and system performance measures, outcome measures, and

satisfaction measures as noted in the regulations at § 441.474(a) and (b).

Comment: One commenter recommended that we require a broad backup plan to account for situations where budgeted funds are prematurely depleted. Additionally, the commenter recommended a reassessment of an individual's ability to participate in the State plan option if the budget plan is not being followed.

Response: We believe that by "broad backup plan", the commenter means that we should require States to have a "template" prepared in advance that would address what to do in situations where budgeted funds are prematurely depleted. We disagree with the commenter because we believe that a backup plan should be individualized and tailored to a participant's identified critical contingencies or incidents that would pose a risk of harm to the participant's health or welfare. As stated previously, there are several options that a State may employ to safeguard participants who have prematurely spent the funds in their service budgets, such as the provision of additional information or counseling on budgeting. Moreover, a reassessment of an individual's ability to self-direct their PAS if the budget plan is not being followed, may not be appropriate in all situations. Again, it would depend on whether additional information or training has helped the participant to stay within the budget restrictions. However, we agree with the commenter insofar as a change in the participant's health status may be the cause of the participant's inability to stay within budget restrictions. As we noted previously in response to a prior comment, in such a situation, a reassessment of the participant's health status would be appropriate.

After consideration of public comments received, we are finalizing § 441.474, with revision, to require that quality measures be available to CMS upon request and include indicators approved or prescribed by the Secretary.

Risk Management (§ 441.476)

We proposed that the State must specify the risk assessment methods it uses to identify potential risks to the participant and the tools or instruments it uses to mitigate identified risks. We further proposed that the State must ensure that each service plan includes the risks that an individual is willing and able to assume, and the plan for how identified risks will be mitigated. Finally, we proposed that the State must ensure that the risk management plan is the result of discussion and negotiation among the persons designated by the

State to develop the service plan, the participant, the participant's representative, if any, and others from whom the participant may seek guidance.

Comment: One commenter urged that CMS require States to specify how they will assess and address potential risks for those with impaired cognition.

Response: The statute and the regulations note that States must specify risk assessment methods, tools, or instruments the State uses to mitigate identified risks, and a plan for how risks will be mitigated. We do not believe that it is necessary to specify how persons with impaired cognition will be assessed and how the potential risks for these individuals will be addressed. As stated in the proposed regulations, how much risk an individual is willing and able to assume is a matter of discussion and negotiation among the persons designated by the State to develop the service plan, the participant, the participant's representative, if any, and others from whom the participant may seek guidance. This process provides flexibility to the State and to the participants to reflect the participants' needs and resources in the service plan and budget plan. We believe this process would adequately address situations where participants have impaired cognition and have not revised the regulations.

Comment: In discussing the tools that may be used, we invited comment on whether criminal background checks should be mandatory under the State plan option or left to the discretion of the States, as is the current practice in programs that offer self-direction. Several commenters provided comments on whether criminal background checks should be mandatory with one commenter stating we should include national background checks for any provider of PAS that has one-to-one contact with participants. Other commenters offered suggestions on how the background checks should be reimbursed. Some commenters indicated that an individual's spouse, parent, close relative, or friend who is to be hired as a provider of PAS should not have to undergo a criminal background check. Some commenters also thought that the individual should retain the decision of whether to hire a person whom the individual or participant knows to have, or discovers to have, a criminal background.

Response: We recognize the commenters' perspective that recommended that criminal background checks be mandatory under this State plan option. However, we agree with the commenters who suggested that

criminal background checks remain at the State's discretion and are not revising § 441.476. Section 441.476 requires States to specify any tools or instruments it uses to mitigate identified risks. We have not prescribed the tools or instruments that States must use because States should have the necessary flexibility to use the instruments or tools that they have found best meets the needs of the participants. These tools may include the use of criminal and worker background checks and States have the option to determine who falls within the scope of such background checks. In addition, if States make criminal or worker background checks available as a tool to mitigate risks to participants, then States would bear the expense of the criminal or worker background checks it performs on behalf of participants. We further believe that the individual, or individual's representative, must retain the authority to decide who the participant will hire to provide their PAS as this decision as to who to employ is inherent in self-direction.

Comment: One commenter suggested that CMS establish procedures for developing negotiated risk agreements. Moreover, the commenter stated that CMS should require State Medicaid programs to develop appropriate linkages with their State long-term care ombudsman and agencies that administer protective service to ensure that there are safeguards against abuse.

Response: Section 441.476(b) requires a State to specify the tools or instruments it uses to mitigate identified risks. As noted in the proposed regulation, we do not prescribe the tools or instruments that States must use because States should have the flexibility necessary to use the instruments or tools they have found best meet the needs of the participants. We noted that examples of risk management tools or instruments might include criminal and worker background checks; job descriptions that clearly set forth the roles and responsibilities of participant, workers, representatives, and all others involved with supporting the participant; and the use of individual risk agreements that permit the participant to acknowledge and accept the responsibility for addressing certain types of risks. Accordingly, we do not believe that CMS should establish procedures for the development of negotiated risk agreements. Moreover, while we encourage States to develop linkages with their State long-term care ombudsman program, we do not believe we should require these relationships.

We have previously addressed the need for access to an independent advocate or advocacy organization in our response to the comments under § 441.464(d) (Support system) that we think would encompass programs such as the State long-term care ombudsman program and protective services programs that exist in the State. We assume and believe that States already have agencies that administer protective services to ensure that there are safeguards against abuse.

Upon consideration of public comments received, we are finalizing § 441.476 without modification.

Qualifications of Providers of Personal Assistance (§ 441.478)

We proposed that States have the option to permit participants to hire any individual capable of providing the assigned tasks, including legally liable relatives, as paid providers of the PAS identified in the service plan and budget. We proposed that participants retain the right to train their workers in the specific areas of personal assistance needed and to perform the needed assistance in a manner that comports with the participant's personal, cultural or religious preferences. Finally, we proposed that participants retain the right to establish additional staff qualifications based on participants' needs and preferences.

Comment: We invited comment on whether a minimum age requirement should be required for the providers of PAS. Three commenters opposed the imposition of a minimum age requirement in order to maximize the degree of flexibility participants have over their workers who will furnish the participant's PAS. However, one commenter cautioned that not including a minimum age requirement may run afoul of a State's child labor laws. Further, one commenter stated that the focus should be on whether the worker is qualified to furnish the service in the service plan. Several commenters suggested that CMS demand some minimum training, worker qualifications, and competency evaluation requirements.

Response: We agree with the commenters that we should not impose a minimum age restriction on providers of PAS; rather, the focus should be on whether the worker is qualified to furnish the service in the service plan according to the participant's personal, cultural, and religious preferences.

As self-directed PAS may include services beyond personal care, any minimum training, worker qualifications, or competency evaluation requirements would have to be tailored to each of the different

provider types that will potentially furnish self-directed PAS under this option. We do not believe that recreating a system of minimum training, worker qualifications, and competency evaluation requirements would be appropriate because it would remove the authority vested in participants to train their providers of PAS and to determine their qualifications.

We agree that participants should have access to additional training for their workers, as needed or desired, provided by or through the State. In this regard, we have revised the regulations at § 441.450(b) to permit participants to have access to other training provided by or through the State so that their PAS providers can meet any additional qualifications that participants think are needed or desired. We also believe that § 441.478(b) should include this requirement and have revised that section similarly. The participant's supports broker or consultant, as needed or desired, should assist the participant in locating and accessing additional training.

Comment: One commenter recommended that all individual assessments include a determination of the ability of the individual to adequately train their PAS provider.

Response: We believe that the regulations afford sufficient supports to the participant, such as, the requirements that ongoing information or counseling be provided to participants, or the use of representatives, as needed, that would enable participants to adequately communicate their needs to a PAS provider and to train their PAS provider in how to meet those needs. Therefore, we are not adopting the commenter's suggestion.

Upon consideration of the public comments received, we are finalizing § 441.478, with modification to permit access to training provided by the State to allow the PAS providers to meet any additional qualifications required or desired by the participant.

Use of a Representative (§ 441.480)

We proposed that States may permit participants to appoint a representative to direct the provision of self-directed PAS on their behalf and listed the types of representatives that are permissible. We also proposed that States could mandate a representative, using criteria approved by CMS, if the participant has demonstrated, after additional counseling, information, training or assistance, the inability to self-direct PAS. We further proposed that a person acting as a representative for a

participant receiving self-directed PAS is prohibited from acting as a provider of self-directed PAS to the participant.

Comment: Two commenters recommended that use of a representative should be required in the rule. In contrast, other commenters urged that CMS amend the rule to permit a representative to be "an individual chosen by the participant" and to permit a spouse or significant other to act as a representative. One commenter noted that it is inappropriate for the participant to appoint a parent or guardian as the representative, since this is the fundamental responsibility of a parent or guardian. Several other commenters stated that the rule should permit representatives to be paid providers of PAS to allow for situations where workers are in short supply, or where a representative is the participant's preferred or only available provider. One commenter was concerned about the use of "legally liable relatives" as paid providers of PAS because the situation would be susceptible to abuse and because the potential exists for violations of State Nurse Practice Acts that delegate skilled nursing care to unpaid but not paid caregivers. Another commenter suggested that we add a definition of "representative" to the rule. One commenter suggested that the language at § 441.480, with respect to who may be a representative, should be moved to the definitions section to strengthen the protections embodied in the regulatory language.

Response: We disagree that use of a representative should be required as this could be overly prescriptive in situations where an individual is able to indicate preferences or manage his own services and budgets with assistance. We further note that while spouses are not expressly included, they are not specifically excluded in the regulations, and would likely be an individual recognized by State law to act on the participant's behalf. We believe that other representatives could be permitted by the State.

The role of the representative is to assist individuals in making decisions with respect to the planning, development, management, and direction of their service plans and budget plans. We encourage States to recognize and permit other representative relationships, so that participants can exercise greater flexibility in their choice of who will assist them with their decisions.

We continue to believe that representatives should not be paid providers of PAS. While it potentially limits a participant's choice of

representative or provider, we think it is important to avoid any potential conflict of interest. We also learned from the experiences of the States participating in the original "Cash & Counseling" demonstration, that it is important to include this limitation in order to avoid the situation of a representative overseeing or making decisions that directly impact them, such as approving their own rate of pay, their own timesheets, and the like. Accordingly, in order to promote participant health and welfare and program integrity, and to ensure that participants actually receive their authorized PAS, we included this necessary protection in the regulation at § 441.480(b). Moreover, we believe that there are sufficient participant and programmatic protections in the regulations that would detect concerns about violations of Nurse Practice Acts. Finally, we disagree that the rule should be amended to add those who may be a representative, or that a separate definition is necessary, because we believe that representative eligibility will vary under State law and agency procedure. Therefore, we have left the regulations unchanged.

Comment: One commenter suggested that the rule address the ability of potential representatives to freely choose or to decline to perform the tasks associated with being the representative; to understand their responsibilities; and to get support, training, and counseling as needed to carry out their responsibilities.

Response: We do not believe that the details of the representative's training and understanding of their responsibilities is needed as we believe that the States will perform this function as part of the pre-enrollment counseling and as necessary on an ongoing basis.

Comment: One commenter suggested that CMS require a representative agreement that lists the tasks the representative agrees to perform on behalf of the participant.

Response: We encourage the voluntary use of an agreement if it would be beneficial to the participant and the representative, but do not believe a requirement for such an agreement should be dictated. We believe that some representatives who are clear about their tasks and responsibilities would find such a requirement unnecessary and burdensome. We further believe that States should have the discretion whether to impose such a requirement on representatives of participants self-directing their PAS under this State plan option.

Upon consideration of public comments received, we are finalizing § 441.480 without modification.

Permissible purchases (§ 441.482)

We proposed that participants may, at the State's option, use their service budgets to pay for items that increase a participant's independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance. We also proposed that the services, supports, and items that are purchased with a service budget must be linked to an assessed participant need established in the service plan.

Comment: One commenter stated that purchases must relate back to an assessed need and must be restricted to those that relate to the individual's medical condition. Furthermore, this commenter stated, individuals in traditional models of service delivery should have access to the same purchase options as participants in the self-directed PAS State plan option, that is, to purchase items that increase independence or substitute for human assistance.

Response: Section 441.482 indicates that permissible purchases must be linked to an assessed participant need established in the service plan. We do not agree that purchases must relate to a participant's "medical condition" because such a limitation may be overly prescriptive and preclude the purchase of some items that may substitute for human assistance, such as a microwave. However, we have revised the regulation further to allow that permissible purchases must be related to an assessed participant need or goal established in the service plan. As service plans must be person-centered and identify participants' preferences, we believe that service plans often include participants' goals such as the desire to live in their own home. Therefore, if a purchase would assist a participant to live in their own home, thereby becoming more independent, then the purchase of an item that would increase independence could be consistent with the requirements in the regulation. In separate guidance, we will issue further direction on permissible purchases. As to the commenter's suggestion that individuals who receive their services in a traditional service delivery model should have the option to purchase items that increase independence or substitute for human assistance, we believe that the statute directs this option only to participants of the self-directed PAS State plan option.

Comment: One commenter noted that the use of the term "medically necessary" in the preamble is not correct in the context of permissible purchases. These purchases could be consistent with a service plan, but not strictly "medically necessary."

Response: We agree with the commenter that in the context of permissible purchases, the item need not be medically necessary. We are clarifying this point here and will take this comment into consideration as we develop the future guidance on permissible purchases.

Comment: One commenter supported the concept of allowing participants to use funds for permissible purchases but cautions that doing so allows for more opportunities for abuse. The commenter recommended more oversight to ensure the fiscal integrity of the State plan option and accountability for the funds.

Response: Section 441.464(a) requires assurances that necessary safeguards be taken to protect the health and welfare of individuals furnished services under the State plan option and to assure the financial accountability for funds expended for self-directed services, which includes permissible purchases. We believe this provides adequate oversight over the fiscal accountability of the funds and protects the overall integrity of this option.

Upon consideration of public comments received, we are finalizing § 441.482 with revision to note that permissible purchases must be linked to a participant need or goal established in the service plan.

Financial Management Services (§ 441.484)

We proposed that States may provide FMS themselves to participants self-directing their PAS, or employ another FMS entity to provide these services. Participants utilizing the cash option who directly perform those functions themselves would not require this service. We proposed that the FMS entity must comply with all applicable requirements of the IRS. We further proposed that States must provide oversight of FMS by performing certain prescribed functions. We also proposed the specific functions that FMS entities must perform and proposed that States not employing an FMS entity must perform those functions. Finally, we proposed that States will be reimbursed for the cost of FMS, either provided directly or through a financial management entity, at the administrative rate of 50 percent to reflect the statutory requirement for reimbursement of FMS.

Comment: One commenter stated that the requirement for FMS would add considerable costs to a State's Medicaid budget and also add to the oversight responsibilities borne by a State.

Response: We acknowledge that States may experience an initial outlay of funds to provide, or employ an entity to provide, the FMS required by this rule. This may be particularly true when a State has not previously offered a self-direction opportunity that included a participant's authority over their workers and services, as well as a service budget. However, we do not believe an FMS option would significantly add to States' fiscal and administrative responsibilities, as States must already provide programmatic and financial oversight of their Medicaid programs, including the functions to be performed by the FMS entity.

Comment: One commenter asserted that agencies who are supposed to serve as "fiscal intermediaries" are, in reality, functioning as home care agencies without any regulatory oversight. One commenter cautioned that the FMS entity cannot be allowed to operate independently without oversight by the State and without oversight responsibility for the expenditures made by a participant.

Response: We believe the commenter has misunderstood the role of the FMS entity. We note that the term "fiscal intermediary" may be interpreted differently by different people and States. "Fiscal intermediaries" are not necessarily synonymous with financial management services. Section 441.484 sets forth minimum mandatory functions that must be performed by the FMS entity and the State's responsibilities for oversight of the FMS entity. Accordingly, we believe that the rule has sufficient safeguards to ensure that the FMS responsibilities are properly carried out and supervised.

Comment: One commenter thought that reimbursing the FMS entity at the 50 percent administrative rate was improper in situations when the State offers an "agency with choice" model. The commenter explained that under this model, the participant may choose to delegate certain functions to the agency such as recruitment, initial and on-going training, and the identification and management of backup services. These functions should be reimbursed at the FMAP rate.

Response: Financial management services, regardless if performed by a stand-alone FMS entity or one that is part of an agency with choice model, will be reimbursed at the statutorily-required 50 percent administrative rate.

Comment: One commenter suggested that we add a requirement to § 441.484(c) that the FMS entity must maintain a separate account for each participant's budget.

Response: This is already a requirement for the FMS entity as noted in Section 441.484(c)(3).

Upon consideration of the public comments received, we are finalizing § 441.484 without modification.

IV. Provisions of the Final Regulation

Generally, this final regulation incorporates the January 18, 2007 provisions of the proposed rule. The provisions of this final regulation that differ from the proposed rule are as follows:

(1) We have revised the final regulation in relevant places by adding "or their representatives, if applicable" when we refer to individuals or participants. The provisions that we revised include: § 441.450(b); § 441.450(c) (that is, the definitions of "Service budget" and "Service plan"); § 441.454(a), (c), (d); § 441.464(a)(2)(ii); § 441.464(d)(3)(i) and (ii); § 441.464(d)(4); § 441.468(b)(2); § 441.468(c)(1) and (2); § 441.468(d); § 441.468(e); § 441.470(c); § 441.470(c)(1); § 441.470(e); § 441.470(f); § 441.472(c); § 441.478(a), (b) and (c); § 441.482(a); and § 441.484(a).

(2) We have revised § 441.450(b) by adding a new requirement in paragraph (4) to include the authority of participants to train their workers and to access training provided by or through the State if additional worker training is required or desired by the participant, or participant's representative, if applicable.

(3) We have revised § 441.450(c), the definition of individualized backup plan, to clarify that the individualized backup plan must demonstrate an interface with the risk management provision at § 441.476.

(4) We have revised § 441.450(c) to add a definition for "supports broker or consultant" and to require that a supports broker or consultant be available to each participant, as part of the support system. We have defined "supports broker or consultant" to mean an individual who supports participants in directing their PAS and service budgets. The supports broker or consultant is an agent of the participants and takes direction from the participants, or their representatives, if applicable, about what support is needed or desired. The supports broker or consultant is primarily responsible for facilitating participants' needs in a manner that comports with the

participants' preferences. The primary functions of the supports broker or consultant are to inform, counsel, train, and assist the participant, or the participant's representative, if applicable, with whatever is needed to develop a service budget and effectively manage the participant's self-directed PAS and budgets. Supports brokers or consultants must be accessible to participants, maintain an ongoing relationship with participants, monitor whether participants' health status has changed, and whether expenditures of funds are being made in accordance with the service budgets. States must develop a monitoring protocol that includes regularly scheduled telephone and face-to-face contact with participants. States must also develop the training requirements and qualifications for supports brokers or consultants that include, at a minimum, the following:

- An understanding of the philosophy of self-direction and person-centered and directed planning.
- The ability to facilitate participants' independence and participants' preferences in managing PAS and budgets, including any risks assumed by participants;
- The ability to develop service budgets and ensure appropriate documentation;
- Knowledge of the PAS and resources available in the participant's community and how to access them.

The availability of a supports broker or consultant to each participant is a requirement of the support system.

(5) We have revised § 441.454(b) to add examples of the types of tax-related requirements that participants, if they have chosen the cash option, or the FMS entity, must perform.

(6) We have revised § 441.456(b) and § 441.458(c) to require that the State specify in the section 1915(j) State plan amendment the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

(7) We have revised § 441.460(a) to insert "PAS" before "providers."

(8) We have revised § 441.464(c) to require that information on feasible alternatives be communicated to the individual in a manner and language understandable by the individual.

(9) We have revised § 441.464(d) to add a requirement that States may arrange for the provision of a support system, in addition to providing the support system themselves.

(10) We have revised § 441.464(d)(1) to add a requirement that before enrollment, the support system

appropriately counsels an individual about disenrollment.

(11) We have revised § 441.464(d)(2) to add a requirement that any information provided to the participant as a part of the support system must be communicated to the participant in a manner and language understandable by the participant.

(12) We have revised § 441.464(d)(2)(vii) to insert the term "PAS" to the requirement that the support activities include the ability to freely choose PAS providers.

(13) We have revised § 441.464(d)(2) by adding a clause (xv) that the list of support activities include information about an advocate or advocacy systems available in the State and how a participant, or a participant's representative, can access the advocate or advocacy systems.

(14) We have revised § 441.468(c)(2) by adding the word "allow" at the beginning of the paragraph.

(15) We have revised § 441.468(c) to add a new paragraph (8) to include that the State ensures that a participant may request revisions to a service plan, based on a change in needs or health status.

(16) We have revised § 441.470(d) to make a technical change to insert the phrase, "to the extent that expenditures would otherwise be made for the human assistance," into the requirement concerning procedures that govern how a participant, at the election of a State, may reserve funds to purchase items that increase independence or substitute for human assistance.

(17) We have revised § 441.470(e) to add the phrase, "or reserved for permissible purchases," to the requirement concerning procedures that govern how a person may use a discretionary amount, if applicable.

(18) We have revised § 441.472 to revise subsection (a) to indicate that the budget methodology is established by the State in such a way as to ensure the State's role in service authorization, and to add a new subsection (e) to require a State to have a procedure to adjust a budget, subject to a State's medical necessity criteria, when a reassessment indicates a change in a participant's medical condition, functional status, or living situation.

(19) We have revised § 441.474(b) to add a new requirement that quality of care measures must be made available to CMS upon request and that the QA/QI plan must include indicators approved or prescribed by the Secretary.

(20) We have revised § 441.478(b) to add a requirement that participants, or their representatives, if applicable, also have the right to access training

provided by or through the State so that their PAS providers can meet any additional qualifications that participants think are needed.

(21) We have revised § 441.482(b) to insert the words, "or goal," to the requirement that the services, supports, and items that are purchased with a service budget must be linked to an assessed participant need or goal established in the service plan.

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 one general comment. We also received public comments on four specific sections contained in the ICRs. The comments and our responses follow:

General

Comment: Two commenters stated that the estimates in the collection of information section do not reflect differences in State Medicaid systems and the populations served and that we have severely underestimated the time and resources that are necessary to meet the requirements.

Response: Our estimates are based on the average time it may take for States to fulfill the requirements of this rule and reflect the appropriate differences in the State Medicaid systems and populations.

Note: The self-directed PAS State plan option pre-print is currently approved under OMB number 09398-1024.

Section 441.454—Use of Cash

Section 441.454(d) requires States to make available a financial management entity to a participant who has demonstrated, after additional counseling, information, training, or assistance, that the participant cannot effectively manage the cash option described in paragraph (a) of this section.

The burden associated with this requirement is the time and effort put forth by the State to counsel and to provide information, training, and or assistance to participants. We believe that it would take a State 1 hour per participant to provide this guidance. The total annual burden of this requirement would vary according to the number of participants in each State who are self-directing their PAS under this State Plan option. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.456 Voluntary Disenrollment

Section 441.456(b) requires States to specify in the State plan the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

The burden associated with this requirement is the time and effort put forth by the State to revise its State plan to include the safeguards. While the burden associated with this requirement is subject to the PRA, the burden associated with the State plan amendment is currently approved under OMB #0938-0933. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.458 Involuntary Disenrollment

Section 441.458(c) requires States to specify in the State plan the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

The burden associated with this requirement is the time and effort put forth by the State to revise its State plan to include the safeguards. While the burden associated with this requirement is subject to the PRA, the burden associated with the State plan amendment is currently approved under OMB #0938-0933. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.464 State Assurances

Section 441.464(a) requires States to provide an assurance that necessary safeguards have been taken to protect the health and welfare of individuals furnished services under the program and to assure the financial accountability for funds expended for self-directed services.

The burden associated with this requirement is the time and effort it would take for each State to meet these conditions. To meet the requirements in § 441.464(a), we estimate it would take each State 80 hours to develop a system of safeguards that protects participants' health and welfare and ensures financial accountability for funds expended, and no further burden would be associated with this requirement. We estimate the total maximum one-time burden for this requirement to be 4,480 hours. (56 States × 80 hours = 4,480 hours)

Comment: One commenter thought that the estimate of 80 hours to develop a system of safeguards was unreasonable given that some States would be developing and promulgating state rules

to implement the new safeguards, in addition to having to adjust contracts, train staff and providers in new procedures and make any needed system modifications.

Response: We do not believe that the estimate of 80 hours to develop a system of safeguards is unreasonable. All Medicaid programs must assure the health and welfare of beneficiaries and fiscal accountability, so these are not new safeguards. Furthermore, we do not believe that all States will have to develop and promulgate rules. We acknowledge that some States may need to adjust contracts, train staff and make system modifications, but do not believe, that making such changes would exceed, on average, 80 hours per State. Many States already offer the opportunity for self-direction in their section 1915(c) waiver programs, so it would not be overly difficult for these States to transition to the opportunity for self-direction offered under the self-directed PAS State plan option. We also note that there would be little, if any, burden to the States associated with the training of PAS providers, as participants bear the responsibility for training their PAS providers. Accordingly, we have not revised the collection of information estimate.

Section 441.464(b) requires States to provide an assurance that they will perform an evaluation of the need for personal care under the State plan or personal services under a section 1915(c) home and community-based services waiver program. The burden associated with this requirement is the time and effort it would take for each State to meet this condition. To meet the requirement in § 441.464(b), we estimate it would take a State 2 hours per participant to perform this evaluation of need. The total annual burden of this requirement would vary according to the number of participants in each State who are (1) entitled to medical assistance for personal care services under the State plan, or receive home and community-based services under a section 1915(c) waiver program; (2) may require self-directed PAS; and (3) may be eligible for self-directed PAS. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.464(c) requires States to provide an assurance that individuals likely to require personal care under the State plan, or home and community-based services under a section 1915(c) waiver program, are informed of the feasible alternatives, if available, under the State's self-directed PAS State plan option, at the choice of these individuals, to the provision of personal

care services under the State plan or PAS under a section 1915(c) home and community-based services waiver program. The burden associated with this requirement is the time and effort it would take for each State to meet this condition. To meet the requirement in § 441.464(c), we estimate it would take a State 15 minutes per participant to inform individuals of feasible alternatives. The total annual burden of this requirement would vary according to the number of participants in each State who are likely to require personal care under the State plan, or home and community-based services under a section 1915(c) waiver program.

Comment: Two commenters stated that the proposed 15-minute time estimate for explaining feasible alternatives to individuals was too brief.

Response: We do not believe that the estimate of 15 minutes to inform individuals of the feasible alternatives is too short. We believe that most States will incorporate information about feasible alternatives within the context of the assessment of the individual's needs, or during some other pre-enrollment contact with the individual. We estimated that the time to advise an individual of the feasible alternatives would only be a small portion of the time spent during the assessment. Accordingly, we have not revised the collection of information estimate.

Section 441.464(d) requires States to provide a support system that meets the following conditions:

- (1) Appropriately assesses and counsels an individual before enrollment.
- (2) Provides appropriate information, counseling, training, and assistance to ensure that a participant is able to manage the services and budgets. The support activities must include at least the following:
 - (i) Person-centered planning and how it is applied.
 - (ii) Information about the services available for self-direction.
 - (iii) Range and scope of individual choices and options.
 - (iv) Process for changing the service plan and service budget.
 - (v) Grievance process.
 - (vi) Risks and responsibilities of self-direction.
 - (vii) Freedom of choice of providers.
 - (viii) Individual rights.
 - (ix) Reassessment and review schedules.
 - (x) Defining goals, needs, and preferences.
 - (xi) Identifying and accessing services, supports, and resources.
 - (xii) Development of risk management agreements.

(xiii) Development of an individualized backup plan.

(xiv) Recognizing and reporting critical events.

(3) Offers additional information, counseling, training, or assistance, including financial management services under either of the following conditions:

(i) At the request of the participant for any reason.

(ii) When the State has determined the participant is not effectively managing the services identified in the service plan or budget.

The burden associated with this requirement is the time and effort it would take for each State to meet these conditions. To meet the requirements in § 441.464(d)(1), we estimate it would take each State 2 hours per participant.

To meet the requirements in § 441.464(d)(2), we estimate it would take each State 1 hour per participant.

To meet the requirements in § 441.464(d)(3), we estimate it would take each State 1 hour per participant.

The total annual burden of these requirements would vary according to the number of participants in each State who are self-directing their PAS under this State plan option. We received no public comment on this section.

Therefore, we have not revised the collection of information estimate.

Section 441.464(e) requires the State to provide to CMS an annual report on the number of individuals served and the total expenditures on their behalf in the aggregate.

The annual burden associated with this requirement is the time and effort it would take for each State to gather the necessary data and provide an annual report to CMS. We estimate that it would take one State no more than 25 hours to meet this requirement;

therefore, the total maximum annual burden is 1,400 hours. (56 States × 25 hours = 1,400 hours) We received no public comment on this section.

Therefore, we have not revised the collection of information estimate.

Section 441.464(f) requires the State to provide to CMS an evaluation of the overall impact on the health and welfare of participating individuals compared to non-participants every three years, as determined by CMS.

The burden associated with this requirement is the time and effort it would take for each State to provide such an evaluation to CMS. We estimate that it would take one State 200 hours to prepare and submit the evaluation to CMS every 3rd year; therefore, the total maximum burden on that 3rd year would be 11,200 hours. (56 States × 200 hours = 11,200)

Comment: One commenter questioned how we arrived at the estimate of 200 hours to prepare and submit an evaluation every three years as we did not include the requirements for the report. The commenter urged use of existing data sources.

Response: We believe that our estimate of the time to prepare and submit the three-year evaluation was reasonable. Our estimate was based on the time we expected it would take a State, on average, to determine the measures it would use to compare the impact of the self-directed PAS State plan option on the health and welfare of participants and non-participants, collect and analyze data, and summarize the findings in a report. Many, if not all, States collect data on performance and outcome measures within the context of their quality management systems in their current Medicaid programs. We believe that it would be appropriate for States to use data they have already collected to satisfy the requirement for the evaluation in § 441.464(f). Therefore, we have not revised the collection of information estimate.

Section 441.468 Service Plan Elements

Section 441.468(b) requires a State to develop a service plan for each program participant using a person-centered and directed planning process to ensure the following:

(1) The identification of each program participant's preferences, choices, and abilities, and strategies to address those preferences, choices, and abilities.

(2) The option for the program participant to exercise choice and control over services and supports discussed in the plan.

(3) Assessment of, and planning for avoiding, risks that may pose harm to a participant.

The burden associated with this requirement is the time and effort it would take for each State to meet these conditions. We estimate it would take each State 3 hours per participant to meet this requirement. The total annual burden of this requirement would vary according to the number of participants in each State who are self-directing their PAS under this State plan option. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.468(d) states that when an entity that is permitted to provide other State plan services is responsible for service plan development, the State must describe the safeguards that are in place to ensure that the service provider's role in the planning process is fully disclosed to the participant and

controls are in place to avoid any possible conflict of interest.

The burden associated with this requirement is the time and effort it would take for the State to fully disclose the required information. We estimate that it would take one State 15 minutes per participant to meet this requirement. The total annual burden of this requirement would vary according to the number of participants in each State who are self-directing their PAS under this State Plan option. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.468(e) requires that an approved self-directed service plan conveys authority to the participant to perform, at a minimum, the following tasks: recruit and hire workers to provide self-directed services, including specifying worker qualifications; fire workers; supervise workers in the provision of self-directed services; manage workers in the provision of self-directed services (determining worker duties, scheduling workers, training workers in assigned tasks, and evaluating workers' performance); determine the amount paid for a service, support, or item; and review and approve provider invoices.

While this information collection is subject to the PRA, we believe this requirement meets the requirements of 5 CFR 1320.3(b)(2), and as such, the burden associated with this requirement is exempt from the PRA. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.470 Service Budget Elements

Section 441.470 states that a service budget must be developed and approved by the State based on the assessment of need and service plan and must include the following:

- (a) The specific dollar amount a participant may utilize for services and supports.
- (b) How the participant is informed of the amount of the service budget before the service plan is finalized;
- (c) The procedures for how the participant may adjust the budget, including the following:
 - (1) How the participant may freely make changes to the budget.
 - (2) The circumstances, if any, that may require prior approval before a budget adjustment is made.
 - (3) The circumstances, if any, that may require a change in the service plan.
- (d) The procedure(s) that governs how a person, at the election of the State,

may reserve funds to purchase items that increase independence or substitute for human assistance including additional goods, supports, services or supplies.

(e) The procedure(s) that governs how a person may use a discretionary amount, if applicable, to purchase items not otherwise delineated in the budget.

(f) How participants are afforded the opportunity to request a fair hearing under § 441.300 if a participant's request for a budget adjustment is denied or the amount of the budget is reduced.

The burden associated with this requirement is the time and effort put forth by the State to develop a service budget. We estimate it would take a State 3 hours per participant to meet this requirement. The total annual burden of this requirement would vary according to the number of participants in each State who are self-directing their PAS under this State plan option. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.472 Budget Methodology

Section 441.472(b) requires a State to have procedures in place to safeguard participants when the budgeted service amount is insufficient to meet a participant's needs.

The burden associated with this requirement is the time and effort it would take for a State to develop its procedures on how to handle this. We estimate that it would take one State 16 hours to develop these procedures and no further burden would be associated with this requirement. The one-time maximum burden associated with this requirement is 896 hours. (56 States × 16 hours = 896 hours) We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.472(c) requires a State to have a method of notifying participants of the amount of any limit that applies to a participant's self-directed PAS and supports.

The burden associated with this requirement is the time and effort it would take for the State to provide this notification. We estimate it would take one State 15 minutes per participant to meet this requirement. The total annual burden of this requirement would vary according to the number of participants in each State who are self-directing their PAS under this State plan option. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

Section 441.474 Quality Assurance and Improvement Plan

Section 441.474(a) requires States to provide a quality assurance and improvement plan that describes the State's system of how it would conduct activities of discovery, remediation, and quality improvement in order to learn of critical incidents or events that affect participants, correct shortcomings, and pursue opportunities for improvement; and

(b) The quality assurance and improvement plan shall also describe the system performance measures, outcome measures, and satisfaction measures that the State would use to monitor and evaluate the self-directed State plan option.

The burden associated with this requirement is the time and effort it would take for the State to customize its quality assurance and improvement plan to the self-directed service delivery model. We estimate that it would take one State 100 hours to customize its quality assurance and improvement plan and no further burden would be associated with this requirement. The one-time maximum burden associated with this requirement is 5,600 hours. (56 States × 100 hours = 5,600 hours)

Comment: One commenter urged that CMS clarify that there will be ongoing burdens associated with quality assurance and improvement activities and not just the one-time burdens indicated in the rule.

Response: As States always retain the ultimate oversight and administrative authority for any Medicaid program, we think that any ongoing burden is subsumed within the State's normal course of doing business. Accordingly, we have not revised the collection of information estimate to account for an ongoing burden as suggested by the commenter.

Section 441.484 Financial Management Services

Section 441.484(a) proposes that States may choose to provide financial management services to participants self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions.

Section 441.484(c) proposes to require that the financial management entity provide functions including, but not limited to, the following:

- (1) Collect and process timesheets of the participant's workers.
- (2) Process payroll, withholding, filing and payment of applicable Federal, State, and local employment-related taxes and insurance.

(3) Maintain a separate account for each participant's budget.

(4) Track and report disbursements and balances of participant funds.

(5) Process and pay invoices for goods and services approved in the service plan.

(6) Provide to participants periodic reports of expenditures and the status of the approved service budget.

Section 441.484(d) requires States not utilizing a financial management entity must perform the functions listed in paragraph (c) of this section on behalf of participants self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions.

The burden associated with this requirement is the time and effort it would take for the financial management entity or State to develop and perform the listed functions. We estimate it would take a financial management entity or the State 320 hours to develop the financial management system. Once the system is in place, the annual burden associated with these functions would vary according to the number of participants in each State who are self-directing their PAS under this State Plan option. We estimate the maximum one-time burden on the States to develop the financial management system to be 17,920 hours during the first year. (56 States \times 320 hours = 17,920)

Note: Annual burden in the following years will vary. We have no data on how many financial management entities would be affected by this requirement; therefore, we are unable to provide total annual burden associated with financial management entities. We received no public comment on this section. Therefore, we have not revised the collection of information estimate.

The total aggregate burden for the requirements in this final regulation that affect States annually is estimated to be 1,400 hours. The total aggregate burden associated with one-time requirements on States is estimated to be 28,896. The total aggregate burden associated with the burden placed on States every 3rd year is estimated to be 11,200 hours.

Note: We are unable to provide aggregate burden totals for those requirements affecting participants because burden will vary according to the number of participants in each State who are self-directing their PAS under this State Plan option. We are also unable to provide aggregate burden for financial management entities affected by § 441.484(a).

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 Statement

A. Overall Impact

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

Executive Order 12866, as amended, directs 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final regulation does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6.5 million to \$31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. An RFA was not prepared because the Secretary has determined that this final regulation would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 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. Analysis for section 1102(b) of the Act was not prepared because the Secretary has determined that this final regulation would not have a significant impact on

the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$130 million. This final regulation would have no consequential effect on State, local, or tribal governments in the aggregate, or on the private sector near the threshold amount of \$130 million.

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

B. Anticipated Effects

FFP will be available for self-directed PAS if the State elects to offer this opportunity through the approved State plan. As self-direction is an alternative service delivery model, it is expected that the impact on Medicaid spending would not be very large. The use of self-directed PAS is estimated to cost a total of \$225 million in FY 2008 to FY 2012, of which, \$127 million is Federal share.

In making this estimate, we considered that costs might increase due to new covered expenses (such as microwave ovens or accessibility ramps) as well as new applicants being attracted to the Medicaid program, because of the permissibility of payments to relatives. Costs could decrease because beneficiaries might require less help and less expensive help. We also noted that some States have already implemented self-directed programs under other Medicaid authorities and thus, in those States, there would be little cost effect to the statute or this new regulation. We first estimated that the projected impact of all our proposals would amount to an overall 0.5 percent increase in personal care service expenditures, if all States and Territories implemented this self-direction PAS State plan option. We then accounted for a partial starting year, a phase-in period and the fact that this is a State plan option. Our final estimate is as noted in the table below.

SECTION 1915(J) SELF-DIRECTED PERSONAL ASSISTANCE SERVICES PROGRAM (CASH & COUNSELING)

[Dollars in Millions]

| | FY 2008 | FY 2009 | FY 2010 | FY 2011 | FY 2012 | Total FY 2008–2012 |
|--------------------|---------|---------|---------|---------|---------|--------------------|
| Federal Cost | 12 | 20 | 29 | 32 | 34 | 127 |
| State Cost | 9 | 15 | 22 | 24 | 26 | 96 |
| Total* | 22 | 35 | 51 | 56 | 61 | 225 |

* Amounts may not equal total due to rounding.

C. Alternatives Considered

In considering alternatives to the proposals presented in this proposed rule, we considered the current practices under section 1115 demonstrations and section 1915(c) waiver programs that implemented self-direction. In particular, we considered whether to allow States the flexibility to offer the option of disbursing cash prospectively to participants. We learned from the experience of the section 1115 demonstrations that participants were able to successfully manage the funds in their budget and maintain financial accountability, with some general guidance and oversight. In light of our desire to provide flexibility to the beneficiaries and to better reflect the intent of the PAS State plan option, we proposed this option.

We also considered the extent to which to include prescriptive support activities that States must include in their support system. We proposed a minimum list of support activities to ensure that participants have the necessary tools to successfully manage their services and budgets. We were concerned that if States were not required to include such activities as part of the support system within the PAS State plan option, the likelihood of successfully self-directing PAS would diminish. As we learned from our experience with the section 1115 demonstrations and section 1915(c) waiver programs, support activities have a crucial role in leading to the success of any self-directed PAS program.

D. Conclusion

As indicated in the estimated expenditures table above, we project the Federal Medicaid program cost of this final rule to be \$127 million over the period from FY 2008 to FY 2012. In addition, we project the total State cost of this final rule to be \$96 million over the period from FY 2008 to FY 2012.

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

List of Subjects in 42 CFR Part 441

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

■ The Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

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. Amend part 441 by adding new subpart J to read as follows:

Subpart J—Optional Self-Directed Personal Assistance Services Program

Sec.

- 441.450 Basis, scope, and definitions.
- 441.452 Self-direction: General.
- 441.454 Use of cash.
- 441.456 Voluntary disenrollment.
- 441.458 Involuntary disenrollment.
- 441.460 Participant living arrangements.
- 441.462 Statewide, comparability, and limitations on number served.
- 441.464 State assurances.
- 441.466 Assessment of need.
- 441.468 Service plan elements.
- 441.470 Service budget elements.
- 441.472 Budget methodology.
- 441.474 Quality assurance and improvement plan.
- 441.476 Risk management.
- 441.478 Qualifications of providers of personal assistance.
- 441.480 Use of a representative.
- 441.482 Permissible purchases.
- 441.484 Financial management services.

Subpart J—Optional Self-Directed Personal Assistance Services Program

§ 441.450 Basis, scope, and definitions.

(a) *Basis.* This subpart implements section 1915(j) of the Act concerning the self-directed personal assistance services (PAS) option through a State Plan.

(b) *Scope.* A self-directed PAS option is designed to allow individuals, or their representatives, if applicable, to exercise decision-making authority in identifying, accessing, managing and purchasing their PAS. This authority

includes, at a minimum, all of the following:

(1) The purchase of PAS and supports for PAS.

(2) Recruiting workers.

(3) Hiring and discharging workers.

(4) Training workers and accessing training provided by or through the State if additional worker training is required or desired by the participant, or participant's representative, if applicable.

(5) Specifying worker qualifications.

(6) Determining worker duties.

(7) Scheduling workers.

(8) Supervising workers.

(9) Evaluating worker performance.

(10) Determining the amount paid for a service, support or item.

(11) Scheduling when services are provided.

(12) Identifying service workers.

(13) Reviewing and approving invoices.

(c) *Definitions.* As used in this part—
Assessment of need means an evaluation of the needs, strengths, and preferences of participants for services. This includes one or more processes to obtain information about an individual, including health condition, personal goals and preferences, functional limitation, age, school, employment, household, and other factors that are relevant to the authorization and provision of services. Assessment information supports the development of the service plan and the subsequent service budget.

Individualized backup plan means a written plan that meets all of the following:

(1) Is sufficiently individualized to address each participant's critical contingencies or incidents that would pose a risk of harm to the participant's health or welfare;

(2) Must demonstrate an interface with the risk management provision at § 441.476 which requires States to assess and identify the potential risks to the participant (such as any critical health needs), and ensure that the risks and how they will be managed are the result of discussion and negotiation among the persons involved in the service plan development;

(3) Must not include the 911 emergency system or other emergency system as the sole backup feature of the plan; and

(4) Must be incorporated into the participant's service plan.

Legally liable relatives means persons who have a duty under the provisions of State law to care for another person. Legally liable relatives may include any of the following:

(1) The parent (biological or adoptive) of a minor child or the guardian of a minor child who must provide care to the child.

(2) Legally-assigned caretaker relatives.

(3) A spouse.

Self-directed personal assistance services (PAS) means personal care and related services, or home and community-based services otherwise available under the State plan or a 1915(c) waiver program that are provided to an individual who has been determined eligible for the PAS option. Self-directed PAS also includes, at the State's option, items that increase the individual's independence or substitutes (such as a microwave oven or an accessibility ramp) for human assistance, to the extent the expenditures would otherwise be made for the human assistance.

Self-direction means the opportunity for participants or their representatives to exercise choice and control over the budget, planning, and purchase of self-directed PAS, including the amount, duration, scope, provider, and location of service provision.

Service budget means an amount of funds that is under the control and direction of a participant, or the participant's representative, if any, when the State has selected the State plan option for provision of self-directed PAS. It is developed using a person-centered and directed process and is individually tailored in accordance with the participant's needs and personal preferences as established in the service plan.

Service plan means the written document that specifies the services and supports (regardless of funding source) that are to be furnished to meet the needs of a participant in the self-directed PAS option and to assist the participant to direct the PAS and to remain in the community. The service plan is developed based on the assessment of need using a person-centered and directed process. The service plan builds upon the participant's capacity to engage in activities that promote community life and respects the participant's preferences, choices, and abilities. The

participant's representative, if any, families, friends and professionals, as desired or required by the participant, will be involved in the service-planning process.

Support system means information, counseling, training, and assistance that support the participant (or the participant's family or representative, as appropriate) in identifying, accessing, managing, and directing their PAS and supports and in purchasing their PAS identified in the service plan and budget.

Supports broker or consultant means an individual who supports participants in directing their PAS and service budgets. The supports broker or consultant is an agent of the participants and takes direction from the participants, or their representatives, if applicable, about what information, counseling, training or assistance is needed or desired. The supports broker or consultant is primarily responsible for facilitating participants' development of a service budget and effective management of the participants' PAS and budgets in a manner that comports with the participants' preferences. States must develop a protocol to ensure that supports brokers or consultants are accessible to participants; have regularly scheduled phone and in-person contacts with participants; monitor whether participants' health status has changed and whether expenditure of funds are being made in accordance with service budgets. States must also develop the training requirements and qualifications for supports brokers or consultants that include, at a minimum, the following:

(1) An understanding of the philosophy of self-direction and person-centered and directed planning;

(2) The ability to facilitate participants' independence and participants' preferences in managing PAS and budgets, including any risks assumed by participants;

(3) The ability to develop service budgets and ensure appropriate documentation; and

(4) Knowledge of the PAS and resources available in the participant's community and how to access them.

The availability of a supports broker or consultant to each participant is a requirement of the support system.

§ 441.452 Self-direction: General.

(a) States must have in place, before electing the self-directed PAS option, personal care services through the State plan, or home and community-based services under a section 1915(c) waiver.

(b) The State must have both traditional service delivery and the self-

directed PAS service delivery option available in the event that an individual voluntarily disenrolls or is involuntarily disenrolled, from the self-directed PAS service delivery option.

(c) The State's assessment of an individual's needs must form the basis of the level of services for which the individual is eligible.

(d) Nothing in this subpart will be construed as affecting an individual's Medicaid eligibility, including that of an individual whose Medicaid eligibility is attained through receipt of section 1915(c) waiver services.

§ 441.454 Use of cash.

(a) States have the option of disbursing cash prospectively to participants, or their representatives, as applicable, self-directing their PAS.

(b) States that choose to offer the cash option must ensure compliance with all applicable requirements of the Internal Revenue Service, including, but not limited to, retaining required forms and payment of FICA, FUTA and State unemployment taxes.

(c) States must permit participants, or their representatives, as applicable, using the cash option to choose to use the financial management entity for some or all of the functions described in § 441.484(c).

(d) States must make available a financial management entity to a participant, or the participant's representative, if applicable, who has demonstrated, after additional counseling, information, training, or assistance, that the participant cannot effectively manage the cash option described in paragraph (a) of this section.

§ 441.456 Voluntary disenrollment.

(a) States must permit a participant to voluntarily disenroll from the self-directed PAS option at any time and return to a traditional service delivery system.

(b) The State must specify in a section 1915(j) State plan amendment the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

§ 441.458 Involuntary disenrollment.

(a) States must specify the conditions under which a participant may be involuntarily disenrolled from the self-directed PAS option.

(b) CMS must approve the State's conditions under which a participant may be involuntarily disenrolled.

(c) The State must specify in the section 1915(j) State plan amendment the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

§ 441.460 Participant living arrangements.

(a) Self-directed PAS are not available to an individual who resides in a home or property that is owned, operated, or controlled by a PAS provider who is not related to the individual by blood or marriage.

(b) States may specify additional restrictions on a participant's living arrangements if they have been approved by CMS.

§ 441.462 Statewide, comparability and limitations on number served.

A State may do the following:

(a) Provide self-directed PAS without regard to the requirements of statewideneess.

(b) Limit the population eligible to receive these services without regard to comparability of amount, duration, and scope of services.

(c) Limit the number of persons served without regard to comparability of amount, duration, and scope of services.

§ 441.464 State assurances.

A State must assure that the following requirements are met:

(a) *Necessary safeguards.* Necessary safeguards have been taken to protect the health and welfare of individuals furnished services under the program and to assure the financial accountability for funds expended for self-directed services.

(1) Safeguards must prevent the premature depletion of the participant directed budget as well as identify potential service delivery problems that might be associated with budget underutilization.

(2) These safeguards may include the following:

(i) Requiring a case manager, support broker or other person to monitor the participant's expenditures.

(ii) Requiring the financial management entity to flag significant budget variances (over and under expenditures) and bring them to the attention of the participant, the participant's representative, if applicable, case manager, or support broker.

(iii) Allocating the budget on a monthly or quarterly basis.

(iv) Other appropriate safeguards as determined by the State.

(3) Safeguards must be designed so that budget problems are identified on a timely basis so that corrective action may be taken, if necessary.

(b) *Evaluation of need.* The State must perform an evaluation of the need for personal care under the State Plan or services under a section 1915(c) waiver program for individuals who meet the following requirements:

(1) Are entitled to medical assistance for personal care services under the State plan or receiving home and community based services under a section 1915(c) waiver program.

(2) May require self-directed PAS.

(3) May be eligible for self-directed PAS.

(c) *Notification of feasible alternatives.* Individuals who are likely to require personal care under the State plan, or home and community-based services under a section 1915(c) waiver program are informed of the feasible alternatives, if available, under the State's self-directed PAS State plan option, at the choice of these individuals, to the provision of personal care services under the State plan, or PAS under a section 1915(c) home and community-based services waiver program. Information on feasible alternatives must be communicated to the individual in a manner and language understandable by the individual. Such information includes, but is not limited to, the following:

(1) Information about self-direction opportunities that is sufficient to inform decision-making about the election of self-direction and provided on a timely basis to an individual or the representative which minimally includes the following:

(i) Elements of self-direction compared to non-self-directed PAS.

(ii) Individual responsibilities and potential liabilities under the self-direction service delivery model.

(iii) The choice to receive PAS through a waiver program administered under section 1915(c) of the Act, regardless of delivery system, if applicable.

(iv) The option, if available, to receive and manage the cash amount of their individual budget allocation.

(2) When and how this information is provided.

(d) *Support system.* States must provide, or arrange for the provision of, a support system that meets the following conditions:

(1) Appropriately assesses and counsels an individual, or the individual's representative, if applicable, before enrollment, including information about disenrollment.

(2) Provides appropriate information, counseling, training, and assistance to ensure that a participant is able to manage the services and budgets. Such information must be communicated to the participant in a manner and language understandable by the participant. The support activities must include at least the following:

(i) Person-centered planning and how it is applied.

(ii) Information about the services available for self-direction.

(iii) Range and scope of individual choices and options.

(iv) Process for changing the service plan and service budget.

(v) Grievance process.

(vi) Risks and responsibilities of self-direction.

(vii) The ability to freely choose from available PAS providers.

(viii) Individual rights.

(ix) Reassessment and review schedules.

(x) Defining goals, needs, and preferences.

(xi) Identifying and accessing services, supports, and resources.

(xii) Development of risk management agreements.

(xiii) Development of an individualized backup plan.

(xiv) Recognizing and reporting critical events.

(xv) Information about an advocate or advocacy systems available in the State and how a participant, or a participant's representative, if applicable, can access the advocate or advocacy systems.

(3) Offers additional information, counseling, training, or assistance, including financial management services under either of the following conditions:

(i) At the request of the participant, or participant's representative, if applicable, for any reason.

(ii) When the State has determined the participant, or participant's representative, if applicable, is not effectively managing the services identified in the service plan or budget.

(4) The State may mandate the use of additional assistance, including the use of a financial management entity, or may initiate an involuntary disenrollment in accordance with § 441.458, if, after additional information, counseling, training or assistance is provided to a participant (or participant's representative, if applicable), the participant (or participant's representative, if applicable) has continued to demonstrate an inability to effectively manage the services and budget.

(e) *Annual report.* The State must provide to CMS an annual report on the number of individuals served and the total expenditures on their behalf in the aggregate.

(f) *Three-year evaluation.* The State must provide to CMS an evaluation of the overall impact of the self-directed PAS option on the health and welfare of participating individuals compared to non-participants every 3 years.

§ 441.466 Assessment of need.

States must conduct an assessment of the participant's needs, strengths, and preferences in accordance with the following:

(a) States may use one or more processes and techniques to obtain information about an individual, including health condition, personal goals and preferences for the provision of services, functional limitations, age, school, employment, household, and other factors that are relevant to the need for and authorization and provision of services.

(b) Assessment information supports the determination that an individual requires PAS and also supports the development of the service plan and budget.

§ 441.468 Service plan elements.

(a) The service plan must include at least the following:

(1) The scope, amount, frequency, and duration of each service.

(2) The type of provider to furnish each service.

(3) Location of the service provision.

(4) The identification of risks that may pose harm to the participant along with a written individualized backup plan for mitigating those risks.

(b) A State must develop a service plan for each program participant using a person-centered and directed planning process to ensure the following:

(1) The identification of each program participant's preferences, choices, and abilities, and strategies to address those preferences, choices, and abilities.

(2) The option for the program participant, or participant's representative, if applicable, to exercise choice and control over services and supports discussed in the plan.

(3) Assessment of, and planning for avoiding, risks that may pose harm to a participant.

(c) All of the State's applicable policies and procedures associated with service plan development must be carried out and include, but are not limited to, the following:

(1) Allow the participant, or participant's representative, if applicable, the opportunity to engage in, and direct, the process to the extent desired.

(2) Allow the participant, or participant's representative, if applicable, the opportunity to involve family, friends, and professionals (as desired or required) in the development and implementation of the service plan.

(3) Ensure the planning process is timely.

(4) Ensure the participant's needs are assessed and that the services meet the participant's needs.

(5) Ensure the responsibilities for service plan development are identified.

(6) Ensure the qualifications of the individuals who are responsible for service plan development reflect the nature of the program's target population(s).

(7) Ensure the State reviews the service plan annually, or whenever necessary due to a change in the participant's needs or health status.

(8) Ensure that a participant may request revisions to a service plan, based on a change in needs or health status.

(d) When an entity that is permitted to provide other State plan services is responsible for service plan development, the State must describe the safeguards that are in place to ensure that the service provider's role in the planning process is fully disclosed to the participant, or participant's representative, if applicable, and controls are in place to avoid any possible conflict of interest.

(e) An approved self-directed service plan conveys authority to the participant, or participant's representative, if applicable, to perform, at a minimum, the following tasks:

(1) Recruit and hire workers to provide self-directed services, including specifying worker qualifications.

(2) Hire workers.

(3) Supervise workers in the provision of self-directed services.

(4) Manage workers in the provision of self-directed services, which includes the following functions:

(i) Determining worker duties.

(ii) Scheduling workers.

(iii) Training workers in assigned tasks.

(iv) Evaluating workers performance.

(5) Determine the amount paid for a service, support, or item.

(6) Review and approve provider invoices.

§ 441.470 Service budget elements.

A service budget must be developed and approved by the State based on the assessment of need and service plan and must include the following:

(a) The specific dollar amount a participant may utilize for services and supports.

(b) How the participant is informed of the amount of the service budget before the service plan is finalized.

(c) The procedures for how the participant, or participant's representative, if applicable, may adjust the budget, including the following:

(1) How the participant, or participant's representative, if applicable, may freely make changes to the budget.

(2) The circumstances, if any, that may require prior approval before a budget adjustment is made.

(3) The circumstances, if any, that may require a change in the service plan.

(d) The procedure(s) that governs how a person, at the election of the State, may reserve funds to purchase items that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance, including additional goods, supports, services or supplies.

(e) The procedure(s) that governs how a person may use a discretionary amount, if applicable, to purchase items not otherwise delineated in the budget or reserved for permissible purchases.

(f) How participants, or their representative, if applicable, are afforded the opportunity to request a fair hearing under § 441.300 if a participant's, or participant's representative, if applicable, request for a budget adjustment is denied or the amount of the budget is reduced.

§ 441.472 Budget methodology.

(a) The State shall set forth a budget methodology that ensures service authorization resides with the State and meets the following criteria:

(1) The State's method of determining the budget allocation is objective and evidence based utilizing valid, reliable cost data.

(2) The State's method is applied consistently to participants.

(3) The State's method is open for public inspection.

(4) The State's method includes a calculation of the expected cost of the self-directed PAS and supports, if those services and supports were not self-directed.

(5) The State has a process in place that describes the following:

(i) Any limits it places on self-directed services and supports, and the basis for the limits.

(ii) Any adjustments that will be allowed and the basis for the adjustments.

(b) The State must have procedures to safeguard participants when the budgeted service amount is insufficient to meet a participant's needs.

(c) The State must have a method of notifying participants, or their representative, if applicable, of the amount of any limit that applies to a participant's self-directed PAS and supports.

(d) The budget may not restrict access to other medically necessary care and services furnished under the plan and approved by the State but not included in the budget.

(e) The State must have a procedure to adjust a budget when a reassessment indicates a change in a participant's medical condition, functional status or living situation.

§ 441.474 Quality assurance and improvement plan.

(a) The State must provide a quality assurance and improvement plan that describes the State's system of how it will perform activities of discovery, remediation and quality improvement in order to learn of critical incidents or events that affect participants, correct shortcomings, and pursue opportunities for system improvement.

(b) The quality assurance and improvement plan shall also describe the system performance measures, outcome measures, and satisfaction measures that the State must use to monitor and evaluate the self-directed State plan option. Quality of care measures must be made available to CMS upon request and include indicators approved or prescribed by the Secretary.

§ 441.476 Risk management.

(a) The State must specify the risk assessment methods it uses to identify potential risks to the participant.

(b) The State must specify any tools or instruments it uses to mitigate identified risks.

(c) The State must ensure that each service plan includes the risks that an individual is willing and able to assume, and the plan for how identified risks will be mitigated.

(d) The State must ensure that the risk management plan is the result of discussion and negotiation among the persons designated by the State to develop the service plan, the participant, the participant's representative, if any, and others from whom the participant may seek guidance.

§ 441.478 Qualifications of providers of personal assistance.

(a) States have the option to permit participants, or their representatives, if applicable, to hire any individual capable of providing the assigned tasks, including legally liable relatives, as paid providers of the PAS identified in the service plan and budget.

(b) Participants, or their representatives, if applicable, retain the right to train their workers in the specific areas of personal assistance needed by the participant and to perform the needed assistance in a manner that comports with the participant's personal, cultural, and/or religious preferences. Participants, or

their representatives, if applicable, also have the right to access other training provided by or through the State so that their PAS providers can meet any additional qualifications required or desired by participants, or participants' representatives, if applicable.

(c) Participants, or their representatives, if applicable, retain the right to establish additional staff qualifications based on participants' needs and preferences.

§ 441.480 Use of a representative.

(a) States may permit participants to appoint a representative to direct the provision of self-directed PAS on their behalf. The following types of representatives are permissible:

(1) A minor child's parent or guardian.

(2) An individual recognized under State law to act on behalf of an incapacitated adult.

(3) A State-mandated representative, after approval by CMS of the State criteria, if the participant has demonstrated, after additional counseling, information, training or assistance, the inability to self-direct PAS.

(b) A person acting as a representative for a participant receiving self-directed PAS is prohibited from acting as a provider of self-directed PAS to the participant.

§ 441.482 Permissible purchases.

(a) Participants, or their representatives, if applicable, may, at the State's option, use their service budgets to pay for items that increase a participant's independence or substitute (such as a microwave oven or an accessibility ramp) for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

(b) The services, supports and items that are purchased with a service budget must be linked to an assessed participant need or goal established in the service plan.

§ 441.484 Financial management services.

(a) States may choose to provide financial management services to participants, or their representatives, as applicable, self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions, utilizing a financial management entity, through the following arrangements:

(1) States may use a reporting or subagent through its fiscal intermediary in accordance with section 3504 of the IRS Code and Revenue Procedure 80-4 and Notice 2003-70; or

(2) States may use a vendor organization that has the capabilities to perform the required tasks in accordance with Section 3504 of the IRS Code and Revenue Procedure 70-6. When private entities furnish financial management services, the procurement method must meet the requirements set forth in 45 CFR 74.40 through 74.48.

(b) States must provide oversight of financial management services by performing the following functions:

(1) Monitoring and assessing the performance of financial management entity, including assuring the integrity of financial transactions they perform.

(2) Designating a State entity or entities responsible for this monitoring.

(3) Determining how frequently financial management entity performance will be assessed.

(c) A financial management entity must provide functions including, but not limited to, the following:

(1) Collect and process timesheets of the participant's workers.

(2) Process payroll, withholding, filing and payment of applicable Federal, State and local employment-related taxes and insurance.

(3) Maintain a separate account for each participant's budget.

(4) Track and report disbursements and balances of participant funds.

(5) Process and pay invoices for goods and services approved in the service plan.

(6) Provide to participants periodic reports of expenditures and the status of the approved service budget.

(d) States not utilizing a financial management entity must perform the functions listed in paragraph (c) of this section on behalf of participants self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions.

(e) States will be reimbursed for the cost of financial management services, either provided directly or through a financial management entity, at the administrative rate of 50 percent.

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 18, 2008.s

Kerry Weems,

*Acting Administrator, Centers for Medicare
& Medicaid Services.*

Approved: August 6, 2008.

Michael O. Leavitt,

Secretary.

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