

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 441

[CMS-2229-P]

RIN 0938-A052

Medicaid Program; Self-Directed Personal Assistance Services

Program State Plan Option (Cash and Counseling)

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

ACTION: Proposed rule.

SUMMARY: This proposed rule provides guidance to States that want to administer self-directed personal assistance services through their State plans.

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

ADDRESSES: In commenting, please refer to file code CMS-2229-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. Electronically. You may submit electronic comments on specific issues in this regulation to

<http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit

electronic comments on CMS regulations with an open comment period.” (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2229-P
P.O. Box 8016,
Baltimore, MD 21244-8016.

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

3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2229-P
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

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

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

Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201; or
7500 Security Boulevard,
Baltimore, MD 21244-1850.

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

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

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

FOR FURTHER INFORMATION CONTACT:

Marguerite Schervish, (410) 786-7200.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-2229-IFC and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday

through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

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

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.

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. 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 and 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 vs. 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 (ICFMR).

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 and 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.

II. Provisions of the Proposed Rule

[If you choose to comment on issues in this section, please include the caption "PROVISIONS OF THE PROPOSED RULE" at the beginning of your comments.]

Section CFR 441.450 Basis, Scope and Definitions

This proposed rule would implement section 1915(j) of the Act, allowing States to provide a self-directed PAS through a State Plan option. We propose to implement this provision in 42 CFR part 441 subpart J. This part would set forth the requirements of the self-directed PAS delivery model administered through the Medicaid State plan and indicates how individuals may qualify to participate in a self-directed PAS State plan option.

The overall purpose of section 1915(j) of the Act is to allow States the option to amend their State Plans to offer individuals the opportunity to self-direct their PAS. This self-directed PAS State plan option is a service delivery model and is premised in the experience and lessons learned from the self-direction and *Independence Plus* section 1115 demonstrations and section 1915(c) waiver programs. Based on the demonstrated success of self-directed services in these programs, we learned that individuals can successfully exercise decision-making authority over their PAS and supports identified in an individualized service plan and budget. Consequently, in 42 CFR 441.450(b), we propose that individuals be allowed to exercise decision-making authority in identifying, accessing, managing and purchasing their PAS. We propose a list of the minimum activities over which individuals may exercise authority, in order to implement the basic elements of self-direction, which convey control over both employer-related and budget-related activities. Individuals' decision-making authority includes, at a minimum, the purchase of PAS and supports for PAS, recruiting workers, hiring and discharging workers, specifying worker qualifications, determining worker duties, scheduling workers, supervising workers, evaluating worker performance, determining the amount paid for a service, support, or item, scheduling when services are provided, identifying service workers, and reviewing and approving

invoices. This proposed list was determined through our review of States' experiences with existing self-directed programs and we believe it represents the minimum authority required by an individual to self-direct care. A State can include additional activities in its submitted State plan option request.

Since we view self-directed care as a method of service delivery rather than cash assistance, we do not view the following Medicaid provisions as a barrier to use of the self-directed PAS option:

- When States elect to offer a cash option to participants, funds made available to the individual solely for the purchase of medically necessary items and services (as outlined in the approved service plan) are not income or resources to the individual. Thus, they would not be counted for purposes of determining or redetermining eligibility (under 1902(a)(10)(A) or 1902(a)(10)(C) of the Act, or any demonstration project).
- Medicaid requirements for direct payment to providers found at section 1902(a)(32) of the Act and prepayment review found at section 1902(a)(37)(B) of the Act may be satisfied by specific responsibilities individuals undertake as part of self-direction, such as activities to effectively manage their funds, review all payment requests, and make payments to providers, either directly or through a financial

management entity. These responsibilities are further described in §441.470.

- In the service delivery model of self-direction, the mechanisms that an individual undertakes to document delivery of services, such as having timesheets signed by the provider of services, should include the basic elements needed to satisfy the objective of the Medicaid requirements on provider agreements found at section 1902(a)(27) of the Act.

There are many terms specific to the self-directed PAS State plan option. Because of the need to be consistent with their usage within the context of section 1915(j), we are proposing to define the following terms for purposes of this section in §441.450(c):

Assessment of Need

Section 1915(j)(5)(B) of the Act requires an assessment of a participant's needs, strengths, and preferences for PAS. Our proposed definition at §441.450(c) reflects this statutory language. An assessment of an individual's needs, strengths and preferences is crucial because it forms the basis for the identification of the needed services and supports that will be authorized in the individual's service plan and the subsequent service budget. It is also important to identify an individual's strengths and preferences that will enable self-direction of PAS. Therefore, we also propose in §441.450(c) that the assessment

includes one or more processes to obtain information about an individual's 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 authorization and provision of services. We believe our proposed definition reflects the need for such an assessment to be a comprehensive assessment of all an individual's needs.

Individualized Backup Plan

We propose to add a definition for an individualized backup plan because we think it is an important beneficiary protection and a necessary communication device to convey important information should a situation occur that would pose a risk of harm to an individual that would necessitate a plan to ensure alternative arrangements for service delivery. Accordingly, in §441.450(c), we would define an individualized backup plan to mean a written plan that addresses critical contingencies or incidents that would pose a risk of harm to the participant's health or welfare. We propose to require that the individualized backup plan be incorporated into the participant's service plan. For example, a typical critical contingency or incident could include the failure of a worker to appear when scheduled to provide necessary services and the individualized backup plan would include the steps necessary to continue to provide the necessary services in such a case. The individualized backup

plan could include arranging for designated provider agencies to furnish staff support on an on-call basis, or use of other services and agencies in existence in the participant's community. We note each backup plan must necessarily be crafted to meet the unique needs and circumstances of each participant.

Legally Liable Relatives

Section 1915(j)(4)(B)(i) of the Act permits, at the State's option, participants in the self-directed PAS option to hire legally liable relatives as paid providers of services. In 42 CFR 441.450(c), we propose to define legally liable relatives to mean persons who have a duty under the provisions of State law to care for another person. Legally liable relatives may include: (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, or (3) a spouse. It has been our experience that these are the most commonly used relationships in providing care, but we solicit comments on other possible relationships that could be used.

Self-Directed Personal Assistance Services

Section 1915(j)(4)(A) of the Act defines self-directed PAS to mean personal care and related services, or home and community-based services otherwise available under the State Plan or a 1915(c) waiver, that are provided to an individual determined to be eligible for the self-directed PAS program. We

propose at §441.450(c) to adopt the statutory language in our definition. We further note that we believe it is clear that “personal care and related services” refers to those services that an individual receives that are within the State’s defined personal care State Plan optional service (for example, activities of daily living, instrumental activities of daily living, supervision, and cueing). Notwithstanding an individual’s eligibility to participate in the self-directed PAS option because of their eligibility for and receipt of services under a State Plan personal care services option or a section 1915(c) waiver program, we also propose that self-directed PAS include, at the State’s option, items that increase an individual’s independence or substitute for human assistance, according to section 1915(j)(4)(B)(ii) of the Act. We believe it is clear that the State has the option to allow the individual to acquire these items, and that these items can be considered as self-directed PAS.

Self-Direction

Section 1915(j)(5)(A) of the Act defines self-direction to mean 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. We propose to reflect this statutory definition in the rule at §441.450(c).

Service Budget

Section 1915(j)(5)(D) of the Act sets out the requirement for a service budget as part of an “approved self-directed services plan and budget.” We propose, at §441.450(c), to define a service budget to mean an amount of funds that is under the control and direction of a participant when the State has selected the State Plan option for provision of self-directed PAS. We further propose that the budget be developed using a person-centered and directed process, and be individually tailored in accordance with the participant’s needs and personal preferences as established in the service plan. We further note that the statutory requirements that the budget be based upon an assessment of need, approved by the State, developed using a valid methodology, is open to public inspection, and includes a calculation of the expected cost of the PAS if not self-directed are inherent in the process for approval of a self-directed PAS State plan option and we are not proposing these requirements as part of the proposed definition.

Service Plan

The statute at section 1915(j)(5)(C) of the Act references the requirement for a service plan to be developed and approved by the State based on an assessment of need through a person-centered process. At §441.450(c), we propose to define a service plan to mean 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 so the participant can successfully direct the PAS and live in the community. We believe that an assessment of an individual's needs, strengths and preferences is crucial because it forms the basis for the identification of the needed services and supports that will be authorized in the individual's service plan and the subsequent service budget.

We also propose to reflect the statutory requirement that the service plan be based on the assessment of need using a person-centered and directed planning process. We also propose to incorporate the principles of a person-centered planning process since we believe that the service plan must build upon the participant's capacity to actively engage in and lead the development of the plan, including identifying persons who will be involved in the process. We anticipate that States will provide individuals with information, assistance and training, as needed or desired, in advance of and during the service planning process in order to help them develop their service plans, thereby ensuring that the plan reflects their needs, strengths and preferences. Specifically, we propose to require that the process build upon the participant's capacity to engage in activities that promote community life and that respects the participant's preferences, choices, and abilities. We also

propose to allow families, friends and professionals, as desired or required by the participant, to be involved in the service-planning process.

Support System

Section 1915(j)(2)(D) of the Act requires that States provide a support system that ensures that participants are appropriately assessed and counseled prior to their decision to participate in the self-directed PAS State Plan option and are able to manage their budgets. The statute further requires that additional counseling and management support may be provided at the request of the individual. In §441.450(c), we propose to define support system to mean 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.

The following proposed provisions of subpart J deal with General Administration.

Section 441.452 Self-Direction: General.

We note that the statute is written such that States must have in place, before electing the self-directed PAS option, personal care services through their State plan, or home and community-based services in a section 1915(c) waiver program. In this way, States that choose to amend their State plans to add

self-directed PAS, will have both the traditional delivery system (that is, non-self-directed) and the self-directed PAS service delivery option available in the event that individuals voluntarily disenroll from or are involuntarily disenrolled from the self-directed PAS service delivery option. This also reflects the choice requirement for such individuals as set forth in section 1915(j)(2)(C) of the Act. In the traditional delivery system, the provider of the PAS is an entity such as a home health agency. The entity, and not the Medicaid recipient, exercises authority over who will furnish the PAS and retains the control and authority over how the services are provided, the worker's hours, and the worker's rate of pay.

We are also proposing to require that the State's assessment of an individual's needs should form the basis for the level of services for which the individual is eligible. This requirement will ensure that, regardless of service delivery system, individuals will receive the services identified in the assessment of need. The proposed regulation should not 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. We are proposing in §441.452 to reflect the general concepts of section 1915(j)(1) statutory requirements as noted above. We are available to all States to provide technical assistance in

structuring this new self-directed PAS State plan option.

Section 441.454 Use of Cash

In the section 1115 self-direction demonstration programs, participants could receive a prospective cash allowance equivalent to the amount of Medicaid expenditures for the services included in the demonstration and could, if they chose this option, directly manage their cash allowance. We learned that participants who chose to directly manage their cash allowance were able to do so successfully and that they became more prudent purchasers of their needed supports and services. Some individuals also chose to perform all the employer tax-related responsibilities that are associated with being an employer of record, while others desired to use a fiscal/employer agent or financial management entity to help them with some or all of these responsibilities.

We are aware that individuals who have been directly receiving and managing their cash allowance wish to continue to have this option. We are also aware that individuals in States where this option has not heretofore been available wish to be able to access this option. Accordingly, we are proposing in §441.454, 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. Further, if the cash option is made available by the State, we

would require States to permit individuals who select the cash option the choice of whether to use a financial management entity. Individuals must be given flexibility to determine whether to use a financial management entity, and the functions, if any, to be performed on their behalf by the financial management entity. For example, some individuals may want the financial management entity to perform all employer-related tax functions, while they retain responsibility for paying their providers of PAS. Individuals choosing not to use a financial management entity must comply with all employer-related tax functions of the IRS requirements. However, we are also proposing that if States choose to allow the cash option, that they make available a financial management entity to participants who have demonstrated, after additional counseling, information, training, or assistance, that they cannot effectively manage the cash option.

Section 441.456 Voluntary Disenrollment

We understand that a self-directed service delivery model may not necessarily work for everyone. Individuals who initially elect to self-direct their PAS may subsequently decide to move to a traditional service delivery system. At §441.456, we propose to specify that individuals may voluntarily disenroll from the self-directed PAS State plan option at any time and elect to receive their services through the traditional service delivery

system. As required by statute, PAS will be offered to the individual so long as the individual still qualifies for State Plan personal care services or home and community based services provided through a 1915(c) waiver program.

If individuals decide to leave the self-directed care option, we want to be assured that individuals continue to receive the services for which they are eligible and that their health and welfare are maintained. Accordingly, we propose to require that States specify in the State plan the safeguards that will be in place to ensure continuity of services during the transition from self-directed services. In order to effectuate a prompt and efficient transition, we would expect that any revisions to the service plan be made promptly and that participants are quickly linked with alternate service providers to prevent a break in the delivery of services.

Section 441.458 Involuntary Disenrollment

We understand there may be circumstances, where in the interest of the participant's health and welfare, the State may wish to involuntarily disenroll the participant from the self-directed PAS option. For example, involuntary disenrollment may be necessary when the individual does not carry out the necessary responsibilities, thereby jeopardizing their health and welfare, or in other circumstances where action must be taken to ensure an individual's health and welfare. Accordingly, in §441.458, we

propose to permit States to determine the conditions under which an individual may be involuntarily disenrolled from the self-directed PAS State plan option. We also note that we propose that we approve these conditions, and plan to do so as part of the review of the State plan amendment to provide self-directed PAS.

Again, we want to be assured that individuals continue to receive the services for which they are eligible and that their health and welfare are maintained. Accordingly, we would also propose to require that States specify in the State plan the safeguards that will be in place to ensure continuity of services during the transition from self-directed services. In order to effectuate a prompt and efficient transition, we would expect that any needed revisions to the service plan would be made promptly and that participants are quickly linked with alternate service providers for a seamless delivery of services.

Section 441.460 Participant Living Arrangements

Section 1915(j)(1) of the Act states that self-directed PAS cannot be made available to individuals who reside 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 are proposing to reflect the statutory requirement in §441.460(a). We note 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 believe 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. For example, if the residential facility also provides and receives payment for the provision of personal care and related services, it may prohibit the self-directed service delivery option for fear of duplication of services. We are also proposing in §441.460(b) to allow States to specify additional restrictions on participant living arrangements, if they have been approved by CMS. We further note that we believe this limitation should be applied to individuals residing in assisted living facilities, as we anticipate that the provider would both control the housing and be expected to provide the PAS. However, we do not believe this limitation would apply to situations in which the individual resides in the home of someone whom they wish to employ under the self-directed PAS option. We invite comment on our proposal as well as on other situations to which this limitation should apply.

Section 441.462 Statewideness, Comparability, and Limitations on Number Served

Section 1915(j)(3) of the Act permits a State to provide self-directed PAS without regard to the requirements for statewideness (section 1902(a)(1) of the Act), comparability of

services or the number of individuals served (section 1902(a)(10)(B) of the Act). In §441.462, we propose to reflect section 1915(j)(3) of the Act. However, we also wish to note below our understanding of the extent to which these provisions provide flexibilities in the State plan PAS option.

1. Geographic Limitations

Under this new State plan option, States are not bound by the "statewideness" requirement of section 1902(a)(1) of the Act. (The statewideness requirement of section 1902(a)(1) of the Act provides, in part, that the provisions of a State plan be in effect in all political subdivisions of the State.) Therefore, consistent with the statute, we propose in §441.462 to permit States to limit the provision of self-directed PAS to any defined location of the State (that is, city, county, community, etc.).

We note that the exception to the statewideness requirement applies only to the provision of self-directed PAS under section 1915(j) of the Act. The statewideness requirement of section 1902(a)(1) of the Act continues to apply to all other Medicaid services for which an individual may be eligible, unless those services are subject to their own statewideness exception. In other words, the State cannot geographically limit other services. Receipt of State plan PAS does not in any way alter an individual's eligibility to receive any other service under the State plan.

2. Comparability

Under this State plan option, the statute permits a State to provide self-directed PAS to individuals without regard to the "comparability" provision in section 1902(a)(10)(B) of the Act. Thus, a State can limit the populations eligible to receive these services. (The "comparability" provision of section 1902(a)(10)(B) of the Act generally requires States to make Medicaid services available in the same amount, duration, and scope to one group of categorically needy individuals as it offers to another group of categorically needy individuals. The comparability provision also requires that the Medicaid services available to any individual in a categorically needy group are not less in amount, duration, and scope than those Medicaid services available to an individual in a medically needy group). Section 1915(j)(3) of the Act thus permits States to offer self-directed PAS to certain populations, such as those with developmental disabilities, physical disabilities or aged.

As with the statewideness exception, we note that the exception to the comparability requirement applies only to the provision of self-directed PAS under section 1915(j) of the Act. For all other Medicaid services for which an individual may be eligible, the comparability requirements of section 1902(a)(10)(B) of the Act continue to apply, unless those services are subject to their own comparability exception. In

other words, receipt of self-directed PAS State plan does not in any way alter an individual's eligibility to receive any other service under the State plan.

3. Limitations on Number of People Served

The statute also permits a State to limit the number of persons served under this State plan option. This means that the State may limit the number of individuals receiving self-directed PAS. For example, States could offer self-directed PAS to only 150 individuals.

Section 441.464 State Assurances

Section 1915(j)(2) of the Act requires States that elect this option to assure the appropriate protection of Medicaid recipients. The statute does not permit us to approve a program that does not provide certain specified assurances.

Specifically, section 1915(j)(2) of the Act requires States to assure the Secretary of the following:

1. Necessary Safeguards

States must assure that necessary safeguards have been taken to protect the health and welfare of individuals furnished services under this program and to assure the financial accountability for funds expended for self-directed services. In proposed §441.464(a), we reflect this general requirement. More specifically, in proposed §441.464(a)(1), we would require that 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. We believe it is important that States have a system to oversee the expenditures being made by participants. Premature depletion of the funds in a budget could signal a health crisis which would require the State to immediately determine the health status of a participant and conduct a new assessment of the participant's needs. It could also signal misuse of the funds, for which the State would need to take corrective action. The corrective action could be the provision of additional counseling and training on how to manage the budget, or recoument of the misspent funds. In contrast, underutilization of the funds could signal a problem with the provision of services, or the lack of understanding of how the funds may be used to purchase PAS and supports.

We propose, in §441.464(a)(2), a minimum list of safeguards that must be provided, but States would have the ability to implement additional safeguards to protect health and welfare and to prevent premature depletion of the participant-directed budget. Our experience with self-direction indicated that, at a minimum, a certain level of oversight by the State is necessary to help flag potential issues, particularly as to budget issues. The proposed list is based, in part, on this experience. We believe that the proposed list represents reasonable activities

that a State should have in place so that any health or other problems associated with use of the budgeted funds will be brought to the attention of a case manager, support broker, financial management entity, or other person with oversight responsibilities. In proposed §441.464(a)(3) we would require that safeguards must be designed so that budget problems are identified on a timely basis so that corrective action may be taken, if necessary, in order to protect health and welfare and ensure financial accountability.

2. Evaluation of Need

States must assure the performance of 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. In addition, section 1915(j)(2)(B) of the Act states that those subject to the evaluation of need are individuals who: (1) are 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; (2) may require self-directed PAS; and (3) may be eligible for self-directed PAS. We would reflect these statutory requirements in proposed §441.464(b).

3. Notification of Feasible Alternatives

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 feasible alternatives, if available under the State's self-directed PAS State plan option, at the choice of such individuals, to the provision of personal care services under the State plan, or personal assistance services under a section 1915(c) home and community-based services waiver program.

With the implementation of this new State plan option, there could be multiple programs offering individuals opportunities to receive their services through different service delivery mechanisms. We believe it is important that individuals be made aware, before enrolling in a program, of feasible alternatives for which they may be eligible and the requirements of all self-directed and non-self-directed programs operating within a State. We have historically required that participation in a self-directed program be voluntary and informed in order to ensure that participants' choice of the self-directed model of service delivery is meaningful. To reflect both the statutory requirement and our longstanding policy, we propose in §441.464(c)(1), that individuals receive 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 individuals or their representatives. The information given to individuals must minimally include the elements of self-direction compared to non-self-directed PAS,

self-direction responsibilities and potential liabilities, their choice to receive PAS under a section 1915(c) waiver program, if applicable, and the option, if available, to receive and manage the cash amount of their individual budget allocation. We also propose to require a State, at §441.464(c)(2), to inform individuals about when and how the information is provided.

4. Support System

Section 1915(j)(2)(D) of the Act requires States to provide a support system to ensure that participants in the self-directed PAS State plan option are appropriately assessed and counseled before enrollment and are able to manage their budgets. Participants may also request additional counseling and management support during participation in the self-directed PAS option in an effort to address any difficulties they may experience.

Based on our experience with self-direction programs, we are aware that individuals of different ages and with different abilities and disabilities, will desire to self-direct their PAS. In consideration of the potential differences in abilities to self-direct services, we have long required that States offer participants a support system that includes information about self-direction, as well as any counseling, training and assistance that may be needed or desired to effectively manage their services and budgets. We propose to reflect both the

statutory requirement and our long-standing policy at §441.464(d). While we do not prescribe the way States are to design their support system in order to allow flexibility, based on our experience, we include in the proposed regulation a minimum list of activities for which individuals may need information, counseling, training and/or assistance, but States may offer supports for additional activities. Generally, the activities requiring support include participant rights information and how the self-directed model of service delivery operates. For example, the list includes providing important beneficiary rights and protections such as freedom of choice of providers, information about the grievance process and how participants would recognize and report critical incidents. In order to convey all the necessary information to individuals, we understand some States have developed a "consumer training manual" and/or an orientation and training program that includes necessary information about self-direction, person-centered planning, the services that may be self-directed, the roles and responsibilities of participants, providers, supports brokers/counselors and financial management service entities, as well as a host of other information about managing and directing the services and supports identified in the service plan and budget. We encourage States to have such a manual or an orientation and training program in place because it will give

clear guidance to the involved and interested parties in the self-directed PAS State plan option.

We also realize that as self-direction assumes a level of independence and the ability of individuals to make decisions and choices, the extent to which individuals use the information and assistance may vary with their abilities and preferences. Individuals may elect whether and to what extent they will avail themselves of the support system, although States must require individuals not participating in the cash option to utilize financial management services. However, we do recognize that situations could arise in which individuals experience episodic difficulty in effectively managing and directing their PAS services and budgets. It has been our experience with self-direction waiver and demonstration programs that States have chosen to increase the level of support an individual may temporarily need and to offer additional information, counseling, training or assistance that may be needed and desired by individuals to overcome the difficulty. States have found that by flexibly providing ongoing support, success in self-directing services can usually be attained.

Based on these States' experiences, we would require at proposed §441.464(d)(3), that States would have information, counseling, training or assistance available, including financial management services, on an ongoing basis to participants at their

request or when the State has determined that the participant is not effectively managing the services identified in the service plan or budget. However, to ensure that participants continue to receive needed services, we are also proposing in §441.464(d)(4), that if, after additional information, counseling, training or assistance is provided, the situation has not improved, States may mandate additional assistance or may initiate an involuntary disenrollment in accordance with §441.458.

5. Annual Report and Evaluation of Impact

Section 1915(j)(2)(E) of the Act requires that the State provide to the Secretary an annual report reflecting the number of individuals served under the State plan option and total expenditures on their behalf. This section also requires that the State provide an evaluation of the overall impact of the self-directed PAS option on participants' health and welfare, in comparison to that of non-participants, every 3 years.

We propose to include these requirements in the regulations at §441.464(e) and (f). We plan to issue further guidance on the requirements and structure of the annual report, and we invite comments on other information that we should consider in the development of this guidance. We also plan to issue further guidance regarding expected requirements and implementation of the evaluation component. We also invite comment on the structure of this evaluation. For purposes of this evaluation

requirement, the comparison group of "non-participants" should be individuals receiving PAS that are not self-directed.

Section 441.466 Assessment of Need

Section 1915(j)(5)(B) of the Act requires that States conduct an assessment of participants' needs, strengths, and preferences for self-directed PAS. We propose to implement this requirement at §441.466. An assessment of an individual's needs, strengths and preferences is crucial because it forms the basis for the identification of the needed services and supports that will be authorized in the individual's subsequent service plan and budget. It is also important to identify an individual's strengths and preferences that will enable self-direction of PAS. The assessment should include a determination of whether there are any persons available to support the individual, including family members. These persons may be able to provide unpaid personal assistance, or fulfill more formal roles such as acting in the capacity of a paid provider of PAS or as an individual's representative. We do not prescribe the assessment tool to be used by States, but we expect that the assessment will be sufficiently comprehensive to support the determination that an individual would require personal care services under the State plan or personal assistance services under a section 1915(c) waiver program and the development of the individual's subsequent service plan and budget. Accordingly, we reflect this

understanding that while the format of the assessment is within the State's discretion, we expect the assessment to be comprehensive and minimally meet the statutory requirement. We propose that it include information about an individual's 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 authorization and provision of services, and support the finding for need of PAS and development of the service plan and budget.

Section 441.468 Service Plan Elements

Section 1915(j)(5)(C) of the Act requires States to develop and approve a service plan for each participant that includes the services and supports for such services, based on the assessment of need through a person-centered process. Section 1915(j)(5)(C) of the Act also requires that the service-planning process build on the participant's capacity to engage in activities that promote community life and that respects the participant's preferences, choices, and abilities, and must involve families, friends, and professionals in the planning or delivery of services or supports as desired or required by the participant. We propose to reflect these requirements at §441.468. Specifically, at proposed §441.468(a), we list those service plan elements we have found to be minimally necessary in developing a service plan that adequately describes the services to be

furnished. We also propose, as explained previously in our Definitions section, that we believe the service plan includes the individualized backup plan.

Furthermore, based on our experience with States' self-direction waivers and demonstrations, we are aware that States implement the person-centered planning process differently. Some States interpret the process to be simply focused on the participant's needs, and do not allow participants to also direct the process. Others allow the process to be person-directed as well as person-centered. We propose to require, at §441.468(b), that the process must be both person-centered and directed because we believe that a person-centered and directed service planning process will ensure that the resultant service 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. Therefore, we would propose at §441.468(b)(1) that each participant's preferences, choices and abilities are identified and strategies to address those preferences, choices and abilities are included in the service plan. We would also propose at §441.468(b)(2) that the participant is permitted to exercise choice and control over services and supports discussed in the plan. Finally, we would propose at §441.468(b)(3) that risks that may pose harm to the participant are assessed and

planned for. For example, we would expect that the assessment would identify potential risks to the participant. The participant, or the participant's representative, if any, together with the persons designated by the State to develop the service plan, and others from whom the participant may seek guidance, would discuss a plan for how any potential risks may be mitigated or eliminated. The resultant plan is the individualized backup plan and would be included in the service plan.

We would also propose at §441.468(c) that States have in place policies and procedures associated with service plan development. In §441.468(c)(1) through (c)(7), we propose a minimum list of policies and procedures that we believe are necessary to ensure the proper administration and development of the service plan. These include that the participant has the opportunity to engage in and direct the process to the extent desired, the participant has the opportunity to involve family, friends, and professionals as desired or required, the planning process is timely, the participant's needs are assessed and services meet the needs, the responsibilities for service plan development are identified, the qualifications of the individuals who are responsible for service plan development are reflective of the nature of the program's target population(s) and that service plans be reviewed annually, or whenever necessary due to

a change in the participant's needs or health status.

In this way, the service plan would continuously address all of the participant's assessed needs and goals, including health and safety factors, and would be updated to add or delete services or modify the amount and frequency of services.

We also propose to require, at §441.468(d), that safeguards be established when an entity that provides other State Plan services is responsible for service plan development 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. Based on our review of the demonstrations and 1915(c) waiver programs, we are aware that States sometimes choose to delegate the service planning function to an entity that provides other State Plan services. In order to ensure free choice of providers, we propose to add this beneficiary protection to the regulation.

We also propose to require that approval of the service plan conveys authority to the participant to perform, at a minimum, the tasks listed in §441.468(e), such as recruiting, hiring, firing, supervising and managing workers. It is the approval of the service plan by the State that authorizes the individual to undertake these activities as part of self-directed service delivery. The service plan must encompass both the general decision-making authority that a participant has and outline the

individualized services and supports to address the participant's needs, abilities, preferences and choices.

Section 441.470 Service Budget Elements

Section 1915(j)(5)(D) of the Act requires the establishment of a budget for the provision of PAS and sets forth certain requirements for the service budget. Specifically, this includes that the budget is developed and approved by the State based on the assessment of need and service plan. We propose to reflect this requirement in §441.470 and also propose to require that States inform participants of the specific dollar amount that may be used for their services and supports so they can properly develop a budget for how they will purchase their services and supports. Similarly, we propose to require that the specific dollar amount that may be used is indicated in the budget so there is no question about the amount available to the participant. We believe these requirements are necessary because it is important for participants to have sufficient and clear information to allow them to adequately plan for how they will use the funds to secure their needed services and supports.

Section 1915(j)(5)(D) of the Act also requires that the budget 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 and sets forth the requirements for determining the budget. We address these statutory

requirements at proposed §441.472. Based on our experience with the self-direction waivers and demonstrations, we learned that participants benefited from the flexibility to be able to shift funds among authorized services within the total amount of the budget without prior review and approval. To require the State's review and approval of each budget modification would be administratively untenable and would run counter to the philosophy of self-direction. Therefore, we propose to require at §441.470(c) that the State have procedures in place that govern how participants may flexibly adjust their budgets. The procedures must minimally include how the participant may freely make changes to the budget; the circumstances that may require prior approval before a budget adjustment is made, for example, purchases above a certain dollar amount; and the circumstances that may also require a modification to the participant's service plan.

Section 1915(j)(4)(B)(ii) of the Act allows States, at their option, to permit individuals to use their budget to acquire items that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance. Based on our experience, we learned that participants benefited from this option and were able to purchase items that allowed them greater independence, such as an accessibility ramp, or that substituted for human

assistance, such as a microwave oven. The States that offered this option required that the items to be purchased related to a need identified in the service plan.

Some of these states also limited participants' purchases to a list of allowable items for which no prior approval was necessary. Still other States required prior approval for all items, while some others provided a list of allowable items and required prior approval for other items not on the list. In addition, each State developed procedures that governed how participants could save an amount of their monthly budget to purchase these items and how and at what intervals the State would recoup funds that were not spent according to the purchase plan.

Accordingly, if a State has elected this option, we propose to require at §441.470(d), that the State have procedures that govern how a person may put aside or reserve funds to purchase items that increase independence or substitute for human assistance. These items could include additional supports, goods, equipment, or supplies, and the State should indicate if prior approval is required. As stated above, participants benefited from this option and the ability to reserve funds to purchase these items likewise proved beneficial to the participants. Accordingly, we believe it is worthwhile to continue this option under this State plan option.

We also recognize that some of the "Cash and Counseling" programs allowed participants to use a small amount of their budget to purchase items not otherwise delineated in the budget or earmarked for savings. For example, participants used this discretionary amount to purchase or supplement needed items or services not otherwise covered by Medicaid, such as non-Medicaid covered prescription drugs or transportation to a doctor's appointment. States typically set a dollar limit on the amount of the discretionary funds and participants were required to account for the expenditures, but not necessarily retain receipts for the discretionary purchases. Based on the success of this practice, we propose, at §441.470(e), to permit participants to use a small amount of their budget to purchase items not otherwise delineated in the budget or earmarked for savings. We anticipate that any budget methodology employed by the State and the participant would take this option into consideration.

Lastly, just as persons who receive traditional services have the ability to grieve a denial or reduction of benefits, we think it is important to ensure that participants in the self-directed PAS State plan option have an opportunity to request a fair hearing if their request for a budget adjustment is denied or the amount of the budget is reduced. Accordingly, we propose to add the opportunity for a fair hearing, as provided in §441.300, in the regulation at §441.470(f).

Section 441.472 Budget Methodology

Section 1915(j)(5)(D) of the Act also sets forth certain requirements concerning the budget methodology. Underlying the requirements are the concepts that the methodology used to develop the service budget must be reasonable and fairly applied to all participants. Specifically, the statute requires that the methodology use 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.

We are not proposing to prescribe the methodology States should use to develop a service budget. We recognize that some States may wish to use a prospective method, a retrospective method, or a combination of methods. However, we propose to require in the regulation at §441.472, that whatever methodology is used, it is objective and evidence-based, using valid, reliable cost data, that is, the method is based on an analysis of historical costs and utilization and other factors that are likely to affect costs. We would also propose to require that it is applied consistently to participants and that the methodology is open to public inspection. We also propose to require that the State's method includes a calculation of the expected cost of the self-directed PAS and supports, if these services and supports were not self-directed. This service budget amount is the cap on the amount of funds available to an individual with

which to purchase self-directed PAS and supports.

We recognize in §441.472(a)(5) that States may place monetary or budgetary limits on self-directed services and supports. Therefore, if a State does so, we would require that the State have a process in place that describes the limits and the basis for the limits, and any adjustments that will be allowed and the basis for the adjustments, such as participant health and welfare.

Additionally, we propose to require certain beneficiary safeguards in light of these possible limitations. First, we propose that States have procedures to safeguard participants when the budgeted service amount is insufficient to meet a participant's needs. Second, we propose that States have a method of notifying participants of the amount of any limit that applies to a participant's self-directed PAS and supports. Third, we propose that the budget 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. We note this proposal not only reflects the statutory requirement at section 1915(j)(5)(D) of the Act, but makes clear that the only limitation would be for self-directed PAS.

Section 441.474 Quality Assurance and Improvement Plan

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. 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 quality assurance and improvement plan that incorporates performance of discovery, remediation, and quality improvement activities and includes system performance measures, outcome measures, and satisfaction measures. We propose to reflect such measures and quality assurance and improvement plan components in the regulation at §441.474(a) and (b) and expect the State to monitor and evaluate these measures.

We will be reviewing the State's description of the quality assurance and improvement plan when we review the State's request to use the self-directed PAS option. The State Medicaid agency must be involved in planning the quality assurance activities and

measures, and the discovery, remediation, and improvement activities, but does not have to execute every activity. However, the State Medicaid Agency must retain the overall oversight and responsibility for the quality assurance plan.

Section 441.476 Risk Management

Section 1915(j)(5)(E) of the Act also requires States to provide appropriate risk management techniques to establish and implement the PAS service plans and budgets. As with quality assurance, these 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. We have learned that self-directed care has empowered individuals to assert their choices and to want to exercise more control over their care and services. 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. 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. In order to facilitate appropriate risk management, we propose to include certain requirements at §441.476.

First, at §441.476(a), we propose to require that the State specify the risk assessment methods it uses to identify potential risks to the participant. We do not prescribe an assessment method States must use but note that a proper assessment of the potential risks should include several perspectives, including any relevant clinical perspective, and involve those responsible for development of the service plan, the participant, the participant's representative, if any, and others from whom the participant may seek guidance.

Second, we also propose, at §441.476(b), that the State specify any tools or instruments it uses to mitigate identified risks. Again, we do not propose to 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. 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 participants, 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. Currently, States have the option, at their own expense, to provide criminal background checks for individuals who are self-directing their

services. We invite comment on whether the provision of criminal background checks should be mandatory under this self-directed PAS State plan option.

Third, at §441.476(c), we propose to require that the State ensure that each participant's service plan includes the risks that the participant is willing and able to assume, and the plan for how the identified risks will be mitigated. In this manner, the service plan adequately includes and documents how these identified risks are to be handled. Finally, at §441.476(d), we would require that the State 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. The input of all the parties interested in the participant's PAS service plan would thus be included and ensure that the service plan and budget reflect the participant's resources and capabilities.

Section 441.478 Qualifications of Providers of Personal Assistance

Section 1915(j)(4)(B) of the Act permits States to elect to allow participants to choose any individual capable of providing the assigned tasks, including legally liable relatives, as paid providers of services. We reflect these requirements in the proposed regulation at §441.478(a). We are not proposing to set

a minimum age requirement in the regulation and invite comment on whether an age requirement should be added, and if so, under what circumstances. At this point, we believe that an age requirement would not allow States the flexibility in setting their own standards should they choose this option. For example, hiring a 16-year-old to perform some homemaker tasks may be appropriate, whereas an adult may be better suited to provide more technically difficult or intimate personal care services. We expect the State to consider these issues prior to making a decision to elect this option.

However, we propose, at §441.478(b), that participants 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. We have learned, through our experience with the self-direction waiver and demonstration programs, that the training for workers furnishing self-directed PAS must be tailored to each individual's preferences, as well as their needs. In this way, workers benefit from clear instructions about how to effectively and appropriately deliver the self-directed PAS, and any potential dissatisfaction with the way services are being delivered can be averted. We further propose, at §441.478(c), that participants retain the right to establish additional staff

qualifications based on their needs and preferences. Again, we believe that the participant is in the best position to set forth the particular staff qualifications needed to meet the particular preferences of the participant. For example, if the participant communicates best using American Sign Language (ASL), the participant may require the worker to be able to communicate using ASL.

Section 441.480 Use of a Representative

Section 1915(j)(5)(A) of the Act indicates the types of participant representatives in the self-directed PAS option. Specifically, the statute includes as representatives a parent or guardian if the participant is a minor child, or an individual recognized by State law to act on behalf of a participant who is an incapacitated adult. We propose to include these requirements at §441.480(a)(1) and (a)(2).

In addition to the statutory listings, we believe that other representatives should 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 budgets. 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.

Furthermore, based on the experience of States with self-direction programs, we believe it is appropriate for States to have the option to mandate the use of a representative if the participant has demonstrated, after additional counseling, information, training, or assistance, the inability to self-direct PAS. We specify this requirement in the proposed regulation at §441.480(a)(5), and also propose to require that CMS approve in the State plan amendment a State's criteria for situations that would result in the State mandating the use of a representative. Examples of these criteria could include a participant not being able to carry out the responsibilities for self-direction after the provision of additional counseling, information, training, or assistance, or because an individual's health or welfare requires the assistance of a representative.

Finally, to protect against conflict of interest, we propose, at §441.480(b), to prohibit a participant's representative from also serving as a paid provider of services to the participant. Based upon the experiences of the States participating in the original "Cash and Counseling" demonstration, we learned that it is important to include this limitation in the self-directed PAS option in order to avoid the situation of a representative overseeing or making decisions that directly impact them, for example, "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 propose to include this necessary protection in the proposed regulation.

Section 441.482 Permissible Purchases

Section 1915(j)(4)(B)(ii) of the Act permits individuals, at the State's option, to use the funds allocated in their budgets to acquire items that increase their independence or substitute for human assistance, to the extent that expenditures would otherwise be made for that human assistance. We propose to implement this provision in the proposed regulation at §441.482(a). The statute specifically gives the examples of a microwave oven and accessibility ramp because these two items could conceivably increase independence or substitute for human assistance.

Moreover, experience under the section 1115 and section 1915 (c) of the Act self-direction and *Independence Plus* programs indicated that when recipients are given the ability to purchase items that increased their independence or substituted for human assistance, they do so prudently and effectively. However, we propose, at §441.482(b), that these purchases must address an assessed participant need included in the service plan, in order to ensure that the item, and insofar as that expenditure would have otherwise been made using human assistance, is medically

necessary and to promote program integrity. We also note that we have previously proposed in §441.470(d) that the State set forth a procedure that governs how such items are to be included in the service budget.

Section 441.484 Financial Management Services

Under section 1915(j)(6) of the Act, States may employ a financial management entity to make payments to providers, track costs, and make reports under the self-directed PAS State plan option. The financial management provisions are noted in the proposed regulation at §441.484. The statute lists very broad responsibilities for a financial management entity to perform. In the context of the self-directed PAS option, these broad statutory categories must be considered and linked to specific duties. For example, financial management services are used for two purposes: (a) to address Federal, State, and local employment tax, labor and workers' compensation insurance rules, and other requirements that apply when the participant functions as the employer of workers, and (b) to make financial transactions on behalf of the participant, such as preparing paychecks for workers and paying invoices for goods and services identified in the participant's service plan. These responsibilities can be generally noted as making payments and tracking costs.

We first note there are different Internal Revenue Service

(IRS) requirements that must be adhered to, depending on how financial management services are provided. For instance, financial management services provided directly by the State, or by a State's reporting or subagent through its fiscal intermediary, must follow section 3504 of the IRS Code and Revenue Procedure 80-4 and Notice 2003-70. Financial management services provided through vendor organizations must follow Section 3504 of the IRS Code and Revenue Procedure 70-6. When private entities furnish financial management services, the procurement method must meet requirements set forth in 45 CFR 74.40 through section 74.48. Accordingly, we propose, at §441.484(a)(1) and (a)(2), the arrangement options available to States for offering financial management services, and specify proposed requirements that must be followed for each option (barring participants who perform these functions themselves).

Furthermore, to ensure appropriate safeguards and recipient protections, we propose to require States to provide oversight of financial management services. Without this oversight there is a risk of inadequate delivery of financial management such as system deficiencies, failure to pay workers timely, and errors in complying with IRS requirements. When utilized, the financial management service is critical to the success of the self-directed PAS State plan option. Specifically, at §441.484(b), we are proposing that States must

perform the following oversight activities, regardless of how financial management services are provided: monitoring and assessing the performance of the financial management entity, including assuring the integrity of financial transactions they perform; designating a State entity or entities responsible for this monitoring; and determining how frequently financial management entity performance will be assessed. While we are not requiring specific oversight activities, examples of State performance monitoring and assessment may include conducting periodic audits of financial management entities, conducting participant satisfaction surveys or other methods or procedures.

Also, as a further beneficiary safeguard, we propose, at §441.484(c), a list of the specific minimum functions that must be provided by financial management entities as noted under the broad statutory requirement (or by States directly, if no financial management entities are utilized).

This list includes, but is not limited to, collecting and processing timesheets of the participant's workers; processing payroll, withholding, filing and payment of applicable Federal, State and local employment-related taxes and insurance; maintaining a separate account for each participant's budget; tracking and reporting disbursements and balances of participant funds; processing and paying invoices for goods and services approved in the service plan; and providing to participants

periodic reports of expenditures and the status of the approved service budget. We believe these proposed functions represent, at a minimum, the standard duties and responsibilities that a financial management entity (or a State) would need to assume in assisting a beneficiary in the self-directed State plan option.

Inherent in the statute is the ability of the State to retain the responsibility of providing financial management entity functions. We are aware that many States with self-direction programs do in fact retain this responsibility. We expect a State to perform the same functions as a financial management entity. We are proposing to explicitly require the State to do such in the absence of utilizing a financial management entity. The purpose of noting this expectation of the States is to clarify to a participant that these services are provided by the State. Accordingly, we propose at §441.482(d) that States not employing a financial management entity must perform all functions that would have been provided by the financial management entity on behalf of all participants self-directing their PAS under this new State plan option, except for participants taking advantage of the cash option, as they directly perform those functions for themselves.

Based on our review of self-directed programs, we are aware that States may choose to allow participants to self-direct services under the "agency with choice" model, which utilizes a

co-employment relationship between the participant and an agency. This agency could be a traditional service provider or a financial management entity, and acts as the employer of record of the PAS worker. If a State allows this option, the financial management services must be separately delineated from other services that the agency may provide in order that the financial management services (FMS) are claimed appropriately.

Section 1915(j)(6) of the Act further states activities of the financial management entity be matched by CMS at "the administrative rate established in Section 1903(a)" of the Act. We are interpreting this reference to apply specifically to section 1903(a)(7) of the Act, which provides for a Federal Medical Assistance Percentage (FMAP) rate of 50 percent for the "amounts expended...as found necessary by the Secretary for the proper and efficient administration of the State plan." We believe the DRA Conference Report language supports this reading as it notes that payment for the activities of the financial management entity will be reimbursed at the "same rate as other Medicaid administrative activities generally...50 percent." H.R. Conf. Rep. No.362, (109th Cong. 301). We will also consider the State's financial management activities to be general administrative activities and likewise matched at 50 percent. Therefore, financial management services, whether provided by a financial management entity, the State, or by another entity

under "agency with choice" will be reimbursed under the 50 percent administrative rate under this new State plan option.

III. Response to Comments

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

IV. Collection of Information Requirements

[If you choose to comment on issues in this section, please include the caption "COLLECTION OF INFORMATION REQUIREMENTS" at the beginning of your comments.]

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

burden.

- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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

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.

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.

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.

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 x 80 hours = 4,480 hours)

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.

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.

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.

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 x 25 hours = 1,400 hours)

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 3 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 x 200 hours = 11,200)

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.

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.

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.

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.

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 x 16 hours = 896 hours)

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.

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 x 100 hours = 5,600 hours)

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 was 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 x 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.

The total aggregate burden for the requirements in this proposed rule 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).

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services,

Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attn.: Melissa Musotto, CMS-2229-P

Room C5-14-03, 7500 Security Boulevard,

Baltimore, MD 21244-1850.

Office of Information and Regulatory Affairs,

Office of Management and Budget,

Room 10235, New Executive Office Building,

Washington, DC 20503,

Attn: Katherine Astrich, CMS Desk Officer, CMS-2229-P

katherine_astrich@omb.eop.gov. Fax (202) 395-6974.

V. Regulatory Impact Statement

[If you choose to comment on issues in this section, please include the caption "REGULATORY IMPACT STATEMENT" at the beginning of your comments.]

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. Executive Order 12866 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 rule 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. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1

year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This rule would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation 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. Since 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
Federal Cost	12	20	29	32	34
State Cost	9	15	22	24	26
Total*	22	35	51	56	61

*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 propose 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. Accounting Statement and Table

As required by OMB Circular A-4 (available at

<http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in the table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. This table provides our best estimate of the increase in Medicaid payment as a result of the changes presented in this proposed rule.

Table: Accounting Statement: Classification of Estimated Expenditures, from FY 2008 to FY 2012 (in Millions)		
Category	TRANSFERS	
Annualized Monetized Transfers	3% Units Discount Rate \$25.2	7% Units Discount Rate \$24.8
From Whom To Whom?	Federal Government to Providers	
Category	TRANSFERS	
Annualized Monetized Transfers	3% Units Discount Rate \$19.0	7% Units Discount Rate \$18.7
From Whom To Whom?	State Governments to Providers	

E. Conclusion

As indicated in the estimated expenditures table above, we project the Federal Medicaid program cost of this proposed rule to be \$127 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 CFR Part 441

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

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

PART 441-SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SEPCIFIC 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, consisting of §441.450 through §441.486, 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 arrangement.

441.462 Statewideness, 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 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) Specifying worker qualifications.
- (5) Determining worker duties.

- (6) Scheduling workers.
- (7) Supervising workers.
- (8) Evaluating worker performance.
- (9) Determining the amount paid for a service, support or item.
- (10) Scheduling when services are provided.
- (11) Identifying service workers.
- (12) Reviewing and approving invoices.
- (c) Definitions.

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 addresses critical contingencies or incidents that would pose a risk of harm to the participant's health or welfare and is 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 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. 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.

§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 disenroll 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 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.

(c) States must permit participants 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 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 the State plan 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 State plan 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 provider of services 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 Statewideness, comparability and limitations on number served.

A State may do the following:

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

(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, 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, including, but 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 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.

(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, the participant 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 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 the opportunity to engage in, and direct, the process to the extent desired.

(2) The participant 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.

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

(e) An approved self-directed service plan conveys authority to the participant 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 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.

§441.472 Budget methodology.

(a) The budget methodology set forth by the State to determine a participant's service budget amount, must meet 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 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.

§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.

§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 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 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.

(c) Participants 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 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 established in the service plan.

§441.484 Financial management services.

(a) 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, 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)

Dated: _____

Leslie V. Norwalk,
Acting Administrator,
Centers for Medicare & Medicaid
Services.

Approved: _____

Michael O. Leavitt,
Secretary.

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