§ 355.16 How do I determine the quantity of extremely hazardous substances present for certain forms of solids?

* * * * *

(b) *Solids in solution.* Multiply the weight percent of non-reactive solids in solution in a particular container by the total weight of solution in the container. Then multiply by 0.2.

* * * * *

3. Section 355.61 is amended by adding in alphabetical order the definition of "Solution" to read as follows:

§ 355.61 How are key words in this part defined?

* * * * *

Solution means any aqueous or organic solutions, slurries, viscous solutions, suspensions, emulsions, or pastes.

* * * * *

[FR Doc. 2011–9096 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 441

[CMS–2296–P]

RIN 0938–AP61

Medicaid Program; Home and Community-Based Services (HCBS) Waivers

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the regulations implementing Medicaid home and community-based services (HCBS) waivers under section 1915(c) of the Social Security Act by providing States the option to combine the existing three waiver targeting groups as identified in § 441.301. In addition, we are proposing other changes to the HCBS waiver provisions to convey expectations regarding person-centered plans of care, to provide characteristics of settings that are not home and community-based, to clarify the timing of amendments and public input requirements when States propose modifications to HCBS waiver programs and service rates, and to describe the additional strategies available to CMS to ensure State compliance with the statutory provisions of section 1915(c) of the Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 14, 2011.

ADDRESSES: In commenting, please refer to file code CMS–2296–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2296–P, P.O. Box 8016, Baltimore, MD 21244–1850.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2296–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 before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

FOR FURTHER INFORMATION CONTACT: Kathryn Poisal, (410) 786–5940.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Section 1915(c) of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to waive certain Medicaid statutory requirements so that a State may offer Home and Community-Based Services (HCBS) to State-specified group(s) of Medicaid beneficiaries who otherwise would require services at an institutional level of care. This provision was added to the Act by the Omnibus Budget and Reconciliation Act of 1981 (Pub. L. 97–35, enacted August 13, 1981) (OBRA'81) (with a number of subsequent amendments). Regulations were published to effectuate this statutory provision, with final regulations issued on July 25, 1994 (59 FR 37719). In the June 22, 2009 **Federal Register** (74 FR 29453), we published the Medicaid Program; Home and Community-Based Services (HCBS) advance notice of proposed rulemaking (ANPRM) that proposed to initiate rulemaking on a number of areas within the section 1915(c) program. We received 313 comments (which can be accessed at *http://www.regulations.gov/*) and held teleconferences with stakeholders. The correspondence included comments from States, health care and community support providers and associations, consumer groups, and social workers, and others. In the following sections, we discuss comments relating to questions

posed by the ANPRM and addressed in this proposed rule.

Along with our overarching interest in making improvements to the Medicaid HCBS program, we seek to ensure that Medicaid is providing needed strategies for States in their efforts to meet their obligations under the Americans with Disabilities Act (ADA) and Supreme Court's decision in *Olmstead* v. *L.C.*, 527 U.S. 581 (1999). In the *Olmstead* decision, the Court affirmed a State's obligations to serve individuals in the most integrated setting appropriate to their needs. A State's obligations under the ADA and section 504 of the Rehabilitation Act are not defined by, or limited to, the scope or requirements of the Medicaid program; however, the Medicaid program provides an opportunity to obtain partial Federal funding to assist in compliance with these laws through the provision of Medicaid services to Medicaid-eligible individuals.

We believe that these proposed changes will have numerous benefits for individuals and States alike. In addition to providing clarity around individual and stakeholder input, these proposed changes will move the system forward by enabling services to be planned and delivered in a manner driven by individual needs rather than diagnosis. These changes will enable States to realize administrative and program design simplification, as well as improve efficiency of operation. The changes related to clarification of HCBS settings will support the use of waiver authority to maximize the opportunities for waiver participants to have access to the benefits of community living and the opportunity to receive services in the most integrated setting appropriate.

A. Responses to Comments Received on ANPRM

1. Target Groups

Under section 1915(c) of the Act, the Secretary is authorized to waive section 1902(a)(10)(B) of the Act, allowing States not to apply comparability requirements and target an HCBS waiver program to a specified Medicaid-eligible group or sub-group of individuals who would otherwise require institutional care. A single section 1915(c) waiver may, under current regulation, serve one of the three target groups identified in § 441.301(b)(6). As provided in the rule, these three target groups are: "Aged or disabled, or both; Mentally retarded or developmentally disabled, or both; and Mentally ill.[1]" States must currently develop separate section 1915(c) waivers in order to serve more than one of the specified target groups. A Federal regulatory change that permits combining targeted groups within one waiver would remove a barrier for States that wish to design a waiver that meets the needs of more than one target population. This regulatory change would enable States to design programs to meet the needs of Medicaid-eligible individuals. For example, a growing number of Medicaid-eligible individuals with intellectual disabilities reside with aging caregivers who are also eligible for Medicaid. The proposed change would enable the State to design a coordinated section 1915(c) waiver structure that meets the needs of the entire family that, in this example, includes both an aging parent and a person with intellectual disabilities. In this illustration, the family would occupy two waiver slots, but with the proposed change, both could now be served under the same waiver program. We also believe the capacity to combine multiple target groups in one waiver may offer some administrative efficiencies for States.

Through the ANPRM, we proposed to initiate rulemaking to allow States the flexibility to combine any or all of the three target groups in one HCBS waiver (74 FR 29453). We sought public comments on how we may establish criteria related to the removal of an existing regulatory barrier that currently prevents States from designing cross-disability section 1915(c) HCBS waiver programs. The comments provided on this provision were largely positive, advising CMS to consider carefully quality elements and protections needed to ensure that all target groups are protected sufficiently in such a structure. Through this proposed rule, we include expectations that each individual within the waiver, regardless of target group, has equal access to the services necessary to meet their unique needs.

2. HCBS Settings

Through the ANPRM, we also sought public input on strategies to define home and community-based settings where waiver participants may receive services. Additionally, the request for input was in response to isolated situations that have emerged where States or other stakeholders are expressing interest in using HCBS waivers to serve individuals in segregated settings or settings with a strong institutional nature. For example, some proposed settings are on campuses of institutional facilities, segregated from the larger community, and do not allow individuals to choose whether or with whom they share a room, limit individuals' freedom of choice on daily living experiences such as meals, visitors, activities, and limit individuals' opportunities to pursue community activities.

We received several comments to the ANPRM strongly urging CMS to clarify in regulations that HCBS funding is not intended to be used for people in segregated facilities. One comment referenced large, campus-based programs and stated "[s]uch settings clearly do not meet the basic understanding of home and community-based settings." Another comment, expressing concern about segregated, residential campuses, added, "that HCBS funding is not intended to be used for these segregated facilities."

More recently, we received a significant amount of correspondence from stakeholders across the country in response to a specific State proposal contemplating a campus-based, segregated setting for HCBS. One correspondent wrote "* * * congregate settings are being planned on the grounds of existing Intermediate Care Facilities for Individuals with Mental Retardation (ICF/MRs) or in other segregated settings in several States, with the intent of using Home and Community-Based (Services) Waiver (HCBW) funding. This type of effort is incompatible with the goals * * * as defined by CMS. Both ADA and *Olmstead* require that services are provided in the most integrated settings appropriate to an individual's needs." Another writer expressed the following concern: "[My son] is very well known in the community and we know he is much safer in the community than in an institution. There are simply more eyes and ears in the community who would certainly telephone us if they even suspected abuse of any kind. The success of my son, and my desired success for those 5000 people * * * with developmental disabilities who are desperately waiting for services, is my motivation to oppose the use of the HCBW for a cluster of large group homes on a campus. They simply will not have the opportunities for growth as human beings * * *."

As a result of the significant comments we received and the subsequent feedback through correspondence and other stakeholder input opportunities, we propose that HCBS settings: must be integrated in the

[1] Although this terminology is still used in the statute and regulations, it is not consistent with the preferred language to describe target groups. In the spirit of Rosa's Law [Pub. L. 111–256], CMS will use the term, "individuals with intellectual disabilities" instead of "mentally retarded or developmentally disabled" where possible.

community; must not be located in a building that is also a publicly or privately operated facility that provides institutional treatment or custodial care; must not be located in a building on the grounds of, or immediately adjacent to, a public institution; or, must not be a housing complex designed expressly around an individual's diagnosis or disability, as determined by the Secretary. In addition, we propose that the settings must not have qualities of an institution, as determined by the Secretary. Such qualities may include regimented meal and sleep times, limitations on visitors, lack of privacy and other attributes that limit individual's ability to engage freely in the community. We invite comments on this portion of the regulations.

Through the ANPRM, we received comments suggesting that we carefully consider any adverse impact that a rule change may have on American Indians and Alaska Natives who reside on Tribal lands where living settings may differ according to cultural norms. To that end, we were advised to be careful that the language of a regulation does not unintentionally prohibit normative cultural living practices. We note that this proposed rule change does not exclude from home and community-based settings culturally appropriate settings on Tribal lands when the individual is an Indian or resides on Tribal lands where culturally acceptable group living arrangements are an integral aspect of the Tribal community. Specifically, Indian means any individual defined at 25 U.S.C. 1601(c), 1603(f), or 1679(b), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual:

(1) Is a member of a Federally-recognized Indian Tribe;

(2) Resides in an urban center and meets one or more of the four criteria:

(a) Is a member of a Tribe, band, or other organized group of Indians, including those Tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(b) Is an Eskimo or Aleut or other Alaska Native;

(c) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(d) Is determined to be an Indian under regulations promulgated by the Secretary.

(3) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(4) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

The comments noted that persons who are older with and without disabilities may choose to live together in assisted living facilities and urged CMS to allow them to exercise this preference and receive waiver services. Similarly, some persons who are older may desire to live in retirement communities, such as continuing care retirement communities. As a result, in accordance with a person-centered plan, we will allow such settings to be permissible under the section 1915(c) HCBS program for older persons under certain circumstances, which are noted below.

However, as previously noted, the Medicaid program's rules do not define or limit other obligations States may have under the ADA and section 504 of the Rehabilitation Act for individuals who seek more integrated settings than assisted living settings (ALS) or other settings not covered by this regulation.

For the purposes of this regulation, we note that ALS for persons who are older, without regard to disability, would not be excluded from home and community-based settings when the following conditions are met:

- Individual has a lease.
- Setting is an apartment with individual living, sleeping, bathing and cooking areas, and individuals can choose whether to share a living arrangement and with whom.
- Individuals have lockable access to and egress from their own apartments.
- Individuals are free to receive visitors and leave the setting at times and for durations of their own choosing.
- Aging in place, or allowing individuals to remain where they live as they age and/or support needs change, must be a common practice of the ALS.
- Leases may not reserve the right to assign apartments or change apartment assignments.
- Access to the greater community is easily facilitated based on the individual's needs and preferences.
- An individual's compliance with their person-centered plan (in the event that the individual has shared his/her plan or the landlord is also the provider of services) is not in and of itself a condition of the lease.

We are particularly interested in gaining comments on these aspects of the proposed rule. In addition, we note that this proposal in no way preempts broad Medicaid requirements, such as an individual's right to obtain services from any willing and qualified provider of a service.

Recognizing the imperative to provide clear guidance to States and in consideration of recent proposals that have clearly exceeded reasonable standards for HCBS, we are proposing to clarify now that certain settings are not home and community-based because they are not integrated in the community. A setting that is integrated in the community is a setting that enables individuals with disabilities to interact with individuals without disabilities to the fullest extent possible. Further, we believe that such settings do not preclude individuals' ability to access community activities at times, frequencies and with persons of their choosing. Such settings are not segregated based on disability, either physically or because of setting characteristics, from the larger community. In addition, such settings will afford individuals choice in their daily life activities, such as eating, bathing, sleeping, visiting and other typical daily activities. We will continue our dialogue with a wide variety of stakeholders on other issues related to the characteristics of HCBS settings.

3. Person-Centered Planning

Underpinning all aspects of successful HCBS is the importance of a complete and inclusive person-centered planning process that addresses health and long-term services and support needs in a manner that reflects individual preferences. To fully meet individual needs and ensure meaningful access to their surrounding community, systems that deliver HCBS must be based upon a strong foundation of person-centered planning and approaches to service delivery. Through the ANPRM process, we received favorable comments regarding our interest in ensuring a person-centered approach to services and support plan development, with recommendations that we articulate expectations for such an approach.

The person-centered approach is a process, directed by the individual with long-term support needs, and may also include a representative whom the individual has freely chosen. The person-centered plan shall identify the strengths, preferences, needs (clinical and support), and desired outcomes of the individual. The person-centered process enables the individual to choose others to serve as important contributors and members of the team in the planning process.

These participants in the person-centered planning process enable and

assist the individual to identify and access a personalized mix of paid and non-paid services. This process and the resulting service and support plan, also called a plan of care, will assist the individual in achieving personally defined outcomes in the most integrated community setting. The process is conducted in a manner that reflects what is important for the individual to meet identified clinical and support needs determined through a person-centered functional needs assessment process and what is important to the individual to ensure delivery of services in a manner that reflects personal preferences and choices and contributes to the assurance of health and welfare. The person-centered plan may also reflect whether and what services an individual may choose to self-direct. The plan should act as the basis for the building of an individual's budget, and the individual's ability to make decisions regarding the resources available to him or her. In collaboration with those that the individual has identified, he or she chooses planning goals to achieve these personal outcomes and to meet personal clinical and support needs. The identified personally-defined outcomes, preferred methods for achieving them, and the training supports, therapies, treatments, and other services the individual needs to achieve those outcomes become part of the written services and support plan.

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

- Include people chosen by the individual;
- Provide necessary support to ensure that the individual has a meaningful role in directing the process;
- Occur at times and locations of convenience to the individual;
- Reflect cultural considerations of the individual;
- Include strategies for solving conflict or disagreement within the process, including strategies to address any conflict of interest concerns among planning participants;
- Include opportunities for periodic and ongoing plan updates as needed and/or requested by the individual; and,
- Offer choices to the individual regarding the services and supports they receive and from whom.

The plan resulting from this process should reflect the individual strengths and preferences, as well as clinical and support needs (as identified through a person-centered functional assessment). The plan should include individually identified goals, which may include goals and preferences related to relationships, community participation, employment, income and savings, health care and wellness, education, and others. The plan should reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals and who provides them. The plan should reflect risk factors and measures in place to minimize them. The plan must be signed by all individuals and providers responsible for its implementation, and should reflect the approach in place to ensure that it is implemented as intended. A copy of the plan must be provided to the individual and their representative(s). We invite comment on the person-centered process and planning elements of this proposed rule.

4. Summary

It is in this context and with the valuable input from the ANPRM that we propose modifications and additions to the regulations governing section 1915(c) HCBS waiver programs. We further seek to use this opportunity to clarify expectations regarding timing of amendments and public input requirements when States propose modifications to HCBS waiver programs and service rates, and strategies available to CMS to ensure State compliance with the statutory assurances of section 1915(c) of the Act.

B. Strategies To Ensure Compliance With Statutory Assurances

Our primary concern in the oversight of the section 1915(c) waivers is the health and welfare of the individuals served within the programs. Section 1915(f) of the Act requires the Secretary to monitor implementation of waivers to assure compliance with all requirements and provides for termination of waivers where the Secretary has found noncompliance. This authority and the process for termination of waivers is currently addressed in the regulations at § 441.304(d), § 441.307, and § 441.308. We seek to add provisions describing other strategies CMS may employ only after all other efforts have not yielded necessary results, to ensure compliance, short of termination or nonrenewal. At present, when we identify serious quality issues, such as potential harm to individual health and welfare or significant financial concerns, and States fail to take appropriate remedial action, the only enforcement options addressed in the regulations are for CMS to refuse to renew the waiver or terminate the waiver, as described at current § 441.304(d). Such action could have a significant detrimental impact on the individuals served (for example, loss of waiver services or Medicaid eligibility). We are interested in specifying a broader array of approaches CMS may take to achieve and maintain full State compliance with the requirements specified in or under section 1915(c) of the Act in addition to waiver termination. We invite comment on the discussion of compliance strategies in this proposed rule.

CMS issues these proposed rules to address issues that are pressing in the design, operation, and oversight of the section 1915(c) waiver program. However, we are committed to continuing a dialogue with all interested stakeholders on issues related to designing services and supports that meet individual needs, and that offer meaningful community participation opportunities.

II. Provisions of the Proposed Regulations

The provisions of this proposed rule would apply to all States offering Medicaid HCBS waivers under section 1915(c) of the Act.

As noted above, our ANPRM encompassed three main areas: Removal of regulatory barriers to serve more than one target group in a single waiver; definition of home and community characteristics; and, underpinning each of those areas, requirements for person-centered planning. Comments were supportive of our interest in setting forth our expectations regarding person-centered service and support plans that reflect what is important for the individual and to the individual. The proposed revisions to § 441.301(b)(1)(i) would require that a written services and support plan be based on the person-centered approach. This provision includes minimum requirements for this approach.

In new paragraph, § 441.301(b)(1)(iv), we would include clarifying language regarding settings that would not be considered home and community-based under section 1915(c) of the Act. We clarify that HCBS settings are integrated in the community and may not include: facilities located in a building that is also a publicly or privately-operated facility that provides inpatient institutional treatment or custodial care; or in a building on the grounds of, or immediately adjacent to, a public or private institution; or a disability-specific housing complex designed expressly around an individual's diagnosis, that is segregated from the larger community, as determined by the Secretary.

We note that this proposed rule change does not exclude living settings on Tribal lands that reflect cultural norms, or ALS for persons who are older

regardless of disability, when the conditions noted above in the background section are met.

The proposed revisions to § 441.301(b)(6) would allow States to combine target groups. We recognize that some States and stakeholders want additional flexibility to combine target groups in order to provide services based upon needs rather than diagnosis or condition, and for administrative relief from operating and managing multiple section 1915(c) waiver programs. Under this proposal, States must still determine that without the waiver, participants would require institutional level of care, in accordance with section 1915(c) of the Act. The proposal will not affect the cost neutrality requirement for section 1915(c) waivers, which requires the State to assure that the average per capita expenditure under the waiver for each waiver year not exceed 100 percent of the average per capita expenditures that would have been made during the same year for the level of care provided in a hospital, nursing facility, or ICF/MR under the State plan had the waiver not been granted. We will provide States with guidance on how to demonstrate cost neutrality for a waiver serving multiple target groups.

In an effort to ensure that safeguards are in place to protect the health and welfare of each waiver participant, we are proposing in a new paragraph § 441.302(a)(4) that to choose the option of more than one target group under a single waiver, States must assure CMS that they are able to meet the unique service needs that each individual may have regardless of target group, and that each individual in the waiver has equal access to all needed services. In addition, to ensure that services are provided in settings that are home and community-based, we are proposing in a new paragraph § 441.302(a)(5) that States provide assurance that the settings where services are provided are home and community based, and comport with new paragraph § 441.301(b)(1)(iv). While we are not changing the existing quality assurances through this rule, we are proposing to clarify that States must continue to assure health and welfare of all participants when target groups are combined under one waiver, and assure that they have the mechanisms in place to demonstrate compliance with that assurance.

At § 441.304, we would make minor revisions to the heading to indicate the rules addressed under this section.

We are proposing to revise § 441.304(d) and redesignate current § 441.304(d) as new § 441.304(g). The new § 441.304(d) would codify and clarify our guidance (*Application for a section 1915(c) Home and Community-Based Waiver, V. 3.5, Instructions, Technical Guide and Review Criteria, January 2008*) regarding the effective dates of waiver amendments with substantive changes, as determined by CMS. Substantive changes may include, but are not limited to changes in eligible populations, constriction of service amount, duration, or scope, or other modifications as determined by the Secretary. We would add regulatory language reflective of our guidance that waiver amendments with changes that we determine to be substantive may only take effect on or after the date when the amendment is approved by CMS, and must be accompanied by information on how the State has assured smooth transitions and minimal adverse impact on individuals impacted by the change.

Additionally, given the important requirement at § 447.205, which describes States' responsibilities to provide public notice when States propose significant changes to their methods and standards for setting payment rates for services, we propose to add a new paragraph § 441.304(e) to remind States of their obligations under § 447.205. We would further include a requirement at a new proposed paragraph § 441.304(f) that States establish public input processes specifically for HCBS changes. These processes, commensurate with the proposed change, could include formalized information dissemination approaches, conducting focus groups with affected parties, and establishing a standing advisory group to assist in waiver policy development. These processes must be identified expressly within the waiver document and utilized for waiver policy development. The input process must be accessible to the public (including individuals with disabilities) and States must make significant efforts to ensure that those who want to participate in the process are able to do so. These processes must include consultation with Federally-recognized Indian Tribes in accordance with Federal requirements and the State must seek advice from Indian health programs or Urban Indian Organizations prior to submission of a waiver request, renewal, amendment or action that would have a direct effect on Indians or Indian health providers or Urban Indian Organizations in accordance with section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, enacted on February 17, 2009). We would be interested in comments on this proposed addition to strengthen the public input process on changes proposed to services and other changes to the structure and operation of the section 1915(c) waivers.

In new paragraph, § 441.304(g), we propose to add language describing additional strategies CMS may employ to ensure State compliance with the requirements of a waiver, short of termination or non-renewal. Our proposed regulation at the new § 441.304(g) reflects an approach to encourage State compliance. We are interested in working with States to achieve full compliance without having to resort to termination of a waiver. Therefore, we are proposing strategies to ensure compliance in serious situations short of termination. These strategies include use of a moratorium on waiver enrollments or withholding of a portion of Federal payment for waiver services or for administration of waiver services in accordance with the seriousness and nature of the State's noncompliance (that is, health and welfare concerns and significant financial issues). These strategies could continue, if necessary, as the Secretary determines whether termination is warranted. Our primary objective is to use such strategies rarely, only after other efforts to resolve issues have not succeeded as necessary to ensure the health and welfare of individuals served.

Once CMS employs a strategy to ensure compliance, the State must submit an acceptable corrective action plan in order to resolve all areas of noncompliance. The corrective action plan must include detail on the actions and timeframe the State will take to correct each area of noncompliance, including necessary changes to the quality improvement strategy and a detailed timeline for the completion and implementation of corrective actions. CMS will determine if the corrective action plan is acceptable.

Selecting Strategies To Ensure Compliance

In consideration of whether and which strategies will be used to ensure compliance, and in accordance with the seriousness and nature of the State's noncompliance (that is, health and welfare concerns and significant financial issues), we will consider such areas as the following:

- The areas of noncompliance and whether they pose immediate concerns or otherwise compromise the State's ability to assure participant's health and welfare.
- The nature and duration of the identified area of serious noncompliance.

- The State's history of noncompliance in general, and specifically with reference to the cited area of serious noncompliance.
- The significance of the deficiencies and whether they indicate a system-wide failure to provide quality services.

III. Collection of Information Requirements

This proposed rule does not contain any new information collection requirements; however, it does make reference to information collection requirements currently approved by OMB. Specifically, the burden associated with the information collection requirements contained in this proposed rule (HCBS Waivers) is currently approved under OMB control number 0938–0499 with a July 31, 2012, expiration date.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

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

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–2296–P] Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

IV. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive 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 for small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 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 proposed 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 Metropolitan Statistical Area for Medicare payment regulations 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 proposed 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. In 2011, that threshold is approximately $136 million. This rule will 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 does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

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

List of Subjects in 42 CFR Part 441

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

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

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

1. The authority citation continues to read as follows:

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

Subpart G—Home and Community-Based Services: Waiver Requirements

2. Section 441.301 is amended by—

A. Revising paragraphs (b)(1)(i) and (b)(6).

B. Adding new paragraph (b)(1)(iv).

The revisions and addition read as follows:

§ 441.301 Contents of request for a waiver.

* * * * *

(b) * * *

(1) * * *

(i) Under a written services and support plan (also called plan of care) that is based on a person-centered approach and is subject to approval by the Medicaid agency.

(A) *Person-Centered Planning Process.* In addition to being led by the individual receiving services, the person-centered planning process:

(*1*) Includes people chosen by the individual.

(*2*) Provides necessary support to ensure that the individual has a meaningful role in directing the process.

(*3*) Occurs at times and locations of convenience to the individual.

(*4*) Reflects cultural considerations of the individual.

(*5*) Includes strategies for solving conflict or disagreement within the process, including any conflict of interest concerns.

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

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

(B) *The Person-Centered Plan.* The person-centered plan must reflect the services that are important for the individual to meet individual services and support needs as assessed through a person-centered functional assessment as well as what is important to the person with regard to preferences for the delivery of such supports. Commensurate with the level of need of the individual, the plan must:

(*1*) Reflect the individual's strengths and preferences.

(2) Reflect clinical and support needs as identified through a person-centered functional assessment.

(3) Include individually identified goals, which may include, as desired by the individual, items related to relationships, community living, community participation, employment, income and savings, health care and wellness, education, and others.

(4) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals and the providers of those services and supports.

(5) Reflect risk factors and measures in place to minimize them, including back-up strategies when needed.

(6) Be signed by all individuals and providers responsible for its implementation.

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

(8) Include a timeline for review.

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

(10) Be distributed to everyone involved (including the participant) in the plan.

(11) Be directly integrated into self-direction where individual budgets are used.

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

* * * * *

(iv) Only in settings that are home and community based, integrated in the community, provide meaningful access to the community and community activities, and choice about providers, individuals with whom to interact, and daily life activities. A setting is not integrated in the community if it is:

(A) Located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment or custodial care; in a building on the grounds of, or immediately adjacent to, a public institution; or a housing complex designed expressly around an individual's diagnosis or disability, as determined by the Secretary; or

(B) Has qualities of an institutional setting, as determined by the Secretary.

* * * * *

(6) Be limited to one or more of the following target groups or any subgroup thereof that the State may define:

(i) Aged or disabled, or both.

(ii) Individuals with Intellectual or Developmental Disabilities, or both.

(iii) Mentally ill.

3. Section 441.302 is amended by adding paragraphs (a)(4) and (a)(5) to read as follows:

§ 441.302 State Assurances.

* * * * *

(a) * * *

(4) Assurance that the State is able to meet the unique service needs that particular target groups may present when the State selects to serve more than one target group under a single waiver, as specified in § 441.301(b)(6) of this subpart.

(5) Assurance that services are provided in home and community based settings, as specified in § 441.301(b)(1)(iv) of this subpart.

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4. Section 441.304 is amended by—

A. Revising the section heading as set forth below.

B. Redesignating paragraph (d) as new paragraph (g).

C. Adding new paragraphs (d), (e), and (f).

D. Revising newly designated paragraph (g).

The additions and revisions read as follows:

§ 441.304 Duration, extension, and amendment of a waiver.

* * * * *

(d) The agency may request that waiver modifications be made effective retroactive to the first day of a waiver year, or another date after the first day of a waiver year, in which the amendment is submitted, unless the amendment involves substantive changes as determined by CMS.

(1) Substantive changes may include, but are not limited to, revisions to services available under the waiver including elimination or reduction in services, and changes in the scope, amount, and duration of the services. Substantive changes may also include a change in the qualifications of service providers, changes in rate methodology or a change in the eligible population.

(2) A request for an amendment that involves a substantive change as determined by CMS, may only take effect on or after the date when the amendment is approved by CMS, and must be accompanied by information on how the State has assured smooth transitions and minimal adverse impact on individuals impacted by the change.

(e) The agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services in accordance with § 447.205 of this chapter.

(f) The agency must establish and use a public input process, for any changes in the services or operations of the waiver.

(1) This process must be described fully in the State's approved waiver application and be sufficient in light of the scope of the changes proposed, to ensure meaningful opportunities for input for individuals served, or eligible to be served, in the waiver.

(2) This process must include consultation with Federally recognized Tribes, and in accordance with section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), Indian health programs and Urban Indian Organizations.

(g)(1) If CMS finds that the Medicaid agency is not meeting one or more of the requirements for a waiver contained in this subpart, the agency is given a notice of CMS' findings and an opportunity for a hearing to rebut the findings.

(2) If CMS determines that the agency is substantively out of compliance with this subpart after the notice and any hearing, CMS may employ strategies to ensure compliance as described in § 441.304(g)(1) of this paragraph or terminate the waiver.

(3)(i) Strategies to ensure compliance may include the imposition of a moratorium on waiver enrollments, other corrective strategies as appropriate to ensure the health and welfare of waiver participants, or the withholding of a portion of Federal payment for waiver services until such time that compliance is achieved, or, ultimately, termination. When a waiver is terminated, the State must comport with § 441.307 of this subpart.

(ii) CMS will provide States with a written notice of the impending strategies to ensure compliance for a waiver program. The notice of CMS' intent to utilize strategies to ensure compliance would include the nature of the noncompliance, the strategy to be employed, the effective date of the compliance strategy, the criteria for removing the compliance strategy and the opportunity for a hearing.

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

Dated: December 1, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 28, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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